# EPA Registration No. 10772-23 Vol. 1

March 16, 2018

Mr. Zeno Bain, PM-33
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard, 2777 S Crystal Drive
Arlington, VA 22202

**SUBJECT:** **Capricorn**
**EPA Reg. No. 10772-23**

Dear Mr. Bain:

On behalf of Church & Dwight Co., Inc. (Church & Dwight), we enclose a label amendment for the above referenced product. Scientific & Regulatory Consultants, Inc. is the agent of record for Church & Dwight. This submission does not include any new data and therefore is not a PRIA action and no fee is required.

This label amendment revises the Precautionary Statements due to a toxicology review completed by California DPR on the already submitted dermal irritation study which was given MRID 50209706. The federal EPA DER review document indicated the study qualified for Toxicity Category 4. However, when California DPR reviewed the study they concluded Toxicity Category 3 should be assigned with the required precautions and first aid. California indicated they would not register the product unless these changes were made. Additionally, we understand the federal EPA allows Toxicity Category 3 language with a Toxicity Category 4 outcome if the registrant desires to include these precautions.

Therefore, the following label revisions are being made with this action:

1. The words "on skin" have been added to the Precautionary Statements.
2. The skin first aid statement has been made required and the optional brackets have been removed.

We look forward to a timely review of this submission. If you need any clarification or issues arise during the review of this information, please contact me immediately via phone (260-244-6270) or email (dswain@srcconsultants.com) for resolution.

Sincerely,

David Swain
Agent for Church & Dwight Co., Inc.

**Capricorn**
**EPA Reg. No. 10772-23**

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

   Scientific & Regulatory Consultants, Inc.
   201 West Van Buren Street
   Columbia City, IN 46725

   AGENT FOR:
   Church & Dwight Co., Inc.
   500 Charles Ewing Blvd.
   Ewing, NJ 08628

2. Regulatory action in support of which this package is submitted:
   Fast Track Label amendment (non-PRIA)

3. Transmittal date:

   March 16, 2018

4. Administrative materials:

   A) Cover letter
   B) Application (8570-1)
   C) Marked up label
   D) Proposed clean label

| | |
|---|---|
| Company Official: | David Swain |
| Company Name: | Agent for Church & Dwight Co., Inc. |
| Company Contact: | David Swain<br>Phone: (260) 244-6270<br>Email: dswain@srcconsultants.com |

Print Form

*Please read instructions on reverse before completing form.*

Form Approved. OMB No. 2070-0060. Approval expires 2-28-

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

| | | |
|---|---|---|
| 1. Company/Product Number<br>10772-23 | 2. EPA Product Manager<br>Zeno Bain | 3. Proposed Classification<br>☑ None ☐ Restricted |
| 4. Company/Product (Name)<br>Capricorn | PM#<br>33 | |
| 5. Name and Address of Applicant *(Include ZIP Code)*<br>Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd. Ewing, NJ 08628<br>☐ *Check if this is a new address* | 6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:<br>EPA Reg. No. _____<br>Product Name _____ | |

## Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Fast Track Label Amendment - non-PRIA, revise Precautionary Statements and First Aid

## Section - III

1. Material This Product Will Be Packaged In:

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes<br>☑ No | ☐ Yes<br>☑ No | ☐ Yes<br>☑ No | ☐ Metal<br>☑ Plastic<br>☐ Glass<br>☐ Paper<br>☐ Other (Specify) _____ |
| ***Certification must be submitted** | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☑ Label ☐ Container | Various. | ☑ On Label<br>☐ On Labeling accompaning product |

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☑ Paper glued ☐ Stenciled ☐ Other _____

## Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| David Swain | Agent for Church & Dwight Co., Inc. | (260) 244-6270 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

| | |
|---|---|
| 2. Signature David Swain | 3. Title Agent for Church & Dwight Co., Inc. |
| 4. Typed Name David Swain | 5. Date 03/16/2018 |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 26, 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BLAKE COWEN
LANDIS INTERNATIONAL, INC.
CHURCH & DWIGHT CO., INC.
PO Box 5126
VALDOSTA, GA 31603-5126

PRODUCT NAME: CAPRICORN
COMPANY NAME: CHURCH & DWIGHT CO., INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 10772-23
EPA RECEIPT DATE: 03/16/18

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 33, at 202-564-5970.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

## Northern, Terria

**From:** dswain@srcconsultants.com
**Sent:** Monday, August 28, 2017 3:30 PM
**To:** Northern, Terria
**Cc:** Bain, Zeno
**Subject:** RE: EPA Completed Action 10722-23
**Attachments:** 08b Capricorn Master Label_Clean_08 28 17a.pdf; 08b Capricorn Master Label_Highlight_08 28 17a.pdf

Hi Terria,

Thanks for the comments.

Here is a marked up label showing changes from the label dated 8/16/17 and a clean label.

1. We have removed the Rhinovirus from the Top Loader section in the organism list on page 30 of 42.
2. We have separated the virus and sanitization Directions for Use for Top Loader on pages 5 of 42 and 6 of 42. We put the virus Directions first and then the sanitization Directions after that.

I hope this will be OK, please let me know if you have any questions. Thanks for your help.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
**SERVICE Portal, *a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Northern, Terria [mailto:Northern.Terria@epa.gov]
**Sent:** Friday, August 25, 2017 12:40 PM
**To:** dswain@srcconsultants.com
**Cc:** Bain, Zeno
**Subject:** Re: EPA Completed Action 10722-23

Hello David - I am providing you the final label comments for EPA Registration Number 10772-23:

For Label Comment #9 in the review in regards to the study with MRID 50209725, the Agency's original position still stands. The Agency request the removal of Rhinovirus from the use as a laundry additive disinfectant in top loading application. The performance standard for viruses has always been consistent with our guidelines, which requires at least a 3 log reduction beyond the cytotoxic level.

The dilution clarification on the label for in-wash laundry additive applications is acceptable (Label Comment #14). However, for Top Loading Machine use directions, option #1 (page 5 of label dated 8/16/17), the Agency requests separate Sanitization and Virucidal uses. Since viruses cannot be associated with sanitization per Agency policy, these two uses cannot be grouped together.

Thank you.

---

**From:** dswain@srcconsultants.com <dswain@srcconsultants.com>
**Sent:** Monday, August 21, 2017 2:49:28 PM
**To:** Northern, Terria
**Cc:** OPP AD Ombudsman; Bain, Zeno
**Subject:** RE: EPA Completed Action 10722-23

Hi Terria,

Thank you, I have received the letter indicating the extra 30 days to work out the label issues. I look forward to receive the Agency response to our revised label submitted last week.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
**SERVICE Portal, *a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Northern, Terria [mailto:Northern.Terria@epa.gov]
**Sent:** Monday, August 21, 2017 1:35 PM
**To:** dswain@srcconsultants.com
**Cc:** OPP AD Ombudsman; Bain, Zeno
**Subject:** EPA Completed Action 10722-23

Hello David – the Agency has completed the review for EPA Reg. No. 10772-23, please note the outstanding efficacy label concerns have not been addressed. Please contact me if you have additional questions on the timeframes.

Thanks!

## Northern, Terria

**From:** dswain@srcconsultants.com
**Sent:** Wednesday, August 16, 2017 1:49 PM
**To:** Northern, Terria
**Cc:** Bain, Zeno
**Subject:** RE: EPA Completed Review 10772-23
**Attachments:** 08b Capricorn Master Label_Clean_08 16 17.pdf; 08b Capricorn Master Label_HL_08 16 17.pdf; Capricorn_10772-23_PredecisionalLetterResponse-081617 ver 9.pdf

**Categories:** Red Category

Hi Terria,

Here is the revised label, both a highlighted label and a clean label.

Also, I have included a chart which explains in detail the changes we have made.

Please let me know if you have any questions. Thanks for your help.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
**SERVICE Portal, *a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Northern, Terria [mailto:Northern.Terria@epa.gov]
**Sent:** Tuesday, August 15, 2017 11:11 AM
**To:** dswain@srcconsultants.com
**Cc:** Bain, Zeno
**Subject:** RE: EPA Completed Review 10772-23

Hello David – we will need the revised label by COB tomorrow.

Thanks!

*Terria Northern*
Registration Risk Manager
Environmental Protection Agency
1200 Penn. Ave., NW (7510P)
Washington, DC 20460
#703-347-0265

Street address: 2777 Crystal Drive
1 Potomac Yard South
Arlington, VA

**From:** dswain@srcconsultants.com [mailto:dswain@srcconsultants.com]
**Sent:** Thursday, August 10, 2017 8:12 AM
**To:** Northern, Terria <Northern.Terria@epa.gov>
**Subject:** RE: EPA Completed Review 10772-23

Hi Terria,

We are still working with the client on the revised label. Hope to have to you by the end of the day tomorrow.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
**SERVICE Portal, *a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Northern, Terria [mailto:Northern.Terria@epa.gov]
**Sent:** Wednesday, August 09, 2017 6:29 PM
**To:** dswain@srcconsultants.com
**Subject:** Re: EPA Completed Review 10772-23

Hello David - I think you forgot to add the revised label. Missing attachment.

Thanks!

---

**From:** dswain@srcconsultants.com <dswain@srcconsultants.com>
**Sent:** Wednesday, August 9, 2017 4:40 PM
**To:** Northern, Terria
**Subject:** RE: EPA Completed Review 10772-23

Hi Terria,

Thank you, have a nice evening.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com

Scientific & Regulatory Consultants Inc.

www.srcconsultants.com

A consulting firm specializing in providing an understanding of regulatory and scientific affairs for antimicrobial products from inception to commercialization.

| 260.244.6270

**SERVICE Portal, *a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Northern, Terria [mailto:Northern.Terria@epa.gov]
**Sent:** Wednesday, August 09, 2017 10:15 AM
**To:** dswain@srcconsultants.com
**Subject:** EPA Completed Review 10772-23

Hello David – the Agency has completed the final product chemistry review for 10772-23. Please contact me if you have any questions.

Thanks!

| Reference | EPA position | Registrant Response |
|---|---|---|
| Efficacy Review Label Comment #9 | The proposed label claim is not acceptable regarding the use of the product, Capricorn, as a laundry in-wash disinfectant additive for top loading machines when used a certain laundry detergent against the following virus using the following dilution rate.<br>12.45 mL test substance (62.4g/L) + 133.5 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 137.41 mL water for at least 18-minute was time in hot (45C) water:<br>Rhinovirus type 37, strain 151-1, ATCC VR-1147. The claims should be removed from the proposed label, including from the organism table on page 30. | The organism Rhinovirus type 37 on page 31 of 42 of Capricorn label under "*Laundry In-Wash Virucidal Top Loader Machines*" remains on the label. Please see the attached Addendum #1 for Church & Dwight rebuttal to the EPA efficacy review requirement to remove this organism. |
| Efficacy Review Label Comment #13 | On page 1, replace "Disinfector" with "Disinfectant". | Revised per Agency comment |
| Efficacy Review Label Comment #14 | For directions for use for in-wash laundry disinfection and sanitization additive (pages 3-6), the dilution type should be 2X, instead of 1X, representing the dosage of 62.4g/L that was tested. Referring to the table for Testing and Dilution Type, 2X dilution type is equivalent to 236 grams Product/gallon of water, which means for every 1 gallon of water, the amount of 236 grams of product should be added to washing. Registrant should revise Table 9 and Table 12 accordingly.<br><br>Therefore, in pages 3-6, instructions should identify scoops or pouches and specify the use of appropriate # of pouches to account for 236 grams of product/gallon of water. The instructions to "Add # {Insert #scoops/pouches/caps to at least equal the dose used in efficacy testing for bacteria to support claims for bacteria and virus HE laundry disinfection} [scoops] [pouches] [caps] [of product] [of powder] [into] [to] [washing machine]..." are too ambiguous.<br><br>These instruction headings should describe the uses as an additive and not | Table 9 was changed to reflect the use of 67.5 grams of product per 1 gallon of water in the scoop and pouch section for HE disinfection and sanitization. HE viral is reflected as 33.8 grams of product per 1 gallon of water. Top Loader Sanitization and Viral are reflected as 19.6 grams of product per 1 gallon of water. Please see Addendum #2 for explanation.<br><br>These dilutions are also reflected in Table 8 and Table 10.<br><br>Table 12 was not changed as it already reflects the use of the correct number of scoops.<br><br>Use directions on pages 3-6 were revised per Agency comment by adding *"{equivalent to X grams product per gallon of water}"* to the administrative text in each section of in-wash laundry Directions for Use referred to in the comment. {For example from Table 9, where the pouch contains 118 grams per pouch, the use directions would say "Add 2 pouches BEFORE adding laundry.)<br><br>Laundry section headings were revised per EPA request to insert "Additive". |

| | | |
|---|---|---|
| Efficacy Review Label Comment #15 | On page 18, the HIV statement should be placed under the use-directions for hard, non-porous surface disinfection (page 7), since efficacy testing against the virus was performed to substantiate this use application. Placing it anywhere else would be confusing for users. | Moved section according to Agency comment. |
| Efficacy Review Label Comment #16 | On page 14, 17, 20, and 22, remove the words "antibacterial protection". This claim implies continuous protection against bacteria, which is not supported by residual data. Registrant should also note that the claim for "all around the house" should not be used to describe disinfection or sanitization. | Revised per Agency comment and replaced with word "protection" with the word "action".<br><br>"All around the house" has been removed. |
| Efficacy Review Label Comment #17 | On page 18, remove "[and disinfected]" from the claim "[This product] will help [you] keep your surfaces clean [and disinfected]". The product may be able to keep the surfaces clean, but keeping the surfaces disinfected implies a residual and prolong efficacy beyond the contact time(s), which was not supported by data. | Revised claim to say "[This product] will clean [and disinfect] your surfaces". The term "keep" has been removed. |
| Efficacy Review Label Comment #18 | On pages 18, 21 and 22, registrant should qualify claims regarding the spread of cold and flu viruses to include "on treated surfaces". | Revised per Agency comment. |
| Efficacy Review Label Comment #19 | Under Hard Non-Porous Surface Sanitizing Claim, registrant should qualify claim #8 and #9 to "Cleans and sanitizes [in One Step] when use directions for sanitizer are followed" and "Cleans, deodorizes, and sanitizes in one step when use directions for sanitizer are followed".<br>The same claims should be qualified under Soft Surface [and] [Carpet] Sanitizer Claims on page 20 with claims #11 and #12. | Revised per Agency comment by adding a qualifier "β" for hard surfaces that will lead the user to the hard surface sanitization directions and adding a qualifier "♦" that will lead the user to the soft surface sanitization directions. |
| Efficacy Review Label Comment #20 | Remove all "99.99%" text or revise to read "99.9%" throughout the label. While a 4-log (99.99%) reduction is allowed for viruses with data showing a 4-log kill, only a 3-log reduction (99.9%) claim is allowed for other disinfection and sanitization claims. | Removed per Agency comment. |

| | | |
|---|---|---|
| Efficacy Review Label Comment #21 | Throughout the label (e.g., pages 19, 20, 23), registrant should remove "hidden bacteria". The term is misleading and implies a greater efficacy than proven by data. | Removed per Agency comment. |
| Efficacy Review Label Comment #22 | On page 20, 21 and 22, registrant should revise all cross contamination claims to "Can help prevent cross contamination between laundry treated in the same wash load." On page 22, the claim "Helps prevent the spread of cold and flu viruses" should also be revised to "Helps prevent the spread of cold and flu viruses between laundry treated in the same wash load". | Revised per Agency comment.<br><br>Added a choice to use "between laundry treated in a wash load" as an option to the Agency revision. |
| Efficacy Review Label Comment #23 | On page 22, remove the claim for "Eliminates [99.9% of] germs* [that ordinary additives [can't] [don't]]". Comparative statements cannot be made unless it is made against the registrant's own product. | Removed per Agency comment. |
| Efficacy Review Label Comment #24 | Under Laundry Disinfection Claims for Presoak and Final Soak on page 21, registrant should remove "soft surfaces" from claims #37 and #38 from this section. Soft spot surface claims were substantiated by data tested using 62.4g/L dilution rate, while presoak laundry disinfectant was tested with 62.4g/2L, which is more diluted than the dilution rate for soft spot surface sanitizer and therefore may not show the same efficacy for general soft surfaces. | Removed per Agency comment. |
| Efficacy Review Label Comment #25 | Under Laundry HE In-Wash Disinfection on page 22, remove claim "Kills [99.9% of] [99.99% of] [Escherichia coli O157:H7 (E. coli)} [and} [Salmonella enterica] [other organisms]". Data for laundry HE in-wash disinfection for E. coli O157:H7 and Salmonella enterica were not submitted for review. | Removed per Agency comment. |

| | | |
|---|---|---|
| Efficacy Review Label Comment #26 | Under Laundry HE and Top Loader In-Wash Sanitization, remove all claims for viruses, germs, and germflighter technology. Claims against viruses and germs are not allowed to describe sanitization. | Removed per Agency comment.<br><br>*Also, added a section called "Laundry Top Loader In-Wash Virucidal" to account for the virucidal claims which ore outside of sanitization.* |

# Addendum #1

## Rebuttal to Efficacy Review Label Comment #7

MRID 50209725 was submitted to support laundry virucidal disinfection in-wash claims for the top loader use pattern against Rhinovirus. The protocol was designed to match the protocol accepted by EPA to support EPA Reg. No. 10324-115 which has an HIV virucidal activity in-wash claim alongside a bacterial laundry sanitization claim. It is the only laundry in-wash virucidal claim accepted by EPA.

The test methodology, replication, fabric to laundry water ratio, inoculum requirements, and test conditions are compliant with 810.2400 (d)(3) Guideline for Disinfecting Laundry. ASTM E2274 and E2406 cited in the Guideline were also followed. These methods and the original EPA performance criteria are based on the Petrocci & Clark test method which states "Since there is evidence that the bacteriological quality of the wash or rinse water may not always provide an accurate index to the bacteriological quality of the finished linens, the method used must employ results from the test fabric itself as the primary index to efficacy and the result on the wash or rinse waters only secondarily." Thus, the authors suggest the performance in the wash water is of less importance.

The organism preparation, growth, and recovery methods were modified to align with ASTM E1053 to accommodate testing of viruses. The EPA bacterial study design was followed for all other aspects of the procedure as EPA does not presently have a guideline for virucidal testing for laundry. The hard surface virucidal criteria EPA has applied during their review of the study was not selected by the testing lab originally as the study design utilized did not conform with 810.2200 for hard surfaces and 810.2200 did not have a criteria for wash water, thus the lab utilized the 810.2400 performance criteria as it more closely followed the study procedure. The EPA laundry disinfection success criteria require:

***(ii) Evaluation of disinfection success.*** *There should be no growth in the subculture from the fabric ond no growth in the subculture from the laundry water for all test microorganisms. This lack of growth should be demonstrated against each test microorgonism within the contact time claimed on the label.*

The laundry disinfection criteria for "bacteria" does not require a 3 log reduction on the fabric or in the wash water, thus viral testing should similarly not be required to measure a 3 log reduction.

Following a 4.6 log CFU/fabric carrier and 4.25 log CFU/mL wash water challenge, Capricorn (MRID 50209725) demonstrated no growth on all 9 fabric swatches and three aliquots of wash water on each of three product test lots. This performance meets the laundry disinfection performance criteria stated in 810.2400 for bacteria. This study design and criteria match that utilized by the only other laundry in-wash disinfection product with a viral claim.

The results of the study also show a >3 log reduction on all 9 swatches for all three lots tested. However, due to cytotoxicity which was the result of assaying the wash water where more product residual was present, thus only a 2.75 log reduction can be calculated from the wash water as EPA as pointed out. This value could be rounded to meet a 3 log reduction.

As requested by EPA the label has been modified to remove all viral claims related to Laundry Sanitization, we have revised the label to better align with the current laundry virucidal claim found on EPA Reg. No. 10324-115 which states the virucidal activity and does not categorize it as disinfection or sanitization performance. We request the EPA reconsider accepting MRID 50209725 based on the above explanation and alongside the claim revision to limit the claim generally to virucidal activity.

# Addendum #2

## Rebuttal to Efficacy Review Label Comment #14

The dilution rates for the in-wash Directions for Use are based upon the following chart.

| Claim | Volume in wash(L) | Volume in wash (gal) | Scoops | Powder in wash (g) | g/L | g/gal |
|---|---|---|---|---|---|---|
| HE In-wash disinfection (45C) | 15.1 | 3.989 | 2 | 269.4 | 17.84 | 67.53 |
| HE In-wash Sanitization (30C) | 15.1 | 3.989 | 2 | 269.4 | 17.84 | 67.53 |
| HE In-wash virucidal (30C) | 15.1 | 3.989 | 1 | 134.7 | 8.92 | 33.76 |
| Top Load In-wash Sanitization (45C) | 52 | 13.738 | 2 | 269.4 | 5.18 | 19.61 |
| Top load In-wash Virucidal (45C) | 52 | 13.738 | 2 | 269.4 | 5.18 | 19.61 |

The dilution rates are based upon the average volume of water in a washing machine. The average volume of water in a HE washer is 15.1 liters of water (3.989 gallons) and in a Top Load washer it is 52 liters (13.738 gallons) of water. Therefore, the amount of product calculated to be used in the efficacy studies was based upon this knowledge and the size of a normal scoop used by Church & Dwight in their product. This "normal" scoop is ~ 135 grams (reflected as 134.7 grams in chart above) of product when completely full. The HE in-wash virucidal testing was conducted at 33.8 grams per gallon dilution rate to reflect the use of 1 scoop. The other studies were conducted based upon the use of 2 scoops of this 135 gram scoop. The Directions for Use are designed to allow for other sized scoops, cups and pouches to be used. If smaller scoops, caps or pouches are used this would be reflected by adding more scoops, caps or pouches in the Directions for Use.

The efficacy studies were conducted by utilizing two dilutions of the product prior to the start of the contact time. For example, in study Volume 20 - A22530 (HE disinfection study with Klebsiella pneumoniae and Staphylococcus aureus) the product was initially diluted at a rate of 62.4 grams of product in 1 liter of water. Additionally, **in a second step**, this initial dilution of 62.4 g/L was further diluted when it was placed into the experimental vessel. 17.15 mL of the 62.4g/L solution was added to a vessel along with 42.66 mL of water and 0.185 mL of detergent. The amount of powder added was then 17.15 mL X (62.4g/1000 mL) = 1.07g.

The total volume in the vessel was 60 mL. So, this corresponds to 1.07g powder in 0.06L of total experimental solution = **17.8 g/L, or 67.5g/gallon**.

This final dilution **correlates to the chart above** in the first row and the dilution rate that appears in the administrative text in the Directions for Use.

Therefore, if the "normal" scoop is used the Directions for Use in this section (page 3 of 43) would say:

"Additive To Disinfect Laundry in HE Washers: Add 2 scoops of product into washing machine BEFORE adding laundry. Add detergent as directed. Wash 16 minutes in hot water."

If a smaller scoop would be used, for example, a 67.5 gram scoop which is half the size of the "normal" scoop then the Directions for Use would be revised to say "Add 4 scoops".

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 21, 2017

David Swain
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street
Columbia City, IN 46725

Subject: PRIA Regulatory Determination
Product Name: Capricorn
EPA Registration Number: 10772-23
Application Date: March 29, 2017
Decision Number: 527916

Dear Mr. Swain:

The Agency has completed its review of your application and has previously communicated to you on August 3, 2017 our pre-decisional determination that identified specific label changes that were necessary in order for the Agency to approve your application. At this time, those label issues have not yet been resolved. In accordance with Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012, your application was assigned a decision review time. The Agency has reviewed the application and has determined that the pesticide "Capricorn" does not meet the criteria for registration under either FIFRA sec. 3(c)(5) or (7) without the specified label changes. This determination marks the end of the PRIA decision review period. Again, EPA is attaching to this letter a marked-up copy of your label that identifies changes that must be made as well as the science reviews that support the need for these label changes.

On August 18, 2017, the Agency communicated with you a series of ongoing concerns persisted with the label submission. You have up to 30 calendar days from the date of this letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within 30 days, EPA intends to proceed with denial of the application. If an agreement is reached, you must submit a revised label to EPA. EPA will then provide you a stamped accepted final label within two (2) business days of receipt of your revised label.

If you have any questions, you may contact Terria Northern at 703-347-0265 or via email at northern.terria@epa.gov.

Sincerely,

Zeno Bain, Acting Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460**

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

June 26, 2017

**MEMORANDUM**

Subject: Efficacy Review for Capricorn,
EPA Reg. File No. 10772-23,
DP Barcode: D440031

From: Sophie Nguyen
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

To: Zeno Bain, RM33/Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Church & Dwight Co., Inc.
500 Charles Ewing Blvd.
Ewing, NJ 08628

**Formulation from the Label:**

| Active Ingredient | % by wt. |
|---|---|
| Sodium Percarbonate | 18.50 |
| Tetraacetylethylenediamine | 4.44 |
| OtherIngredients | 76.66 |
| Total | 100.00% |

## I. BACKGROUND

The product, Capricorn (EPA Reg. No.10772-23), is an EPA-registered product designed as a concentrated solid product to be diluted as instructed as a laundry pre-soak or post-soak disinfectant and sanitizer and hard surface disinfectant (bactericide, virucide) and sanitizer for use in sites such as homes, schools, hospital and office buildings. The registrant is proposing to add various claims to the label, including additional claims for hard, non-porous surface disinfection, hard, non-porous surface sanitization, soft, non-food contact sanitization, and laundry presoak disinfection and sanitization, and new claims for laundry disinfection and sanitization additives as well as for carpet sanitization. The studies were conducted at Accuratus Lab Services, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated March 29, 2017), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), 20 efficacy studies (MRID Nos. 50209709 through 50209728), and the product's proposed label. Statement of No Data Confidentiality Claims, Compliance Statement and Quality Assurance Unit Summary were included with each study.

Note: On Nov. 10, 2015, the Agency confirmed via email that the contact times for laundry pre-soak sanitization at 10 minutes and laundry pre-soak disinfection at 15 minutes are acceptable claims for this product.

## II. USE DIRECTIONS

The product, Capricorn or Oxiclean is an antibacterial cleaner, laundry additive, stain remover with disinfection, toilet bowl cleanser, and laundry sanitizer and disinfectant.
Laundry Use: Residential Laundry Sanitization and Disinfection: High Efficiency Machine Front Loader Machine

Directions on the proposed label provide the following information regarding preparation and use of the product:

**{HE Washer Section – <u>Option 1</u>}**
[To] Disinfect [Laundry] [In-Wash] [in HE] [Washers][/] [top] [and] [front load[er]] [machines]]: Add # {Insert #scoops/pouches/caps to at least equal the dose used in efficacy testing for bacteria to support claims for bacteria and virus HE laundry disinfection} [scoops] [pouches] [caps] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. Add [regular] [laundry] detergent as directed. Wash [for] [at least] 16 minutes in hot [45°C] water. [Effective against {insert HE laundry disinfectant bacteria and viruses from Table 7}]

[To] Sanitize {Laundry] [In-Wash] [in HE] [Washers] [/] [top] [and] [front load[er]] [machines]]: Add # {Insert # scoops/pouches/caps to at least equal the dose used in efficacy testing for bacteria for HE Laundry Sanitization} [scoops] [pouches] [caps] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. Add [regular] [laundry] detergent as directed. Wash [for] [at least] 15 minutes in warm [30°C] water. [Effective against {Insert HE laundry sanitization bacteria from Table 7}]

**{HE Washer Section – Option 2}**
[To] Disinfect [Kill][Bacteria][in][Laundry] [In-Wash] [in HE] [Front-Load[er]] [Washers] [/] [top] [and] [front load[er]] [machines]]: Add # {Insert # scoops/pouches/caps to at least equal the dose used in efficacy testing for bacteria to support claims for bacteria HE laundry disinfection} [scoops] [pouches] [caps] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. Add [regular] [laundry] detergent as directed. Wash [for] [at least] 16 minutes in hot [45°C] water. [Effective against {insert HE laundry disinfectant bacteria from Table 7}]

[To] [Disinfect] [Kill] Viruses [in] [Laundry] [In-Wash] [in HE] [Front-Load[er]] [Washers] [/] [top] [and] [front load[er]] [machines]]: Add # {Insert # scoops/pouches/caps to at least equal the dose used in efficacy testing for viruses to support claims for virus HE laundry disinfection} [scoop] [pouch] [cap] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. Add [regular] [laundry] detergent as directed. Wash [for] [at least] 15 minutes in warm [30°C] water. [Effective against {insert HE laundry viruses from Table 7}]

[To] Sanitize [Laundry] [In-Wash] [in HE] [Washers] [Front-Load[er]] [/] [top] [and] [front load[er]] [machines]]: Add #{Insert # scoops/pouches/caps to at least equal the dose used in efficacy testing for bacteria to support claims for HE laundry sanitization} [scoops] [pouches] [caps] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. Add [regular] [laundry] detergent as directed. Wash [for] [at least] 15 minutes in warm [30°C] water. [Effective against {insert HE laundry sanitization bacteria from Table 7}]

**{HE Washer Section – Option 3 – Table} {organism column optional} – Refer to label.**

**[Top Load [Standard] [Washers] [with large agitator] [non-HE]] {Top Loader graphic}**

**{Top Loader Section – Option 1}**
[To] Sanitize and Kill Viruses [in] [Laundry] [In-Wash] [in Top Load] [Standard] [Washers] [with large agitator] [non-HE]: Add # {Insert # scoops/pouches/caps to at least equal the dose used in efficacy testing for bacteria to support claims for HE laundry sanitization and virucidal action} [scoops] [pouches] [caps] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. Add [regular] [laundry] detergent as directed. Wash [for] [at least] 18 minutes in hot [45°C] water. [Effective against {Insert Top Loader laundry sanitization bacteria from Table 7}]

**{Top Loader Section – Option 2}**
[To] Sanitize [Laundry] [In-Wash] [in Top Load] [Standard] [Washers] [with large agitator] [non-HE]: Add # {Insert # scoops/pouches/caps to at least equal the dose used in efficacy testing for bacteria to support claims for HE laundry sanitization} [scoops] [pouches] [caps] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. Add [regular] [laundry] detergent as directed. Wash [for] [at least] 18 minutes in hot [45°C] water. [Effective against {Insert Top Loader laundry sanitization bacteria from Table 7}]
For [Laundry] Virucidal Action [in Top Load] [Standard] [Washers] [with large agitator] [non-HE]: Add # {Insert # scoops/pouches/caps to at least equal the dose used in efficacy testing for virus to support claims for virucidal action} [scoops] [pouches] [caps] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. Add [regular] [laundry] detergent as directed. Wash [for] [at least] 18 minutes in hot [45°C] water. [Effective against {Insert Top Loader laundry virucidal action viruses from Table 7}]

**{Top Loader Washer Section – Option 3 – Table} {organism column optional} – Refer to label.**

**[To] Disinfect [Laundry][by presoaking]:**
[To kill] bacteria, fungi and viruses†[:] {Insert directions for 1X dilution type and applicable measuring device from Table 9 (scoops/pouches) or Table 10 (caps)} . Immerse laundry for [at least] 15 minutes for bacteria and virus†, or 30 minutes for fungi[Trichophyton mentagrophytes][T.][Athlete's Foot Fungus] prior to starting the wash cycle. [Light soils do not require precleaning.] [Effective against {insert laundry disinfection bacteria, fungi, and/or viruses from Table 7}.]

**{Final Rinse Section}**
[To] Disinfect [Laundry] [ in the final rinse]:
[Post-Wash [Sanitization/Disinfection] [Use]: For additional sanitization/disinfection, refill washing machine with [clean] water. {insert directions for "1X" and applicable measuring device from Table 9 (scoops/pouches) or Table 10 (caps)} in washing machine. Immerse laundry for [at least] 10 minutes for

bacteria sanitization, or 15 minutes for bacteria and virus† disinfection, or 30 minutes for fungi [Trichophyton mentagrophytes][Athlete's Foot Fungus]. [Rinse thoroughly.] [Effective against {insert laundry pre-soak disinfection bacteria, fungi, and/or viruses from Table 7}.]

**CARPET[S] [SANITIZATION]**
[To [spot] sanitize carpet [Carpet Sanitization] [:]
[1] Remove [Vacuum] heavy soil.
[2] {Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.
[3] Spray [Apply] until thoroughly damp.
[4] Scrub carpet with moderate pressure for 30 seconds. Let stand for 5 minutes.
[5] Allow carpet to dry. Repeat as needed.]

## III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surface Environments (Additional Microorganisms):
Effectiveness of disinfectants against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. This section addresses efficacy testing for limited, broad-spectrum or hospital disinfectants which bear label claims against bacteria other than *S. enterica* (ATCC10708), *S. aureus* (ATCC 6538) or *P. aeruginosa* (ATCC 15442). The effectiveness of disinfectant against specific bacteria must be determined by AOAC Use-Dilution Method (UDM). Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. The product should kill all the test microorganisms on all carriers in ≤ten minutes. The minimum carrier counts to make the test valid should be $1 \times 10^4$ CFU/carrier. For a valid test, no contamination of any carrier is allowed.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least $10^4$ from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi):
Efficacy testing should be conducted against *Trichophyton mentagrophytes* (ATCC 9533). Effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 samples representing 2 different batches at LCL, using AOAC Fungicidal Test. The test should be conducted at 5, 10, and 15 minute exposure times. The inoculum employed should provide a concentration of $\geq 5 \times 10^6$ conidia/mL. **Performance requirements for this test:** the highest dilution that kills all fungal spores is the minimum effective concentration.

Alternatively, the AOAC Use Dilution Method, modified to conform to appropriate elements in the AOAC Fungicidal Test, may be employed. If the product is intended for use as a spray, the AOAC Germicidal Spray Product Test must be employed. Ten carriers for each of two samples representing two different batches of the product should be evaluated. The inoculum employed should provide a concentration of $1 \times 10^4 - 1 \times 10^5$

conidia/carrier. **Performance requirements:** for AOAC International Fungicidal Activity of Disinfectant test, all fungal spores at 10 and 15 minutes should be killed. For the AOAC Use-Dilution Methods, all fungal spores on all 10 carriers should be killed in ≤ten minutes.

Sanitizer Test (for inanimate, non-food contact surfaces):
The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The Agency recommends the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) (Ref. 1). The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. For hard, porous surface label claims use unglazed ceramic tile. For hard, nonporous surface label claims use stainless steel carrier or glass slide. Use 5 test carriers and 3 control carriers. Tests should be performed with each of 3 product samples, representing 3 different product lots, tested at LCL against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least $7.5 \times 10^5$ colony forming units per carrier. The performance measure should demonstrate a reduction of ≥99.9% (a 3-log10 reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

Sanitizers (For Non-Food Contact Surfaces; Additional Bacteria):
Effectiveness of sanitizers for non-food contact surfaces against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. In these cases, confirmatory test standards would apply. The effectiveness of sanitizers for non-food contact surfaces against specific bacteria must be determined by the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153). Two product samples, representing 2 different product lots, should be tested against each additional microorganism. Use 5 test carriers and 3 control carriers. The ASTM method states that the inoculum employed should provide a count of at least $7.5 \times 10^5$ colony forming units per carrier. The performance measure should demonstrate a reduction of ≥99.9% (a 3-$\log_{10}$ reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

Spot Soft Surface Sanitization:
The study is designed to evaluate the antimicrobial efficacy of sanitizers on pre-cleaned or lightly soiled, non-food contact soft surfaces. For sanitizer products intended for use on soft, non-food contact surfaces, a fabric carrier method is used to generate efficacy data. The test system proposed is a modification of the ASTM approved method for the evaluation of the antimicrobial efficacy of sanitizers on non-food contact surfaces. The method is modified for spray product application. The Agency recommends the use of The American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153-03). Three product samples, representing three different batches, at the LCL should be tested against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). The ASTM method states "an average of at least $7.5 \times 10^5$ organisms must have survived the inoculated control squares for the test to be valid." Two different fabric types should be tested. The fabrics should represent natural fabrics, such as cotton, and synthetic fabrics, such as polyester or rayon. A film of bacterial cells, dried on fabric carriers, is exposed to the test substance for a specified contact time. After exposure, the carriers are transferred to vessel containing neutralizing subculture media and assayed for survivors. Appropriate viability and sterility of organism population and neutralization controls are performed. Carrier type claimed on the label must be consistent with the test system. The test material meets effectiveness requirements of kill an average of at least 99.9% (3 log reduction) of the required organism on the 5 replicate carriers within 5 minutes. Controls must always meet the stipulated criteria.

Laundry Disinfectant – Pre-Soak Treatment for Use in Hospital or Medical Environments:

The effectiveness of disinfectants as pre-soak treatment for use on soiled fabrics by total immersion in the use solution prior to routine laundry operations in hospital or medical environments must be substantiated by data derived using the AOAC International Use-Dilution Method (Ref.1) (for water soluble powders and liquid products) modified to include 5% organic soil. Sixty carriers must be tested against each of the three batches of the product at the lower certified limit(s) (LCL) of the active ingredient(s) against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). A mean log density of at least 6.0 (corresponding to a geometric mean density of $1.0 \times 10^6$) and not above 7.0 (corresponding to a geometric mean density of $1.0 \times 10^7$) for both organisms is required. A mean log density <6.0 or >7.0 invalidates the test. To support products labeled as "disinfectants", conduct three independent tests (i.e., three batches at the LCL tested on three different test days) against the test microbes. The performance standard for both organisms is 0-1 positive carrier out of sixty. Sixty carriers are required per test, without contamination in the subculture media. Contamination of only one carrier (culture tube) is allowed per 60-carrier set; occurrence of more than one contaminated carrier invalidates the test results. To be deemed an effective product, the product must pass all tests for both microbes. All products should meet the performance standard associated with the method and microbe at ≤ 10 minutes of contact. For additional microorganisms other than those named as the designated test microorganism(s), refer to Disinfectants for Use on Hard Surface Environments (Additional Microorganisms) section above (test with 5% organic soil).

Laundry Sanitizing– Pre-Soak Treatment:
The effectiveness of sanitizers as pre-soak treatment for use on soiled fabrics by total immersion in the use solution prior to routine laundry operations must be substantiated by data derived using the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) modified to include 5% organic soil. Three product samples, representing three different batches, tested at the lower certified limit(s) of the active ingredient(s), should be tested against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (*K. pneumoniae*) (ATCC 4352). *Enterobacter aerogenes* (ATCC 13048) may be substituted for *K. pneumoniae*. Unglazed ceramic tile should be used for the test carrier. Five (5) test carriers and 3 control carriers should be used for each test. According to the ASTM method, "an average of at least $7.5 \times 10^5$ organisms must have survived the inoculated control squares for the test to be valid." The performance standard should demonstrate a reduction of ≥99.9 percent (a 3-$\log_{10}$ reduction) in the number of each test microorganism over the parallel control count in ≤5 minutes. To be deemed an effective product, the product must pass all tests for the indicated microbes. For additional microorganisms other than those named as the designated test microorganism(s), refer to Sanitizers (For Non-Food Contact Surfaces; Additional Bacteria) section above (test with 5% organic soil).

Laundry Sanitizer – For Use During Commercial-Industrial-Institutional Laundry Operations:
The effectiveness of laundry sanitizers must be supported by data that show that the product will substantially reduce the numbers of test bacteria on fabric and in laundry water. Laundry additives may either be used as soaking treatments prior to laundering or as treatments added during laundry operations. The label must specify the type of use. Laundry additives may be recommended for household/coin-operated machine use or commercial-industrial-institutional use. The label must specify the type of use. There is a significant difference in the water to fabric ratio between these two uses, which may affect the efficacy of the product. Tests should be conducted using a simulated-use procedure such as Petrocci and Clarke's "Proposed Test Method for Antimicrobial Laundry Additives" or a simulated use study involving washing machines. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old. Tests should be conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Products labeled as being suitable for hospital use must also be tested against *Pseudomonas aeruginosa* (ATCC 15442). Each product lot must be tested with 3 fabrics swatches against each of the test organisms. The method employed must include subculturing of both the fabric and the laundry water. The laundry water to media volume ratio must not exceed 1:40. Testing of a 0.5 mL sample of laundry water from the simulated washing device (or a 5 mL sample from the automatic washer) is recommended. Results from a quantitative bacteriological assay must be reported. Results must show a bacterial reduction of 99.9% over the control count for both fabric and laundry water for each organism tested. The label directions for use of laundry additives should specify the machine cycle in which the

product is to be added, as well as water level, temperature, and treatment time. Compatibility of the treatment with other laundry additives should be determined in testing and addressed in labeling, when applicable. These Agency standards are presented in DIS/TSS-13, and do not apply to sodium-calcium hypochlorites, sodium-potassium dichloro-s-triazinetriones, or trichloro-s-triazinetrione.

Note: The water to fabric ratio in industrial laundering operations is about 5:1. Dosages may be based on pounds of fabric for industrial machines.

Laundry Disinfectants: The effectiveness of laundry disinfectants must be supported by data that show that the product will completely kill test bacteria on fabric and in laundry water. Laundry additives may either be used as soaking treatments prior to laundering or as treatments added during laundry operations. The label must specify the type of use. Laundry additives may be recommended for household/coin-operated machine use or commercial-industrial-institutional use. The label must specify the type of use. There is a significant difference in the water to fabric ratio between these two uses, which may affect the efficacy of the product. Tests should be conducted using a simulated-use procedure such as Petrocci and Clarke's "Proposed Test Method for Antimicrobial Laundry Additives" or a simulated use study involving washing machines. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old. Tests should be conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Products labeled as being suitable for hospital use must also be tested against *Pseudomonas aeruginosa* (ATCC 15442). Each product lot must be tested with 9 fabrics swatches against each of the test organisms. The method employed must include subculturing of both the fabric and the laundry water. The laundry water to media volume ratio must not exceed 1:40. Testing of a 0.5 ml sample of laundry water from the simulated washing device (or a 5 ml sample from the automatic washer) is recommended. Results must be reported after a 48-hour incubation period. Results must show no growth in the fabric subcultures and no growth in the laundry water subcultures. The label directions for use of laundry additives should specify the machine cycle in which the product is to be added, as well as water level, temperature, and treatment time. Compatibility of the treatment with other laundry additives should be determined in testing and addressed in labeling, when applicable. These Agency standards are presented in DIS/TSS-13, and do not apply to sodium-calcium hypochlorites, sodium-potassium dichloro-s-triazinetriones, or trichloro-s-triazinetrione.

Note: The water to fabric ratio in industrial laundering operations is about 5:1. Dosages may be based on pounds of fabric for industrial machines.

Carpet Sanitization:
Products bearing label claims for effectiveness as sanitizers for pre-cleaned carpeting must be tested by a protocol incorporating the basic elements of the attached recommended method. If the product is intended to be represented in labeling as a "one-step" cleaner-sanitizer, the method must be modified by including an appropriate soil with the bacterial inoculum. Three product samples representing 3 separate batches, one of which is at least 60 days old, must be tested against *Staphylococcus aureus* ATCC 6538 and *Enterobacter aerogenes* ATCC 13048 with 2 different types of representative synthetic carpeting, such as acrylic and polypropylene tufted-loop types. If the application is intended for hospitals or medical institutions, the product must also be tested against *Pseudomonas aeruginosa* ATCC 15442. If the product is also intended for use on wool carpeting, an additional representative sample of wool carpet must be tested; otherwise, the label must bear a disclaimer for use on wool. All carpet samples tested must be fully identified by the pile fiber type, pile yarn weight of finished carpet, pile density, and tuft height. Adequate controls must demonstrate that bacteriostatic agents in the carpet pile or backing do not yield false-negative data which interfere with the test results. The amount of solution applied to the sample carpeting in the tests must be determined and extrapolated to obtain the amount of the solution of product to be applied to carpeting (volume per unit area) as stated on the label. A 99.9% reduction of test bacteria over the scrubbed control count must be demonstrated.

Supplemental Claims:

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

## IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY

The active ingredients' concentrations of **Batch No. 4562-132** were reported to be 3.99% TAED and 17.69% Sodium percarbonate, **Batch No. 4699-40** were reported to be 3.97% TAED and 17.41% Sodium percarbonate, and **Batch No. 4779-9** were 4.00% TAED and 17.48% Sodium percarbonate. The product's Tetraacetylethylenediamine (TAED) and Sodium percarbonate nominal concentrations are 4.44% and 18.90%, respectively, and the Lower Certified Limits of the product are 4.00% and 17.58%, respectively.

1. **MRID 50209709 "AOAC Use-Dilution Method," Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) for Capricorn, EPA Reg. No. 10772-23, by Melissa Bruner. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016. Project Identification No. A19754.**

Objective: Hard, Non-Porous Surface Disinfectant

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two batches (Batch# 4562-132 and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.3 (copy provided). The test substance was diluted to an equivalent of 62.4g/L, defined as 1 pre-weighed packet of test substance plus 1 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 20 minutes. The test solution was used within 40 minutes after mixing. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20.0°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A stock slant culture was transferred to an initial 10 mL tube of nutrient broth and incubated for 24±2 hours at 35-37°C. Daily transfers were made, and the final test culture was incubated for 48- 54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. No organic soil load was included in the culture. Ten (10) stainless steel penicylinders per product lot were inoculated with the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 36.7°C and at 52.9% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations. The carriers were exposed for 9.5 minutes at 20.0°C. After the exposure time, each medicated carrier was transferred to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

2. **MRID 50209710 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces" Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442) for Capricorn, EPA Reg. No. 10772-23, by Jamie Herzan. Study conducted at**

**Accuratus Lab Services. Study completion date – January 7, 2016. Project Identification No. A19766.**

Objective: Hard, Non-Porous, Non-Food Contact Surface Sanitizer

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Two batches (Nos. 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.3 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. An initial tube of 10 mL of culture broth was inoculated with a stock slant of original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours in nutrient broth. On the day of use, the pellicle was aspirated from the culture. The upper portion of the culture was transferred to sterile tube. A 48-54 hour culture was vortex-mixed. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The culture was diluted using 2.00 mL test organism suspension and 2.00mL sterile growth medium. The culture was thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile glass 1" x 1" carriers were inoculated with 0.02 mL (20.0 µL) of culture by spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carriers were dried for 20 minutes at 36.1°C and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 32% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

3. **MRID 50209711 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces" Test Organisms: *Salmonella enterica* (ATCC 10708) for Capricorn, EPA Reg. No. 10772-23, by Jamie Herzan. Study conducted at Accuratus Lab Services. Study completion date – January 11, 2016. Project Identification No. A19768.**

Objective: Hard, Non-Porous, Non-Food Contact Surface Sanitizer

This study was conducted against *Salmonella enterica* (ATCC 10708). Two batches (Nos. 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.4 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. An initial tube of 10 mL of culture broth was inoculated with a stock slant of original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours in nutrient broth. A 48-54 hour culture was vortex-mixed. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The culture was thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to

yield a 5% Fetal Bovine Serum organic soil load. Sterile glass 1" x 1" carriers were inoculated with 0.02 mL (20.0 µL) of culture by spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carriers were dried for 20 minutes at 36.1°C and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 30% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

4. **MRID 50209712 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces" Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442) for Capricorn, EPA Reg. No. 10772-23, by Maggie Brusky. Study conducted at Accuratus Lab Services. Study completion date – January 26, 2016. Project Identification No. A19901.**

Objective: Soft-Surface, Non-Food Contact Sanitizer

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Two batches (Nos. 4562-132, and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85112415.NFS.2 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days. Each daily transfer was incubated for 24±2 hours in Nutrient broth. The pellicle was aspirated from the culture and care was taken to avoid disrupting the pellicle. The upper portion of the culture was transferred to a sterile tube. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The cultures were thoroughly mixed prior to use. A 0.20 mL aliquot of FBS was added to 3.80 mL of prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Two types of carriers (100% cotton weave fabric and 100% polyester fabric) were prepared and rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Sterile carriers were inoculated with 0.03 mL (30.0 µL) of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated carriers were dried for 30 minutes at 35-37°C (36.0°C) and 40% relative humidity with the Petri dish lids intact. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room

temperature (19°C) and 21% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Glass beads were utilized to aid in organism recovery from the modified fabric substrate. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation and storage, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count.

Note

Per Sponsor's request the protocol is amended to change Lot 4699-40 to Lot 4779-9. No protocol deviations occurred during this study.

5. **MRID 50209713 "Fungicidal Use-Dilution Method," Test Organisms: *Trichophyton mentagrophytes* (ATCC 9533) for Capricorn, EPA Reg. No. 10772-23, by Melissa Bruner. Study conducted at Accuratus Lab Services. Study completion date – June 29, 2016. Project Identification No. A20050.**

Objective: Laundry pre-soak disinfectant.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two batches (Batch# 4562-132 and Batch# 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85122215.FUD.2 (copy provided). The test substance was diluted to an equivalent of 62.4g/L, defined as 1 pre-weighed packet of test substance plus 1 liter of diluent of 100 ppm AOAC synthetic hard water. The solution was allowed to stir until all powder was dispersed, but no longer than 20 minutes. The test solution was used within 40 minutes after mixing. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20.0-20.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. The culture was prepared by inoculating 30 agar plates with stock culture and incubating for 10 days at 35-37°C. The mycelia were removed from sufficient plates and transferred to sterile glassware containing glass beads at a ratio of 25.0 mL of saline/Triton Solution (0.85% saline + 0.05% Triton X-100) per 5 plates harvested, and agitated. Hyphal fragments were removed from the culture. The conidial concentration was estimated by hemacytometer. The culture was stored at 2-8°C for 1-3 weeks prior to use. The 01/12/16 culture was diluted by combining 2.00 mL of test organism suspension with 28.0 mL of 0.85% Saline + 0.05% Triton X-100. The 05/10/16 culture was diluted by combining 2.00 mL of test organism suspension with 18.0 mL of the same solution. Aliquots of FBS was added to the prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) stainless steel penicylinders per product lot were immersed in the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 36.6-36.7°C and at 52.1-53.4% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations. On 01/12/16, the carriers were exposed for 29.5 minutes at 20.5°C. On 05/10/16, the carriers were exposed for 30 minutes at 20.0°C. After the exposure time, each medicated carrier was transferred to 20mL of neutralizing subculture medium (Sabouraud Dextrose Broth + 0.14% Lecithin + 1.0% Tween 80). All neutralized subcultures were incubated for 10 days at 25-30°C. The agar plate subcultures were incubated for 66-67 house at 25-30°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. On 01/22/16, representative test and positive control cubculture tubes showing growth from the 01/12/16 test date were subcultured to Glucose Agar and incubated at 25-30°C for 3 days. The resultant growth was visually examined and stained by lactophenol cotton blue to confirm or rule out the presence of the test organism. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population.

Note

Protocol amendments: Per Sponsor request, additional testing will be added to this protocol. Lot 4779-9 will also be tested at a 30 minute exposure.

Protocol deviations: On 04/04/16, a 4.4% fetal bovine serum organic soil load was inadvertently used instead of the requested 5% fetal bovine serum organic soil load. Testing from this date was invalidated and repeated due to a population control falling below the minimum 4.0 log10. Therefore, this deviation has no impact on the overall intent of the protocol. On 05/04/16, the exposure time used in the assay was 29.5 minutes instead of the requested 30 minutes. Testing from this date was invalidated and repeated prior to the generation of test substance data because population control was above the maximum 5.0 log10 requirement. Therefore, this deviation has no impact on the overall intent of the protocol.

Test History

The assay was originally tested on 01/12/16, resulting in a valid assay with data presented in the body of this report. Per Sponsor request, additional testing of lot 4779-9 at a 30 minute exposure was added to this protocol and ran on 02/25/16.

Testing on 02/25/16 did not meet validity criteria because the population control was above the maximum 5.0 log10 requirement. The neutralization controls from this test date are valid and presented in Table 3. The remaining data from this test date is considered invalid and can be found in Attachment I.

Testing was repeated on 04/04/16 and did not meet validity criteria because the population control fell below the minimum 4.0 log10 requirement. Testing from 04/04/16 is considered invalid and can be found in Attachment II.

Testing was repeated on 05/04/16 and did not meet validity criteria because the population control was above the maximum 5.0 log10 requirement. Testing from 05/04/16 was invalidated prior to the generation of test substance data. Testing from 05/04/16 is considered invalid and can be found in Attachment III.

Testing was repeated on 05/10/16 resulting in a valid assay, which is presented in the body of this report. Both valid assays presented in the body of this report were performed the same unless otherwise noted.

6. **MRID 50209714 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)" Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442) for Capricorn, EPA Reg. No. 10772-23, by Maggie Brusky. Study conducted at Accuratus Lab Services. Study completion date – January 7, 2016. Project Identification No. A19763.**

Objective: Laundry pre-soak sanitizer.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Two batches (Nos. 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.7 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. An initial tube of 10 mL of culture broth was inoculated with a stock slant of original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours in Nutrient broth. On the day of use, the pellicle was aspirated from the culture. The upper portion of the culture was transferred to sterile tube. A 48-54 hour culture was vortex-mixed. The upper portion of the culture was removed and transferred to a sterile vessel for use in testing. The culture was diluted using 2.00 mL of test organism suspension and 2.00 mL sterile growth medium. The culture was thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. One (1)" x 1" unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture by spreading the inoculum to within approximately 3mm of

the edges of the carrier. The inoculated carriers were dried for 20 minutes at 36.1°C and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The carriers were allowed to expose at room temperature (20°C) and 32% relative humidity for 9.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.1% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

7. **MRID 50209715 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)" Test Organisms: *Salmonella enterica* (ATCC 10708) for Capricorn, EPA Reg. No. 10772-23, by Maggie Brusky. Study conducted at Accuratus Lab Services. Study completion date – January 12, 2016 (Amended Report Dates – January 29, 2016 and February 3, 2016). Project Identification No. A19762.**

Objective: Laundry pre-soak sanitizer.

This study was conducted against *Salmonella enterica* (ATCC 10708). Two batches (Nos. 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.8 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. An initial tube of 10 mL of culture broth was inoculated with a stock slant of original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10 mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours in Nutrient broth. On the day of use, the pellicle was aspirated from the culture. The upper portion of the culture was transferred to sterile tube. A 48-54 hour culture was vortex-mixed. The upper portion of the culture was removed and transferred to a sterile vessel for use in testing. The culture was centrifuge concentrated at 3500 RPM for 10 minutes. A total of 24.0 mL of culture was concentrated to 2.40 mL. The culture was thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. One (1)" x 1" unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture by spreading the inoculum to within approximately 3 mm of the edges of the carrier. The inoculated carriers were dried for 20 minutes at 36.1°C and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2 oz. (60 mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The carriers were allowed to expose at room temperature (20°C) and 32% relative humidity for 9.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.1% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were

incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

8. **MRID 50209716 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-23, by Maggie Brusky. Study conducted at Accuratus Lab Services. Study completion date – January 26, 2016 (Amended Report Date – March 27, 2016). Project Identification No. A19796.**

Objective: Laundry pre-soak sanitizer.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (Nos. 4562-132, 4699-40, and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85111815.NFS.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed but not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium (Nutrient broth). A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The *Staphylococcus aureus* culture was diluted by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. For testing on 12/28/15, the *Klebsiella pneumoniae* culture was centrifuge concentrated at 3700 RPM for 15 minutes. A total of 35.0 mL of culture was concentrated to 5.00 mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile 1" x 1" unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3 mm of the edges of the carrier. The inoculated carriers were dried for 20 minutes at 36.1°C and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2 oz. (60 mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (19-20°C) and 16-30% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. For testing performed on 12/11/16, the subcultures were placed at 2-8°C for two days prior to examination. Following incubation and storage (for testing performed on 12/11/16), the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

Test History

Testing performed on December 11, 2015 resulted in a carrier population control failure for *Klebsiella pneumoniae*. Test data for *Klebsiella pneumoniae* from this date is therefore considered invalid and presented in Attachment I. The Neutralization Confirmation Control for *Klebsiella pneumoniae* performed on December 11, 2015 was deemed acceptable and valid, and is reported in the body of the report. Testing against *Staphylococcus aureus* performed on December 11, 2015 is considered valid and presented in the body of the report. Testing of *Klebsiel/a pneumoniae* was repeated on December 28, 2015. Test data from this date is considered valid and presented in the body of the report.

9. **MRID 50209717 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Escherichia coli* O157:H7 (ATCC 43888), for Capricorn, EPA Reg. No. 10772-23, by Maggie Brusky. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19793.**

Objective: Laundry pre-soak sanitizer.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 43888). Two batches (Nos. 4562-132, and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85111815.NFS.2 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10 mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10 mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium (Synthetic broth). A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The cultures were thoroughly mixed prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile 1" x 1" unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3 mm of the edges of the carrier. The inoculated carriers were dried for 20 minutes at 36.0°C and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2 oz. (60 mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0 mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 39% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±2 hours. For testing performed on 12/10/5, the subcultures were placed at 2-8°C for two days prior to examination. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count.

Note:

Protocol Amendment: Per Sponsor's request the protocol is amended to chane lot 4699-40 to Lot 4779-9.

Protocol Deviations: As the protocol states, the neutralization confirmation control treatment (NCT) control is performed by immersing a sterile carrier in test substance and treating it as in the test. The timing for this control was inadvertently not recorded so it was unverifiable as to whether the contrls were done with the correct exposure time.

Test History:

Testing performed on December 10, 2015 was inadvertently completed without timing being recorded for the neutralization confirmation controls (see Protocol Deviation). The neutralization confirmation controls from this date are therefore considered invalid and presented in Attachment I. The efficacy data from December 10, 2015 is valid and presented in the body of the report. The neutralization confirmation controls were repeated on January 11, 2016, are valid and presented in the body of the report.

10. **MRID 50209718 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)" Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442) for Capricorn, EPA Reg. No. 10772-23, by Maggie Brusky. Study conducted at Accuratus Lab Services. Study completion date – January 7, 2016. Project Identification No. A19794.**

Objective: Laundry pre-soak sanitizer.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Two batches (Nos. 4562-132 and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85111815.NFS.3 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. An initial tube of 10 mL of culture broth was inoculated with a stock slant of original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours in Nutrient broth. On the day of use, the pellicle was aspirated from the culture. The upper portion of the culture was transferred to sterile tube. A 48-54 hour culture was vortex-mixed. The upper portion of the culture was removed and transferred to a sterile vessel for use in testing. The culture was diluted using 2.00 mL of test organism suspension and 2.00 mL sterile growth medium. The culture was thoroughly mixed prior to use. A 0.10 mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. One (1)" x 1" unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture by spreading the inoculum to within approximately 3 mm of the edges of the carrier. The inoculated carriers were dried for 20 minutes at 36.2°C and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2 oz. (60 mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The carriers were allowed to expose at room temperature (20°C) and 37% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. The subcultures were placed at 2-8°C for two days prior to examination. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count.

Note:

Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4699-40 to Lot 4779-9.

No protocol deviations occurred during this study.

11. **MRID 50209719 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)" Test Organisms: *Salmonella enterica* (ATCC 10708) for Capricorn, EPA Reg. No. 10772-23, by Maggie Brusky. Study conducted at**

**Accuratus Lab Services. Study completion date – January 6, 2016. Project Identification No. A19795.**

Objective: Laundry pre-soak sanitizer.

This study was conducted against *Salmonella enterica* (ATCC 10708). Two batches (Nos. 4562-132 and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85111815.NFS.4 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. An initial tube of 10 mL of culture broth was inoculated with a stock slant of original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10 mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours in Nutrient broth. On the day of use, the pellicle was aspirated from the culture. The upper portion of the culture was transferred to sterile tube. A 48-54 hour culture was vortex-mixed. The upper portion of the culture was removed and transferred to a sterile vessel for use in testing. The culture was centrifuge concentrated at 3500 RPM for 10 minutes. A total of 7.5 mL of culture was concentrated to 2.5 mL. The culture was thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. One (1)" x 1" unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture by spreading the inoculum to within approximately 3 mm of the edges of the carrier. The inoculated carriers were dried for 20 minutes at 36.2°C and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2 oz. (60 mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0 mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The carriers were allowed to expose at room temperature (20°C) and 39% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. The subcultures were placed at 2-8°C for two days prior to examination. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count.

Note:

Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4699-40 to Lot 4779-9.

No protocol deviations occurred during this study.

12. **MRID 50209720 "Standard Test Method for Evaluation of Laundry Disinfectants", Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-23, by Jamie Herzan. Study conducted at Accuratus Lab Services. Study completion date – March 17, 2017. Project Identification No. A22530.**

Objective: Disinfecting efficacy of a laundry detergent or laundry additive – simulated-use study.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (Nos. 4779-124, 4779-126, and 4779-127) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85120916.LDIS (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed but not longer than 20 minutes. The prepared test substance was homogenous. Appropriate volumes of each prepared test substance concentrate (17.15 mL), detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) (185.0 µL), and 100 ppm AOAC Synthetic Hard Water (42.66 mL) were added to individual sterile "exposure chamber" Nalgene jars and equilibrated to 44.0 – 44.5°C. The test substance to fabric ratio was indicated to be 4:1

(weight/weight) for HE application. Each test organism was transferred on Nutrient Agar A slants and incubated at 33-37°C for 24±2 hours under aerobic conditions. After the slant was washed with Phosphate Buffer Dilution Water (PBDW), the growth suspension was aspirated and 1.0 mL was transferred to each of four Nutrient Agar B culture bottles. The bottles were incubated for 18-24 hours at 33-37°C under aerobic conditions with the agar side down. On the day of the test, each test organism was harvested from the Nutrient Agar B bottles by adding a 3.0 mL aliquot of PBDW and sterile glass beads. A spectrophotometric analysis was performed using a wavelength of 620 nm. For testing performed on 1/19/17, the final absorbance value was determined to be 1.631 for *K. pneumoniae* and 1.962 for *S. aureus*. For testing performed on 1/26/17, the final absorbance value was determined to be 1.510 for *K. pneumoniae* and 1.764 for *S. aureus*. A 0.20 mL aliquot of FBS was added to 3.80 mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. A scouring solution prepared on 6/15/16 included 3.20 grams Na2CO3 and 3.20 grams of Triton X-100 to 6.4 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 640 grams of test fabric was added to each 6.4 L of scouring solution. A scouring solution prepared on 12/30/16 included 4.80 grams Na2CO3 and 4.80 grams of Triton X-100 to 9.6 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 960 grams of test fabric was added to each 9.6 L of scouring solution. A scouring solution prepared on 1/13/17 included 5.50 grams Na2CO3 and 5.50 grams of Triton X-100 to 11 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 1100 grams of test fabric was added to each 11 L of scouring solution. Each solution was boiled for approximately 60 minutes, when the fabric was removed and rinsed in boiling water for a minimum of 5 minutes and then placed into cold water for a minimum of 5 minutes. The fabric was air dried for at least 1 day. The scoured and dried fabric was cut into approximately 5 cm (2 in.) wide strips and weighed. Each strip of fabric was wrapped around a stainless steel spindle at least twelve, but fewer than thirteen times. Fabric swatch carriers of approximately 1 inch x 1.5 inch were cut from the scoured fabric. The fabric-wrapped spindles and carriers were autoclave sterilized and were allowed to cool/dry at room temperature. Fabric swatch carriers were inoculated with 30 µL if prepared test organism, and the carriers were dried in a 36.3 – 36-6°C incubator at 41.5 – 64.5% relative humidity for 28-30 minutes. Up to three fabric carriers were placed individually into the spindle pockets between the 6th and 7th folds of the spindle. The inoculated carriers were not allowed to overlap. Nine test carriers were evaluated per test condition. Carriers were used within 1 hour of drying. The spindle wire was aseptically removed from the fabric spindle. The spindles containing the carriers were placed into the jars containing the test substance. The jars were placed into a launderometer device to simulate a tumbler-wash at 51.3-53.5 RPM for a 15-minute and 15.5-minute exposure times at 44.0 – 44.5°C. After the simulated wash, prior to the end of the exposure time, the fabric spindle was removed from the jar. The liquid from the spindle was fully wrung out. The fabric carriers were aseptically removed and placed individually into jars containing 10 mL of the neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase). A 0.50 mL aliquot of the "wash" water was transferred to a vessel containing 10 mL of the neutralizer. All plates were incubated at 35-37°C for 46-50 hours, and the subcultures were visually examined for the presence or absence of growth. All test and control subculture tubes were subcultured to Tryptic Soy Agar + 5% Sheep's blood and incubated at 35-37°C for one day. The agar plates were visually examined for the presence or absence of growth. Controls included carrier population control, sterility, purity, viability, numbers control, and neutralization confirmation.

Note:

Protocol Amendment: Due to an inadvertent omission of one of the test organism on page 10 of the protocol, the protocol is amended to include *Klebsiella pneumoniae* (ATCC 4352) as a test organism. Per Sponsor's request, the protocol is amended to include additional testing of Lot 4779-124 against *Klebsiella pneumoniae* at an exposure time of 15.5 minutes.

No protocol deviations occurred during this study.

Test History:

Testing of Lot 4779-126 against *Staphylococcus aureus* and Lot 4779-127 against *Klebsiella pneumoniae* performed on January 19, 2017, resulted in contamination present in the subcultures for each lot of test substance. Testing of Lot 4779-126 against *Staphylococcus aureus* and testing of

Lot 4779-127 against *Klebsiella pneumoniae* performed on January 19, 2017, with the exception of the Neutralization Confirmation Controls, are invalid and reported in Attachment I.
Testing of Lot 4779-124 against *Klebsiella pneumoniae* performed on January 19, 2017, resulted in failing efficacy results. Per Sponsor's request, the protocol was amended to include additional testing of Lot 4779-124 against *Klebsiella pneumoniae* at an exposure time of 15.5 minutes (See Protocol Amendment 2). Lot 4779-124 was tested against *Klebsiella pneumoniae* on January 26, 2017, using an exposure time of 15.5 minutes, which resulted in passing efficacy results.

13. **MRID 50209721 "Virucidal Efficacy of a Laundry Additive", Test Organisms: Human Coronavirus, for Capricorn, EPA Reg. No. 10772-23, by Shanen Conway. Study conducted at Accuratus Lab Services. Study completion date – February 15, 2017. Project Identification No. A22316.**

Objective: Disinfecting efficacy of a laundry detergent or laundry additive – simulated-use study.

This study was conducted against Human Coronavirus, Strain 229 E, ATCC VR-740. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Cultures of WI-38 (human lung) cells, ATCC CCL-75, were used as the indicator cell line in the infectivity assays. The test medium used was Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Two batches (Nos. 4779-124 and 4779-126) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85111616.COR (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed but not longer than 20 minutes. The prepared test substance was homogenous. Appropriate volumes of each prepared test substance concentrate (8.58 mL), detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) (185 µL), and 100 ppm AOAC Synthetic Hard Water (51.25 mL) were added to individual laundrometer bottles. The test substance to fabric ratio was indicated to be 4:1 (weight/weight) for HE application. A scouring solution prepared using 5.20 grams Na2CO3 and 5.20 grams of Triton X-100 to 10.4 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 1040 grams of test fabric was added to each 10.4 L of scouring solution. The solution was boiled for approximately 60 minutes, when the fabric was removed and rinsed in boiling water for a minimum of 5 minutes and then placed into cold water for a minimum of 5 minutes. The fabric was air dried for at least 1 day. The scoured and dried fabric was cut into approximately 5 cm (2 in.) wide strips and weighed. Each strip of fabric was wrapped around a stainless steel spindle at least twelve, but fewer than thirteen times. Fabric swatch carriers of approximately 1 inch x 1.5 inch were cut from the scoured fabric. The fabric-wrapped spindles and carriers were autoclave sterilized and were allowed to cool/dry at room temperature. Individual scoured, sterile cotton swatches, 1 x 1.5 inches, were placed on the bottom of sterile glass or plastic petri dishes. A 300 µL aliquot of virus was inoculated onto the surface of each swatch and air dried at 21.0°C in a relative humidity of 7.6% until visibly dry at 30 minutes. For each test substance, nine dried and inoculated swatches were placed individually into the fabric wrapped spindles between the sixth and seventh lap, three swatches per spindles. The spindles were placed individually into a sterile Nalgene jar containing the indicated amount of the test substance concentrate, detergent, and water. The jar was capped and placed in the agitator and rotated at 51.0 RPM for 15 minutes at 30.0°C. Just prior to the end of the exposure time, the spindle was aseptically removed from the virus-test substance mixture and the three swatches were removed from the fabric wrapped spindle. At the end of the exposure time, the swatches were placed into individual tubes containing 3.0 mL of test medium. The tubes were mixed and the contents were passed through Sephadex column to detoxify the mixture. The filtrates were tittered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. Immediately following the exposure time, a 3.0 mL aliquot of the "wash" water was passed through a Sephadex column. The filtrate was then tittered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. Cells in multiwell culture dishes were inoculated in quadruplicate with 500 µL of the dilutions prepared from test and control groups. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for nine days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included carrier population control, sterility, purity, viability, numbers control, and neutralization confirmation. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration

endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization.

Note:

Protocol Amendment: Per Sponsor's request, this protocol is amended to include the name of the detergent to be used in testing. The name of the detergent was inadvertently not specified in the protocol. The detergent to be used in testing is Arm & Hammer Clean Burst Batch HH6244 3 0417. This protocol is amended to correct a typographical error on page 6 of the protocol. In the infectivity assay section, it incorrectly states that the cell cultures will be incubated for approximately 7 days. The correction incubation time for Human Coronavirus is approximately ten days.

Protocol Deviation: The technician incubated the test at 31-35°C which is a deviation from the protocol. On page 6 of the protocol, it incorrectly states that the incubation temperature for Human Coronavirus is 36-38°C. The technician incubated the test at the correct temperature for Human Coronavirus.

**14. MRID 50209722 "Virucidal Efficacy of a Laundry Additive", Test Organisms: Influenza A (H1N1) virus, for Capricorn, EPA Reg. No. 10772-23, by Shanen Conway. Study conducted at Accuratus Lab Services. Study completion date – February 23, 2017. Project Identification No. A22317.**

Objective: Disinfecting efficacy of a laundry detergent or laundry additive – simulated-use study.

This study was conducted against Influenza A (H1N1) virus, strain NPR/8/34, ATCC VR-1469. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Cultures of MDCK (canine kidney) cells, ATCC CCL-34, were used as the indicator cell line in the infectivity assays. The test medium used was Minimum Essential Medium (MEM) supplemented with 2 µg/mL TPCK-trypsin, 25 mM HEPES, 0,2% bovine serum albumin (BSA) fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Two batches (Nos. 4779-124 and 4779-126) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85111616.FLUA (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed but not longer than 20 minutes. The prepared test substance was homogenous. Appropriate volumes of each prepared test substance concentrate (8.58 mL), detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) (185 µL), and 100 ppm AOAC Synthetic Hard Water (51.25 mL) were added to individual laundrometer bottles. The test substance to fabric ratio was indicated to be 4:1 (weight/weight) for HE application. A scouring solution prepared using 5.00-5.20 grams Na2CO3 and 5.00-5.20 grams of Triton X-100 to 9.9-10.4 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 990-1040 grams of test fabric was added to each 9.9-10.4 L of scouring solution. The solution was boiled for approximately 60 minutes, when the fabric was removed and rinsed in boiling water for a minimum of 5 minutes and then placed into cold water for a minimum of 5 minutes. The fabric was air dried for at least 1 day. The scoured and dried fabric was cut into approximately 5 cm (2 in.) wide strips and weighed. Each strip of fabric was wrapped around a stainless steel spindle at least twelve, but fewer than thirteen times. Fabric swatch carriers of approximately 1 inch x 1.5 inch were cut from the scoured fabric. The fabric-wrapped spindles and carriers were autoclave sterilized and were allowed to cool/dry at room temperature. Individual scoured, sterile cotton swatches, 1 x 1.5 inches, were placed on the bottom of sterile glass or plastic petri dishes. A 300 µL aliquot of virus was inoculated onto the surface of each swatch and air dried at 21.0°C in a relative humidity of 16.5% until visibly dry at 30 minutes. For each test substance, nine dried and inoculated swatches were placed individually into the fabric wrapped spindles between the sixth and seventh lap, three swatches per spindles. The spindles were placed individually into a sterile Nalgene jar containing the indicated amount of the test substance concentrate, detergent, and water. The jar was capped and placed in the agitator and rotated at 54-55 RPM for 15 minutes at 30.0°C. Just prior to the end of the exposure time, the spindle was aseptically removed from the virus-test substance mixture and the three swatches were removed from the fabric wrapped spindle. At the end of the exposure time, the swatches were placed into individual tubes containing 3.0 mL of test medium. The tubes were mixed and the contents were passed through Sephadex column to detoxify the mixture. The filtrates were tittered by 10-fold serial dilution and assayed for infectivity and/or

cytotoxicity. Immediately following the exposure time, a 3.0 mL aliquot of the "wash" water was passed through a Sephadex column. The filtrate was then tittered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. Cells in multiwell culture dishes were inoculated in quadruplicate with 500 µL of the dilutions prepared from test and control groups. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included carrier population control, sterility, purity, viability, numbers control, and neutralization confirmation. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization.

Note:

Protocol Amendment: Per Sponsor's request, this protocol is amended to include the name of the detergent to be used in testing. The name of the detergent was inadvertently not specified in the protocol. The detergent to be used in testing is Arm & Hammer Clean Burst Batch HH6244 3 0417. No protocol deviations occurred during this study.

**15. MRID 50209723 "Virucidal Efficacy of a Laundry Additive", Test Organisms: Rhinovirus type 37, for Capricorn, EPA Reg. No. 10772-23, by Shanen Conway. Study conducted at Accuratus Lab Services. Study completion date – February 15, 2017. Project Identification No. A22318.**

Objective: Disinfecting efficacy of a laundry detergent or laundry additive – simulated-use study.

This study was conducted against Rhinovirus type 37, strain 151-1, ATCC VR-1147. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Cultures of MRC-5 (human embryonic lung) cells, ATCC CCL-171, were used as the indicator cell line in the infectivity assays. The test medium used was Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Two batches (Nos. 4779-124 and 4779-126) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85111616.R37 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed but not longer than 20 minutes. The prepared test substance was homogenous. Appropriate volumes of each prepared test substance concentrate (8.58 mL), detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) (185 µL), and 100 ppm AOAC Synthetic Hard Water (51.25 mL) were added to individual laundrometer bottles. The test substance to fabric ratio was indicated to be 4:1 (weight/weight) for HE application. A scouring solution prepared using 5.20 grams Na2CO3 and 5.20 grams of Triton X-100 to 10.4 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 1040 grams of test fabric was added to each 10.4 L of scouring solution. The solution was boiled for approximately 60 minutes, when the fabric was removed and rinsed in boiling water for a minimum of 5 minutes and then placed into cold water for a minimum of 5 minutes. The fabric was air dried for at least 1 day. The scoured and dried fabric was cut into approximately 5 cm (2 in.) wide strips and weighed. Each strip of fabric was wrapped around a stainless steel spindle at least twelve, but fewer than thirteen times. Fabric swatch carriers of approximately 1 inch x 1.5 inch were cut from the scoured fabric. The fabric-wrapped spindles and carriers were autoclave sterilized and were allowed to cool/dry at room temperature. Individual scoured, sterile cotton swatches, 1 x 1.5 inches, were placed on the bottom of sterile glass or plastic petri dishes. A 300 µL aliquot of virus was inoculated onto the surface of each swatch and air dried at 21.0°C in a relative humidity of 19.0% until visibly dry at 30 minutes. For each test substance, nine dried and inoculated swatches were placed individually into the fabric wrapped spindles between the sixth and seventh lap, three swatches per spindles. The spindles were placed individually into a sterile Nalgene jar containing the indicated amount of the test substance concentrate, detergent, and water. The jar was capped and placed in the agitator and rotated at 54.1 RPM for 15 minutes at 30.0°C. Just prior to the end of the exposure time, the spindle was aseptically removed from the virus-test substance mixture and the three swatches were removed from the fabric wrapped spindle. At the end of the exposure time, the swatches were placed into individual tubes containing 3.0 mL of test medium. The tubes were mixed and the contents were passed through Sephadex column to detoxify the mixture. The filtrates were tittered by

10-fold serial dilution and assayed for infectivity and/or cytotoxicity. Immediately following the exposure time, a 3.0 mL aliquot of the "wash" water was passed through a Sephadex column. The filtrate was then tittered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. Cells in multiwell culture dishes were inoculated in quadruplicate with 500 µL of the dilutions prepared from test and control groups. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included carrier population control, sterility, purity, viability, numbers control, and neutralization confirmation. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization.

Note:

Protocol Amendment: Per Sponsor's request, this protocol is amended to include the name of the detergent to be used in testing. The name of the detergent was inadvertently not specified in the protocol. The detergent to be used in testing is Arm & Hammer Clean Burst Batch HH6244 3 0417. To correct a typographical error in the infectivity assay section of the protocol on page 6. The protocol incorrectly states that the cultures are incubated at 36-380C. The correct incubation temperature for this virus is 31-35°C.

No protocol deviations occurred during this study.

**16. MRID 50209724 "Virucidal Efficacy of a Laundry Additive", Test Organisms: Influenza A (H1N1) virus, for Capricorn, EPA Reg. No. 10772-23, by Shanen Conway. Study conducted at Accuratus Lab Services. Study completion date – March 7, 2017. Project Identification No. A22464.**

Objective: Disinfecting efficacy of a laundry detergent or laundry additive – simulated-use study.

This study was conducted against Influenza A (H1N1) virus, strain NPR/8/34, ATCC VR-1469. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Cultures of MDCK (canine kidney) cells, ATCC CCL-34, were used as the indicator cell line in the infectivity assays. The test medium used was Minimum Essential Medium (MEM) supplemented with 2 µg/mL TPCK-trypsin, 25 mM HEPES, 0,2% bovine serum albumin (BSA) fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Two batches (Nos. 4779-124 and 4779-126) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85120916.FLUA (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed but not longer than 20 minutes. The prepared test substance was homogenous. Appropriate volumes of each prepared test substance concentrate (12.45 mL), detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) (133.5 µL), and 100 ppm AOAC Synthetic Hard Water (137.41 mL) were added to individual laundrometer bottles. The test substance to fabric ratio was indicated to be 10:1 (weight/weight) for top loading application. A scouring solution prepared using 3.20-5.50 grams Na2CO3 and 3.20-5.50 grams of Triton X-100 to 6.4-11 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 640-1100 grams of test fabric was added to each 6.4-11 L of scouring solution. The solution was boiled for approximately 60 minutes, when the fabric was removed and rinsed in boiling water for a minimum of 5 minutes and then placed into cold water for a minimum of 5 minutes. The fabric was air dried for at least 1 day. The scoured and dried fabric was cut into approximately 5 cm (2 in.) wide strips and weighed. Each strip of fabric was wrapped around a stainless steel spindle at least twelve, but fewer than thirteen times. Fabric swatch carriers of approximately 1 inch x 1.5 inch were cut from the scoured fabric. The fabric-wrapped spindles and carriers were autoclave sterilized and were allowed to cool/dry at room temperature. Individual scoured, sterile cotton swatches, 1 x 1.5 inches, were placed on the bottom of sterile glass or plastic petri dishes. A 300 µL aliquot of virus was inoculated onto the surface of each swatch and air dried at 22.0°C in a relative humidity of 9.4-35.3% until visibly dry at 30 minutes. For each test substance, nine dried and inoculated swatches were placed individually into the fabric wrapped spindles between the sixth and seventh lap, three swatches per spindles. The spindles were placed individually into a sterile Nalgene jar containing the indicated amount of the test substance concentrate, detergent, and water. The jar was

capped and placed in the agitator and rotated at 54.7 RPM for 18 minutes at 45.0°C. Just prior to the end of the exposure time, the spindle was aseptically removed from the virus-test substance mixture and the three swatches were removed from the fabric wrapped spindle. At the end of the exposure time, the swatches were placed into individual tubes containing 3.0 mL of test medium. The tubes were mixed and the contents were passed through Sephadex column to detoxify the mixture. The filtrates were tittered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. Immediately following the exposure time, a 3.0 mL aliquot of the "wash" water was passed through a Sephadex column. The filtrate was then tittered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. Cells in multiwell culture dishes were inoculated in quadruplicate with 500 µL of the dilutions prepared from test and control groups. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included carrier population control, sterility, purity, viability, numbers control, and neutralization confirmation. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization.

Note:

Protocol Amendment: Per Sponsor's request, this protocol is amended to correct a typographical error in the attachment to the protocol. The protocol number is changed from SRC85121216.FLUA to SRC85120916.FLUA.

No protocol deviations occurred during this study.

SOP Deviations: For spindles used in testing, performed on January 11, 2017, EGN-FORM-0104 was inadvertently not filled out when the spindles were prepared for testing. This is a deviation from SOP ALS-0008 and CGT-0036. The remaining spindles for the lot used in testing were weighed and found to be within the required weight range. The lot number, scour date of the fabric and autoclave date for the spindles is known. The spindles were observed to be prepared per SOP CGT-0036 (fabric was ~2 inches wide and wrapped around the stainless steel spindle for at least 12 but not more than 13 revolutions, a safety pin was used to secure the fabric in place), therefore there is no impact on the overall intent of the protocol.

Test History:

Testing of the cytotoxicity control, neutralization control and input virus control were originally tested on January 11, 2017. The results for the neutralization control demonstrated infectious units that were much higher than is accepted by ASTM E1053 method for testing. The cytotoxicity control, neutralization control and input virus control were repeated on February 22, 2017, to confirm neutralization control results were valid and obtain results for the infectious units that are within the acceptable range of 1 ,000 to 5,000 infectious units as is suggested in ASTM E 1053. Results from testing performed on both test dates are considered valid and can be found in the body of this report.

**17. MRID 50209725 "Virucidal Efficacy of a Laundry Additive", Test Organisms: Rhinovirus type 37, for Capricorn, EPA Reg. No. 10772-23, by Shanen Conway. Study conducted at Accuratus Lab Services. Study completion date – March 6, 2017. Project Identification No. A22536.**

Objective: Disinfecting efficacy of a laundry detergent or laundry additive – simulated-use study.

This study was conducted against Rhinovirus type 37, strain 151-1, ATCC VR-1147. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Cultures of MRC-5 (human embryonic lung) cells, ATCC CCL-171, were used as the indicator cell line in the infectivity assays. The test medium used was Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Two batches (Nos. 4779-124 and 4779-126) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85120916.R37 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed

to stir until all the powder was evenly dispersed but not longer than 20 minutes. The prepared test substance was homogenous. Appropriate volumes of each prepared test substance concentrate (12.45 mL), detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) (133.5 µL), and 100 ppm AOAC Synthetic Hard Water (137.41 mL) were added to individual laundrometer bottles. The test substance to fabric ratio was indicated to be 10:1 (weight/weight) for top loading application. A scouring solution prepared using 3.20-5.50 grams Na2CO3 and 3.20-5.50 grams of Triton X-100 to 6.4-11 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 640-1100 grams of test fabric was added to each 6.4-11 L of scouring solution. The solution was boiled for approximately 60 minutes, when the fabric was removed and rinsed in boiling water for a minimum of 5 minutes and then placed into cold water for a minimum of 5 minutes. The fabric was air dried for at least 1 day. The scoured and dried fabric was cut into approximately 5 cm (2 in.) wide strips and weighed. Each strip of fabric was wrapped around a stainless steel spindle at least twelve, but fewer than thirteen times. Fabric swatch carriers of approximately 1 inch x 1.5 inch were cut from the scoured fabric. The fabric-wrapped spindles and carriers were autoclave sterilized and were allowed to cool/dry at room temperature. Individual scoured, sterile cotton swatches, 1 x 1.5 inches, were placed on the bottom of sterile glass or plastic petri dishes. A 300 µL aliquot of virus was inoculated onto the surface of each swatch and air dried at 20.0°C in a relative humidity of 25.3% until visibly dry at 30 minutes. For each test substance, nine dried and inoculated swatches were placed individually into the fabric wrapped spindles between the sixth and seventh lap, three swatches per spindles. The spindles were placed individually into a sterile Nalgene jar containing the indicated amount of the test substance concentrate, detergent, and water. The jar was capped and placed in the agitator and rotated at 53.4 RPM for 18 minutes at 45.0°C. Just prior to the end of the exposure time, the spindle was aseptically removed from the virus-test substance mixture and the three swatches were removed from the fabric wrapped spindle. At the end of the exposure time, the swatches were placed into individual tubes containing 3.0 mL of test medium. The tubes were mixed and the contents were passed through Sephadex column to detoxify the mixture. The filtrates were tittered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. Immediately following the exposure time, a 3.0 mL aliquot of the "wash" water was passed through a Sephadex column. The filtrate was then tittered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. Cells in multiwell culture dishes were inoculated in quadruplicate with 500 µL of the dilutions prepared from test and control groups. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture lahware. The cultures were scored periodically for ten days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included carrier population control, sterility, purity, viability, numbers control, and neutralization confirmation. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization.

Note:

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**18. MRID 50209726 "Standard Test Method for Evaluation of Laundry Sanitizers", Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352), for Capricorn, EPA Reg. No. 10772-23, by Jamie Herzab. Study conducted at Accuratus Lab Services. Study completion date – March 8, 2017. Project Identification No. A22333.**

Objective: Sanitizing efficacy of a laundry detergent or laundry additive – simulated-use study.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (Nos. 4779-124, 4779-126, and 4779-127) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85111616.LSAN (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed but not longer than 20 minutes. The prepared test substance was homogenous. On test date 1/5/17, appropriate volumes of each prepared test substance concentrate (8.58 mL), detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) (185.0 µL), and 100 ppm AOAC Synthetic Hard Water (51.25 mL) were added to individual laundrometer bottles. On test date 2/3/17, appropriate volumes of each prepared test substance concentrate (17.15 mL),

detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) (185.0 µL), and 100 ppm AOAC Synthetic Hard Water (42.66 mL) were added to individual laundrometer bottles. The test substance to fabric ratio was indicated to be 4:1 (weight/weight) for HE application. Each test organism was transferred on Nutrient Agar A slants and incubated at 33-37°C for 24±2 hours under aerobic conditions. After the slant was washed with Phosphate Buffer Dilution Water (PBDW), the growth suspension was aspirated and 1.0 mL was transferred to each of four Nutrient Agar B culture bottles. The bottles were incubated for 18-24 hours at 33-37°C under aerobic conditions with the agar side down. On the day of the test, each test organism was harvested from the Nutrient Agar B bottles by adding a 3.0 mL aliquot of PBDW and sterile glass beads. A spectrophotometric analysis was performed using a wavelength of 620 nm. For testing performed on 1/5/17, the final absorbance value was determined to be 1.606 for *K. pneumoniae* and 2.079 for *S. aureus*. For testing performed on 2/3/17, the final absorbance value was determined to be 1.764 for *S. aureus*. A 0.10 mL aliquot of FBS was added to 1.90 mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. For fabric prepared on 11/29/16, a scouring solution prepared using 5.2 grams Na2CO3 and 5.2 grams of Triton X-100 to 10.4 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 1040 grams of test fabric was added to each 10.4 L of scouring solution. For fabric prepared on 12/13/16, a scouring solution prepared using 5.0 grams Na2CO3 and 5.0 grams of Triton X-100 to 9.9 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 990 grams of test fabric was added to each 9.9 L of scouring solution. For fabric prepared on 1/13/17, a scouring solution prepared using 5.50 grams Na2CO3 and 5.50 grams of Triton X-100 to 11 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 1100 grams of test fabric was added to each 11 L of scouring solution. The solution was boiled for approximately 60 minutes, when the fabric was removed and rinsed in boiling water for a minimum of 5 minutes and then placed into cold water for a minimum of 5 minutes. The fabric was air dried for at least 1 day. The scoured and dried fabric was cut into approximately 5 cm (2 in.) wide strips and weighed. Each strip of fabric was wrapped around a stainless steel spindle at least twelve, but fewer than thirteen times. Fabric swatch carriers of approximately 1 inch x 1.5 inch were cut from the scoured fabric. The fabric-wrapped spindles and carriers were autoclave sterilized and were allowed to cool/dry at room temperature. Individual scoured, sterile cotton swatches, 1 x 1.5 inches, were placed on the bottom of sterile glass or plastic petri dishes. A 30 µL aliquot of prepared test organism was inoculated onto the fabric swatch carriers and air dried at 36.4-36.6°C in a relative humidity of 50.4-56.0% until visibly dry at 28-29 minutes. Following the drying procedure, up to three fabric carriers were placed into the spindle pockets between the 6$^{th}$ and 7$^{th}$ folds of the spindle. Three test carriers were evaluated per test condition and were used as soon as possible within 1 hour of drying. The fabric spindles containing the carriers were placed into the jars containing the test substance. The jars were placed into a launderometer device to simulate a tumble-wash at 53.0-53.6 RPM for a 15-minute exposure time at 30.0°C. Just prior to the end of the exposure time, the fabric spindle was removed from the jar and the liquid from the spindle was fully wrung out. The fabric carriers were placed into jars containing 10 mL of the neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase). A 0.50 mL aliquot of the "wash" water was transferred to a vessel containing 9.5 mL of the neutralizer. The subcultures were vortex mixed. Ten-fold serial dilutions were prepared and 1.0 mL of the $10^0$ and 0.1 m aliquots of the $10^0$ through $10^{-3}$ dilutions were spread plated in duplicate. The remaining neutralized "wash" water (6.8 mL) was transferred to filter units pre-wetted with 10 mL of sterile diluent. The contents were evacuated and each filter was rinsed with 50 mL of diluent. Each filter was transferred to the recovery agar medium. All plates were incubated at 33-37°C for 46-50 hours. Subcultures were stored at 2-8°C for 1-2 days prior to examination. Following incubation and storage, standard plate count procedures were used to determine the average colony forming units per carrier and per milliliter of wash water. On 1/9/17, representative test and positive control subcultures showing growth were visually examined, Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, viability, numbers control, and neutralization confirmation.

Note:

Protocol amendments: Per Sponsor's request, the protocol is amended to include additional testing of Lot 4779-124, 4779-126, and Lot 4779-127 against Staphylococcus aureus with a test substance diluted using 17.15 mL concentrate, 185 µL detergent, and 42.66 mL of hard water.

No protocol deviations occurred during this study.
Test History: Testing the three lots on 1/5/15 resulted in failing efficacy results against Staphylococcus aureus. The protocol was amended to include additional testing of the three lots against S. aureus with a different dilution (Protocol Amendment) on 2/3/17.

**19. MRID 50209727 "Standard Test Method for Evaluation of Laundry Sanitizers", Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352), for Capricorn, EPA Reg. No. 10772-23, by Jamie Herzab. Study conducted at Accuratus Lab Services. Study completion date – March 21, 2017. Project Identification No. A22601.**

Objective: Sanitizing efficacy of a laundry detergent or laundry additive – simulated-use study.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (Nos. 4779-124, 4779-126, and 4779-127) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85121416.LSAN.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed but not longer than 20 minutes. The prepared test substance was homogenous. Appropriate volumes of each prepared test substance concentrate (12.45 mL), detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) (133.5 µL), and 100 ppm AOAC Synthetic Hard Water (137.41 mL) were added to individual laundrometer bottles. The test substance to fabric ratio was indicated to be 10:1 (weight/weight) for HE application. Each test organism was transferred on Nutrient Agar A slants and incubated at 33-37°C for 24±2 hours under aerobic conditions. After the slant was washed with Phosphate Buffer Dilution Water (PBDW), the growth suspension was aspirated and 1.0 mL was transferred to each of four Nutrient Agar B culture bottles. The bottles were incubated for 18-24 hours at 33-37°C under aerobic conditions with the agar side down. On the day of the test, each test organism was harvested from the Nutrient Agar B bottles by adding a 3.0 mL aliquot of PBDW and sterile glass beads. A spectrophotometric analysis was performed using a wavelength of 620 nm. For testing performed on 2/7/17, the final absorbance value was determined to be 1.458 for *K. pneumoniae* and 1.691 for *S. aureus*. For testing performed on 2/3/17, the final absorbance value was determined to be 1.627 for *S. aureus*. A 0.10 mL aliquot of FBS was added to 1.90 mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. For fabric prepared on 1/13/17, a scouring solution prepared using 5.50 grams Na2CO3 and 5.50 grams of Triton X-100 to 11 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 1100 grams of test fabric was added to each 11 L of scouring solution. For fabric prepared on 2/14/17, a scouring solution prepared using 4.95 grams Na2CO3 and 4.95 grams of Triton X-100 to 9.9 L of deionized water. The fabric used was a plain cotton weave containing 80x80 threads/inch, and 990 grams of test fabric was added to each 9.9 L of scouring solution. The solution was boiled for approximately 60 minutes, when the fabric was removed and rinsed in boiling water for a minimum of 5 minutes and then placed into cold water for a minimum of 5 minutes. The fabric was air dried for at least 1 day. The scoured and dried fabric was cut into approximately 5 cm (2 in.) wide strips and weighed. Each strip of fabric was wrapped around a stainless steel spindle at least twelve, but fewer than thirteen times. Fabric swatch carriers of approximately 1 inch x 1.5 inch were cut from the scoured fabric. The fabric-wrapped spindles and carriers were autoclave sterilized and were allowed to cool/dry at room temperature. Individual scoured, sterile cotton swatches, 1 x 1.5 inches, were placed on the bottom of sterile glass or plastic petri dishes. A 30 µL aliquot of prepared test organism was inoculated onto the fabric swatch carriers and air dried at 36.3-36.4°C in a relative humidity of 47.1-54.0% until visibly dry at 28-29 minutes. Following the drying procedure, up to three fabric carriers were placed into the spindle pockets between the 6th and 7th folds of the spindle. Three test carriers were evaluated per test condition and were used as soon as possible within 1 hour of drying. The fabric spindles containing the carriers were placed into the jars containing the test substance. The jars were placed into a launderometer device to simulate a tumble-wash at 51.2-53.1 RPM for an 18-minute exposure time at 43.0-43.5°C. Just prior to the end of the exposure time, the fabric spindle was removed from the jar and the liquid from the spindle was fully wrung out. The fabric carriers were placed into jars containing 10 mL of the neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase). A 0.50 mL aliquot of the "wash" water was transferred to a vessel containing 9.5 mL of the neutralizer. The subcultures were vortex mixed. Ten-fold serial dilutions were prepared and

1.0 mL of the $10^0$ and 0.1 m aliquots of the $10^0$ through $10^{-3}$ dilutions were spread plated in duplicate. The remaining neutralized "wash" water (6.8 mL) was transferred to filter units pre-wetted with 10 mL of sterile diluent. The contents were evacuated and each filter was rinsed with 50 mL of diluent. Each filter was transferred to the recovery agar medium. All plates were incubated at 36°C for 46.75 hours. On 3/9/17, representative test and positive control subcultures showing growth were visually examined, Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, viability, numbers control, and neutralization confirmation.

Note:

No protocol amendments were required for this study. No protocol deviations occurred during this study.

Test History:

Testing of Lot 4779-124 against *Staphylococcus aureus* was performed on February 7, 2017, which resulted in scientifically unreasonable results due to growth of the test organism on higher dilutions but no growth of the test organism on the preceding lower dilutions. The Neutralization Confirmation Control for Lot 4779-124 against *Staphylococcus aureus* met the acceptance criteria, is valid and presented in the body of the report. Testing of Lot 4779-124 against *Staphylococcus aureus* performed on February 7, 2017, with the exception of the Neutralization Confirmation Control, is considered invalid and presented in Attachment I.

Testing of Lot 4779-124 against *Staphylococcus aureus* was repeated on February 22, 2017, which resulted in scientifically unreasonable results due to the erratic growth of the test organism on the agar plates. Testing of Lot 4779-124 against *Staphylococcus aureus* performed on February 22, 2017, is considered invalid and presented in Attachment II.

Testing of Lot 4779-124 against *Staphylococcus aureus* was repeated on March 7, 2017, which resulted in valid results and are presented in the body of the report.

**20. MRID 50209728 "Carpet Sanitizer", Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048), for Capricorn, EPA Reg. No. 10772-23, by Maggie Brusky. Study conducted at Accuratus Lab Services. Study completion date – March 16, 2017. Project Identification No. A21720.**

Objective: Carpet sanitizer.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three batches (Nos. 4779-80, 4779-86, and 4779-87) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85022916.CSAN (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1 L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed but not longer than 20 minutes. The prepared test substance was homogenous. Each test organism was transferred on Nutrient Agar A slants for ≥3 but ≤30 transfers. The growth was washed with Phosphate Buffer Dilution Water (PBDW), and the growth suspension was aspirated and added to 99.0 mL PBDW. A 2.0 mL aliquot of this suspension was then added to sufficient Nutrient Agar B bottles. The bottles were incubated agar side down for 18-24 hours at 25-30°C for *Enterobacter aerogenes* and 35-37°C for *Staphylococcus aureus*. Following incubation, a 3.0 mL aliquot of PBDW and 15-20 sterile glass beads were added to each bottle to suspend the growth. The growth suspension was removed and filtered through sterile gauze pre-wetted with 1.0 mL of PBDW. The culture suspensions were adjusted to target approximately $1.0 \times 10^9 - 1.0 \times 10^{10}$ CFU/mL using a spectrophotometer set to 620 nm. An aliquot of FBS was added to each broth culture to yield a 5% Fetal Bovine Serum organic soil load. The nylon and olefin carpet used in testing was cut into approximately 8 in. x 12 in. pieces. Six approximately 2 in. x 2 in. square carriers were cut into the carpet, which was fastened to a mounting tray and was autoclaved sterilized for ≥20 minutes prior to use in testing. The recorded face weight, pile density and tuft height, respectively, of the carpets are as follow: Olefin (polypropylene): 22 oz./yd$^2$ face weight, 5280.0 pile density, 0.25 in. tuff height; Olefin (polypropylene): 20 oz./yd$^2$ face weight, 4615 pile density, 0.15625 in. tuff height; Nylon: 26 oz./yd$^2$ face weight, 5258.0 pile density, 0.178 in. tuff height. Each cut square carrier was inoculated with 100µL of the prepared test culture. The inoculum was

spread over the upper surface of the carpet. The inoculated carpet was dried in an incubator at 36.5-36.6°C in a relative humidity of 48.6-55.8% for 60 minutes with sterile foil loosely covering the carpet. After drying, 13.0 mL of the test substance was applied to each carrier over the entire 2 in. by 2 in. concentrating on the middle (on test date 1/18/17, 15 mL of test substance was applied). Each carrier was then scrubbed for approximately 30 seconds using 30 circular clockwise strokes and 30 circular counterclockwise strokes. A circular area of pile approximately 3 in. (7.6 cm) in diameter around the center of each carrier was scrubbed using this treatment. Moderate to heavy pressure was applied downward on the brush to work the solution to the base of the pile. A new sterile brush was used for each carpet square. The treated and scrubbed carpet remained at 19-21°C and 20-45% relative humidity, uncovered, for the exposure time of 4.5 minutes, 4 minutes 45 seconds, and 4 minutes 55 seconds. Exposure began once the test substance had been applied. Each carrier was then removed from the larger carpet piece within 15 seconds and transferred to individual vessels containing 100 mL of neutralizer broth (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) and 10 stainless steel penicylinders, representing a $10^0$ dilution. Each carrier was placed carpet side down within the neutralizer vessel. Each vessel was shaken vigorously for at least 1 minute on an orbital shaker at approximately 200 RPM, to free the bacteria from the carpet fibers. Ten-fold serial dilutions were prepared and 1.00 mL aliquots of the $10^0$ dilution and 0.100 mL aliquots of the $10^0$ through $10^{-2}$ dilutions were plated in duplicate onto the recovery agar medium. All test plates were incubated at for 48±4 hours at 25-30°C for *Enterobacter aerogenes* and at 35-37°C for *Staphylococcus aureus*. For testing performed on 9/15/16, 11/3/16, and 11/23/16 subcultures were stored at 2-8°C for 3 days prior to examination. Following incubation and storage, the subcultures were visually examined for growth. On 9/20/16, 11/3/16, 11/8/16, 11/28,16, 12/30/1, and 1/20/17, representative test and positive control subcultures showing growth were visually examined, Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control (scrubbed population control and unscrubbed population control), sterility, purity, and neutralization confirmation.

Note:

Protocol Amendments:

1. Per Sponsor's request, the test substance name and lots will be updated to: Capricorn C, Lot 4779-80 and Capricorn Lot 4779-86 and Lot 4779-87.
2. At the request of the Sponsor, the following lot/organism/carpet type combinations will be tested with an exposure time of 4 minutes 45 seconds:
   Lot 4779-86 against *Staphylococcus aureus* on olefin carpet
   Lot 4779-87 against *Staphylococcus aureus* on olefin carpet
   Lot 4 779-80 against *Enterobacter aerogenes* on nylon carpet
   Lot 4779-87 against *Enterobacter aerogenes* on nylon carpet
3. At the request of the Sponsor and due to a carrier population control failure, the following lot/organism/carpet type combination will be tested with an exposure time of 4 minutes 55 seconds:
   Lot 4779-86 against Staphylococcus aureus on olefin carpet
4. At the request of the Sponsor and due to a carrier population control failure, testing of Lot 4779-86 against Staphylococcus aureus on olefin carpet with an exposure time of 4 minutes and 45 seconds will be cancelled prior to the generation of valid data.
5. At the request of the Sponsor, the following lot/organism/carpet type combination will be tested at an exposure time of 4 minutes and 45 seconds by applying 15 ml of test substance.
   Capricorn, Lot 4779-87 against *Staphylococcus aureus* on olefin carpet

Protocol Deviation:

As stated in the protocol, the acceptance criterion for the carrier sterility control is no growth. Testing on 1/18/17 resulted in a carrier sterility that had growth (two isolated colonies). Because there were only two isolated colonies and the product still passed efficacy, the deviation has no impact on the overall intent of the protocol.

Test History:

Due to the difference in the amount of test substance used for application, the amount of test substance applied will only be differentiated by test date and all relevant pages. Testing was completed the same on each day unless otherwise noted.

## V. RESULTS

### 1. Hard Non-Porous Surface Bactericidal Disinfectant (62.4g/L) Against Additional Organism

| Contact Time | MRID No. | Organism | No. Carriers Exhibiting Growth/Total Carriers | | Carrier Population ($Log_{10}$ CFU/Carrier) |
|---|---|---|---|---|---|
| | | | Batch #4562-132 | Batch #4699-40 | |
| 9.5 minutes | 50209709 | *Klebsiella pneumoniae* (ATCC 4352) | 0/10 | 0/10 | 6.89 |

### 2. Hard Non-Porous Non-Food Contact Surface Sanitizer (62.4g/2L):

| Contact Time | MRID No. | Organism | Results | | | Carrier Population CFU/Carrier (Avg. $Log_{10}$) |
|---|---|---|---|---|---|---|
| | | | Batch# | CFU/Carrier (Average $log_{10}$) | Percent Reduction | |
| 4.5 minutes | 50209710 | *Pseudomonas aeruginosa* (ATCC 15442) + 5% FBS | 4562-132 | <2.51 x $10^1$ (<1.40) | >99.9 | 1.12 x $10^6$ (6.05) |
| | | | 4699-40 | <2.51 x $10^1$ (<1.40) | >99.9 | |
| | 50209711 | *Salmonella enterica* (ATCC 10708) + 5% FBS | 4562-132 | <2.51 x $10^1$ (<1.40) | >99.9 | 2.57 x $10^4$ (4.41) |
| | | | 4699-40 | <2.51 x $10^1$ (<1.40) | >99.9 | |

### 3. Soft, Non-Food Contact Surface Sanitizer (62.4g/L)

| Contact Time | MRID No. | Organism | Results | | | | |
|---|---|---|---|---|---|---|---|
| | | | | 100% Plain Cotton Weave | | 100% Polyester | |
| | | | Batch# | CFU/Carrier (Average $log_{10}$) | Percent Reduction | CFU/Carrier (Average $log_{10}$) | Percent Reduction |
| 4.5 minutes | 50209712 | *Pseudomonas aeruginosa* (ATCC 15442) + 5% FBS | 4562-132 | <2.51 x $10^1$ (<1.40) | >99.9 | <2.51 x $10^1$ (<1.40) | >99.9 |
| | | | 4779-9 | <2.51 x $10^1$ (<1.40) | >99.9 | <2.51 x $10^1$ (<1.40) | >99.9 |
| | | **Carrier Population CFU/Carrier (Avg. $Log_{10}$)** | | **2.14 x $10^5$ (5.33)** | | **4.79 x $10^6$ (6.68)** | |

### 4. Laundry Presoak Fungicidal Disinfectant (62.4g/L):

| Contact Time | MRID No. | Organism | No. Carriers Exhibiting Growth/Total Carriers | | Carrier Population ($Log_{10}$ CFU/Carrier) |
|---|---|---|---|---|---|
| | | | Batch #4562-132 | Batch #4779-9 | |
| 29.5 minutes (1/12/16) | 50209713 | *Trichophyton mentagrophytes* (ATCC 9533) + 5% FBS | 0/10 | 1/10 | 4.52 |
| 30 minutes (5/10/16) | | | -- | 0/10 | 4.17 |

5. **Laundry Presoak Sanitizer (62.4g/2L):**

| Contact Time | MRID No. | Organism | Results | | | Carrier Population CFU/Carrier (Avg. $Log_{10}$) |
|---|---|---|---|---|---|---|
| | | | Batch# | CFU/Carrier (Average $log_{10}$) | Percent Reduction | |
| 9.5 minutes | 50209714 | *Pseudomonas aeruginosa* (ATCC 15442) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >99.9 | 2.45 x $10^6$ (6.47) |
| | | | 4699-40 | <3.02 x $10^1$ (<1.48) | >99.9 | |
| | 50209715 | *Salmonella enterica* (ATCC 10708) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >99.9 | 6.76 x $10^5$ (5.83) |
| | | | 4699-40 | <3.02 x $10^1$ (<1.48) | >99.9 | |

6. **Laundry Presoak Sanitizer (62.4g/L)**

| Contact Time | MRID No. | Organism | Results | | | Carrier Population CFU/Carrier (Avg. $Log_{10}$) |
|---|---|---|---|---|---|---|
| | | | Batch# | CFU/Carrier (Average $log_{10}$) | Percent Reduction | |
| 4.5 minutes | 50209716 | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >99.9 | 1.10 x $10^6$ (6.04) |
| | | | 4779-9 | <3.02 x $10^1$ (<1.48) | >99.9 | |
| | | | 4699-40 | <3.02 x $10^1$ (<1.48) | >99.9 | |
| | | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >99.9 | 6.61 x $10^6$ (6.82) |
| | | | 4779-9 | <3.02 x $10^1$ (<1.48) | >99.9 | |
| | | | 4699-40 | <3.02 x $10^1$ (<1.48) | >99.9 | |
| | 50209717 | *Escherichia coli* O157:H7 (ATCC 43888) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >99.9 | 3.16 x $10^5$ (5.50) |
| | | | 4779-9 | <3.02 x $10^1$ (<1.48) | >99.9 | |
| | 50209718 | *Pseudomonas aeruginosa* (ATCC 15442) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >99.9 | 2.34 x $10^6$ (6.37) |
| | | | 4779-9 | <3.02 x $10^1$ (<1.48) | >99.9 | |
| | 50209719 | *Salmonella enterica* (ATCC 10708) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >99.9 | 1.95 x $10^5$ (5.29) |
| | | | 4779-9 | <3.02 x $10^1$ (<1.48) | >99.9 | |

7. **Laundry Bactericidal Disinfectant (62.4g/L) (4:1 HE Application)**

| MRID No. | Organism | Contact Time | Test Date | Total Carriers/ Wash Water | No. Carriers Exhibiting Growth/Total Carriers | | | Carrier Population (CFU/Carrier) |
|---|---|---|---|---|---|---|---|---|
| | | | | | Batch #4779-124 | Batch #4779-126 | Batch #4779-127 | |
| 50209720 | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS | 15.5 min. | 1/26/17 | 9 carriers | 0 | | | 5.13 x $10^5$ (5.71) |
| | | | | 3 wash water | 0 | | | 2.0 x $10^5$ |
| | | 15 min. | | 9 carriers | | | 0 | 7.76 x $10^5$ (5.89) |
| | | | | 3 wash water | | | 0 | 3.19 x $10^5$ |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | 1/19/17 | 9 carriers | 1 | 0 | | ~3.68 x $10^5$ (5.57) |
| | | | | 3 wash water | 0 | 0 | | 3.01 x $10^5$ |
| | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | | 1/19/17 | 9 carriers | 0 | | 0 | ~3.91 x $10^6$ (6.57) |
| | | | | 3 wash water | 0 | | 0 | 9.05 x $10^4$ |
| | | | 1/26/17 | 9 carriers | | 0 | | 1.38 x $10^6$ (6.14) |
| | | | | 3 wash water | | 0 | | 5.7 x $10^4$ |

**8. Laundry Virucidal Disinfectant (62.4g/L):**

| 4:1 HE Application – 15 Min. Exposure Time | | | | | | | |
|---|---|---|---|---|---|---|---|
| **MRID No.** | **Organism** | **Batch** | **Jar #: Swatch** | **Results** | | | **Dried Virus Control ($TCID_{50}$/500µL)** |
| | | | | **Complete Inactivation** | **$TCID_{50}$/ 500µL** | **Log Reduction** | |
| 50209721 | Human Coronavirus, strain 229E, ATCC VR-740 + 5% FBS | **B1: #4779-124** | **1: S 1-3** | $10^{-2}$ to $10^{-6}$ dilutions | $\leq 10^{1.50}$ | $\geq$3.00 | **$10^{4.50}$** |
| | | | **2: S4-5** | $10^{-2}$ to $10^{-6}$ dilutions | $\leq 10^{1.50}$ | $\geq$3.00 | |
| | | | **3: S6-9** | $10^{-2}$ to $10^{-6}$ dilutions | $\leq 10^{1.50}$ | $\geq$3.00 | |
| | | **B2: #4779-126** | **1: S 1-3** | $10^{-2}$ to $10^{-6}$ dilutions | $\leq 10^{1.50}$ | $\geq$3.00 | |
| | | | **2: S4-5** | $10^{-2}$ to $10^{-6}$ dilutions | $\leq 10^{1.50}$ | $\geq$3.00 | |
| | | | **3: S6-9** | $10^{-2}$ to $10^{-6}$ dilutions | $\leq 10^{1.50}$ | $\geq$3.00 | |
| | | **Wash Water** | **B1 & B2** | $10^{-2}$ to $10^{-6}$ dilutions | $\leq 10^{1.50}$ | $\geq$3.00 | |
| 50209722 | Influenza A (H1N1) virus, strain A/PR/8/34, ATCC VR-1469 + 5% FBS | **B1: #4779-124** | **1: S1-3** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.18 | **$10^{4.68}$** |
| | | | **2: S4-5** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.18 | |
| | | | **3: S6-9** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.18 | |
| | | **B2: #4779-126** | **1: S1-3** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.18 | |
| | | | **2: S4-5** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.18 | |
| | | | **3: S6-9** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.18 | |
| | | **Wash Water** | **B1 & B2** | $10^{-2}$ to $10^{-8}$ dilutions | $\leq 10^{1.50}$ | $\geq$3.50 | **$10^{5.00}$** |
| 50209723 | Rhinovirus type 37, strain 151-1, ATCC VR-1147 + 5% FBS | **B1: #4779-124** | **1: S1-3** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.74 | **$10^{5.24}$** |
| | | | **2: S4-5** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.74 | |
| | | | **3: S6-9** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.74 | |
| | | **B2: #4779-126** | **1: S1-3** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.74 | |
| | | | **2: S4-5** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.74 | |
| | | | **3: S6-9** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.74 | |
| | | **Wash Water** | **B1 & B2** | $10^{-2}$ to $10^{-6}$ dilutions | $\leq 10^{1.50}$ | $\geq$3.25 | **$10^{4.75}$** |
| **10:1 Top Loading Application – 18 Min. Exposure Time** | | | | | | | |
| 50209725 | Rhinovirus type 37 Strain 151-1 ATCC VR-1147 + 5% FBS | **B1: #4779-124** | **1: S 1-3** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.10 | **$10^{4.60}$** |
| | | | **2: S4-5** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.10 | |
| | | | **3: S6-9** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.10 | |
| | | **B2: #4779-126** | **1: S 1-3** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.10 | |
| | | | **2: S4-5** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.10 | |
| | | | **3: S6-9** | $10^{-1}$ to $10^{-6}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.10 | |
| | | **Wash Water** | **B1 & B2** | $10^{-2}$ to $10^{-6}$ dilutions | $\leq 10^{1.50}$ | $\geq$2.75 | **$10^{4.25}$** |
| 50209724 | Influenza A (H1 N1) virus, strain A/PR/8/34, ATCC VR-1469 + 5% FBS | **B1: #4779-124** | **1: S 1-3** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.00 | **$10^{4.50}$** |
| | | | **2: S4-5** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.00 | |
| | | | **3: S6-9** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.00 | |
| | | **B2: #4779-126** | **1: S 1-3** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.00 | |
| | | | **2: S4-5** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.00 | |
| | | | **3: S6-9** | $10^{-1}$ to $10^{-8}$ dilutions | $\leq 10^{0.50}$ | $\geq$4.00 | |
| | | **Wash Water** | **B1 & B2** | $10^{-1}$ to $10^{-8}$ dilutions B1, Jar# 2: | $\leq 10^{0.50}$ B1, Jar#2: | $\geq$4.00 B1, Jar#2: | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | $10^{-2}$ to $10^{-8}$ dilutions | $\leq 10^{1.50}$ | $\geq 3.00$ | |

**9. Laundry Sanitizer (62.4g/L):**

| MRID No. | Contact Time | Organism | Results | | | |
|---|---|---|---|---|---|---|
| | | | Batch# | CFU/Carrier (Average $\log_{10}$) | Percent Reduction | Wash Water |
| **4:1 HE Application** | | | | | | |
| 50209726 | 15 min. | *Staphylococcus aureus* (ATCC 6538) + 5% FBS (2/3/17) | B1: 4779-124 | <1 x $10^1$ (<1.00) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | B2: 4779-126 | <1 x $10^1$ (<1.00) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | B3: 4779-127 | <1 x $10^1$ (<1.00) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | **Carrier Population (Avg. $\log_{10}$)** | 3 Carriers: 2.09 x $10^6$ CFU/Carrier (6.32) | | 1.1 x $10^5$ CFU/mL |
| | | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS (1/5/17) | B1: 4779-124 | <1 x $10^1$ (<1.00) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | B2: 4779-126 | <1 x $10^1$ (<1.00) | >99.9 | 1 x $10^1$ CFU/mL >99.9% LR |
| | | | B3: 4779-127 | <1 x $10^1$ (<1.00) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | **Carrier Population (Avg. $\log_{10}$)** | 3 Carriers: 1.17 x $10^6$ CFU/Carrier (6.07) | | 2.84 x $10^5$ CFU/mL |
| **10:1 Top Loading Application** | | | | | | |
| 50209727 | 18 min. | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | B1: 4779-124 (3/7/17) | <8.51 x $10^1$ (<1.93) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | B2: 4779-126 (2/7/17) | <1 x $10^1$ (<1.00) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | B3: 4779-127 (2/7/17) | <1 x $10^1$ (<1.00) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | **Carrier Population (Avg. $\log_{10}$)** | 3 Carriers: (2/7/17): 1.38 x $10^6$ CFU/Carrier (6.14) (3/7/17: 6.92 x $10^5$ CFU/Carrier (5.84) | | (2/7/17): 1.60 x $10^4$ CFU/mL (3/7/17): 2.92 x $10^4$ CFU/mL |
| | | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS (2/7/17) | B1: 4779-124 | <1 x $10^1$ (<1.00) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | B2: 4779-126 | <1 x $10^1$ (<1.00) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | B3: 4779-127 | <1 x $10^1$ (<1.00) | >99.9 | <3 CFU/mL >99.9% LR |
| | | | **Carrier Population (Avg. $\log_{10}$)** | 3 Carriers: 8.32 x $10^5$ CFU/Carrier (5.92) | | 6.00 x $10^4$ CFU/mL |

**10. MRID No. 50209728: Carpet Sanitizer (62.4 g/L):**

| Organism | Material Type | Results | | | Carrier Population Avg. CFU/Carrier ($Log_{10}$) | |
|---|---|---|---|---|---|---|
| | | Batch# | Avg. CFU/Carrier (Average $log_{10}$) | % Reduction (Log Red.) | Scrubbed Carriers | Unscrubbed Carriers |
| **4.5 Min. Exposure Time, 13 mL Treatment** | | | | | | |
| *Enterobacter aerogenes* (ATCC 13048) + 5% FBS | Olefin | B1: 4779-80 (9/15/16) | $1.02 \times 10^4$ (4.01) | >99.9 (>4.36 $log_{10}$) | >$2.34 \times 10^8$ (>8.37) | >$1.82 \times 10^8$ (>8.26) |
| | | B2: 4779-86 (9/15/16) | $7.08 \times 10^4$ (4.85) | >99.9 (>3.52 $log_{10}$) | | |
| | | B3: 4779-87 (9/15/16) | $1.15 \times 10^4$ (4.06) | >99.9 (>4.31 $log_{10}$) | | |
| | Nylon | B2: 4779-86 (9/15/16) | $6.17 \times 10^3$ (3.79) | >99.9 (3.65 $log_{10}$) | $2.75 \times 10^7$ (7.44) | $2.29 \times 10^8$ (8.36) |
| *Staphylococcus aureus* (ATCC 6538) + 5% FBS | Olefin | B1: 4779-80 (9/15/16) | $6.17 \times 10^3$ (3.79) | 99.9 (3.11 $log_{10}$) | $7.94 \times 10^6$ (6.90) | $1.95 \times 10^7$ (7.29) |
| | Nylon | B1: 4779-80 (9/15/16) | $7.59 \times 10^3$ (3.88) | >99.9 (3.62 $log_{10}$) | $3.16 \times 10^7$ (7.50) | $6.03 \times 10^7$ (7.78) |
| | | B2: 4779-86 (9/15/16) | $9.12 \times 10^3$ (3.96) | >99.9 (3.54 $log_{10}$) | | |
| | | B3: 4779-87 (9/15/16) | $3.39 \times 10^3$ (3.53) | >99.9 (3.97 $log_{10}$) | | |
| **4 Min. + 45 Sec. Exposure Time, 13 mL Treatment** | | | | | | |
| *Enterobacter aerogenes* (ATCC 13048) + 5% FBS | Nylon | B1: 4779-80 (11/1/16) | <$2.95 \times 10^2$ (<2.47) | >99.9 (>4.50 $log_{10}$) | $9.33 \times 10^6$ (6.97) | $3.31 \times 10^7$ (7.52) |
| | | B3: 4779-87 (11/3/17) | <$2.63 \times 10^2$ (<2.42) | >99.9 (>4.51 $log_{10}$) | $8.51 \times 10^6$ (6.93) | $3.98 \times 10^7$ (7.60) |
| *Staphylococcus aureus* (ATCC 6538) + 5% FBS | **15 mL Treatment** | | | | | |
| | Olefin | B3: 4779-87 (1/18/17) | $1.12 \times 10^3$ (3.05) | 99.9 (3.21 $log_{10}$) | $1.82 \times 10^6$ (6.26) | $1.02 \times 10^6$ (6.01) |
| **4 Min. + 55 Sec. Exposure Time, 13 mL Treatment** | | | | | | |
| *Staphylococcus aureus* (ATCC 6538) + 5% FBS | Olefin | B2: 4779-86 (11/23/16) | $1.86 \times 10^3$ (3.27) | >99.9 (3.31 $log_{10}$) | $3.80 \times 10^6$ (6.58) | $3.72 \times 10^6$ (6.57) |

## VI. CONCLUSION

1. The submitted efficacy data **support** the use of the product, Capricorn (EPA Reg. No. 10772-23), as a disinfectant with bactericidal activity against the following (additional) microorganism tested in the absence of 5% organic soil load on hard, non-porous surfaces when diluted using 62.4 g of product in 1 L of water of up to 100 ppm hardness for a 9.5-minute contact time.

   MRID 50209709 *Klebsiella pneumoniae* (ATCC 4352)

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of the product, Capricorn (EPA Reg. No. 10772-23), as a non-food contact sanitizer against the following (additional) microorganisms, tested in the

presence of 5% fetal bovine serum as organic soil load, on hard, non-porous surface when diluted using 62.4 g of product in 2 L of water of up to 100 ppm hardness for a 4.5-minute contact time.

MRID 50209710 *Pseudomonas aeruginosa* (ATCC 15442)
MRID 50209711 *Salmonella enterica* (ATCC 10708)

Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

3. The submitted efficacy data **support** the use of the product, Capricorn (EPA Reg. No. 10772-23), as a non-food contact sanitizer against the following (additional) microorganisms, tested in the presence of 5% fetal bovine serum as organic soil load, on soft surface when diluted using 62.4 g of product in 1 L of water of up to 100 ppm hardness for a 4.5-minute contact time (using plain cotton weave and polyester as the types of carriers).

   MRID 50209712 *Pseudomonas aeruginosa* (ATCC 15442)

   Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

4. The submitted efficacy data **support** the use of the product, Capricorn (EPA Reg. No. 10772-23), as a laundry presoak disinfectant with fungicidal activity against the following microorganisms, tested in the presence of 5% fetal bovine serum as an organic soil load, on stainless steel penicylinders when diluted using 62.4 g of product in 1 L of water of up to 100ppm hardness for a 30-minute contact time.

   MRID 50209713 *Trichophyton mentagrophytes* (ATCC 9533)

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

5. The submitted efficacy data **support** the use of the product, Capricorn (EPA Reg. No. 10772-23), as a presoak sanitizer against the following (additional) microorganisms, tested in the presence of 5% fetal bovine serum as organic soil load, on unglazed ceramic tiles when diluted using 62.4 g of product in 2 L of water of up to 100 ppm hardness for a 9.5-minute contact time.

   MRID 50209714 *Pseudomonas aeruginosa* (ATCC 15442)
   MRID 50209715 *Salmonella enterica* (ATCC 10708

   Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

6. The submitted efficacy data **support** the use of the product, Capricorn (EPA Reg. No. 10772-23), as a presoak sanitizer against the following microorganisms, tested in the presence of 5% fetal bovine serum as organic soil load, on unglazed ceramic tiles when diluted using 62.4 g of product in 1 L of water of up to 100 ppm hardness for a 4.5-minute contact time.

MRID 50209716 *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352)
MRID 50209717 *Escherichia coli* O157:H7 (ATCC 43888)
MRID 50209718 *Pseudomonas aeruginosa* (ATCC 15442)
MRID 50209719 *Salmonella enterica* (ATCC 10708)

Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

7. The submitted efficacy data **support** the use of the product, Capricorn (EPA Reg. No. 10772-23), as a disinfectant as laundry additive with bactericidal activity in HE application (4:1) against the following microorganisms, tested in the presence of 5% fetal bovine serum as an organic soil load, on plain cotton weave when diluted as follow in water of up to 100 ppm hardness.

   Solution: 17.15 mL test substance (62.4/L) + 185.0 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 42.66 mL 100 ppm hard water:

   MRID 50209720 *Staphylococcus aureus* (ATCC 6538) – 15 min.
   *Klebsiella pneumoniae* (ATCC 4352) – 15.5 min.

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

8. The submitted efficacy data **support** the use of the product, Capricorn (EPA Reg. No. 10772-23), as a disinfectant as laundry additive with virucidal activity against the following microorganisms, tested in the presence of 5% fetal bovine serum as an organic soil load, on plain cotton weave when diluted as follow in water of up to 100 ppm hardness.

   <u>HE application (4:1), 15-minute contact time:</u>

   Solution: 8.58 mL test substance (62.4/L) + 185.0 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 51.25 mL 100 ppm hard water:

   MRID 50209721 Human Coronavirus, strain 229E, ATCC VR-740
   MRID 50209722 Influenza A (H1N1) virus, strain A/PR/8/34, ATCC VR-1469
   MRID 50209723 Rhinovirus type 37, strain 151-1, ATCC VR-1147

   <u>Top-loading application (10:1), 18-minute contact time:</u>

   Solution: 12.45 mL test substance (62.4/L) + 133.5 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 137.41 mL 100 ppm hard water:

   MRID 50209724 Influenza A (H1N1) virus, strain A/PR/8/34, ATCC VR-1469

   Recoverable virus titer of at least 4 $\log_{10}$ were achieved for the required product lots. Complete inactivation (no growth) was demonstrated in all dilutions tested. When cytotoxicity is evident, at least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

9. The submitted efficacy data **does not support** the use of the product, Capricorn (EPA Reg. No. 10772-23), as a disinfectant as laundry additive with virucidal activity against the following

microorganism, tested in the presence of 5% fetal bovine serum as an organic soil load, on plain cotton weave when diluted as follow in water of up to 100 ppm hardness.

Top-loading application (10:1), 18-minute contact time:

Solution: 12.45 mL test substance (62.4/L) + 133.5 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 137.41 mL 100 ppm hard water:

MRID 50209725 Rhinovirus type 37, strain 151-1, ATCC VR-1147

When cytotoxicity is evident, at least a 3-log reduction in titer was not demonstrated beyond the cytotoxic level for the wash water.

10. The submitted efficacy data **support** the use of the product, Capricorn (EPA Reg. No. 10772-23), as a sanitizer as laundry additive with bactericidal activity in against the following microorganisms, tested in the presence of 5% fetal bovine serum as an organic soil load, on plain cotton weave when diluted as follow in water of up to 100 ppm hardness.

    MRID 50209726: HE application (4:1), 15-minute contact time:

    1/5/17 Solution: 8.58 mL test substance (62.4/L) + 185.0 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 51.25 mL 100 ppm hard water:
    *Klebsiella pneumoniae* (ATCC 4352)

    2/3/17 Solution: 17.15 mL test substance (62.4/L) + 185.0 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 42.66 mL 100 ppm hard water:
    *Staphylococcus aureus* (ATCC 6538)

    MRID 50209727: Top Loading application (10:1), 18-minute contact time:

    12.45 mL test substance (62.4/L) + 133.5 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 137.41 mL 100 ppm hard water:
    *Klebsiella pneumoniae* (ATCC 4352)
    *Staphylococcus aureus* (ATCC 6538)

    Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

11. The submitted efficacy data support the use of the product, Capricorn (EPA Reg. No. 10772-23), as a presoak sanitizer against the following microorganisms, tested in the presence of 5% fetal bovine serum as organic soil load, on the following materials when diluted using 62.4 g of product in 1 L of water of up to 100 ppm hardness for the following contact times.

    MRID 50209728:
    *Enterobacter aerogenes* (ATCC 13048)
    Olefin: 4.5 min., 13 mL treatment
    Nylon: 4 min. + 45 sec., 13 mL treatment
    *Staphylococcus aureus* (ATCC 6538)
    Olefin: 4 min. + 55 sec., 15 mL treatment
    Nylon: 4.5 min., 13 mL treatment

Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

## VII. LABEL RECOMMENDATIONS (For proposed clean label dated 3/29/17))

1. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a disinfectant with bactericidal activity against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 10-minute contact time with pre-cleaning instructions.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):

   *Klebsiella pneumoniae* (ATCC 4352)

   These claims **are supported** by the applicant's data

2. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a non-food contact sanitizer against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 5-minute contact time.

   31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):

   *Pseudomonas aeruginosa* (ATCC 15442)
   *Salmonella enterica* (ATCC 10708)

   These claims **are supported** by the applicant's data.

3. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a non-food contact sanitizer against the following organisms for use on soft (plain cotton weave and polyester) surfaces using the following dilution rate in a 5-minute contact time.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):

   *Pseudomonas aeruginosa* (ATCC 15442)

   These claims **are supported** by the applicant's data.

4. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry presoak disinfectant with fungicidal activity against the following organism for use in laundry using the following dilution rate and total immersion application for a 30-minute contact time.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):

   *Trichophyton mentagrophytes* (ATCC 9533)

   These claims **are supported** by the applicant's data.

5. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry presoak sanitizer against the following organisms for use in laundry using the following dilution rate and total immersion application for a 10-minute contact time.

   31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):
   *Pseudomonas aeruginosa* (ATCC 15442)

*Salmonella enterica* (ATCC 10708

These claims **are supported** by the applicant's data.

6. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry presoak sanitizer against the following organisms for use in laundry using the following dilution rate and total immersion application for a 5-minute contact time.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):

   *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352)
   *Escherichia coli* O157:H7 (ATCC 43888)
   *Pseudomonas aeruginosa* (ATCC 15442)
   *Salmonella enterica* (ATCC 10708)

   These claims **are supported** by the applicant's data.

7. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry in-wash disinfectant additive for HE machines when used with a laundry detergent against the following organisms using the following dilution rate.

   17.15 mL product (62.4g/L) + 185.0 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 42.66 mL water for at least a 16-minute wash time in hot (45C) water:
   *Staphylococcus aureus* (ATCC 6538)
   *Klebsiella pneumoniae* (ATCC 4352)

   8.58 mL product (62.4g/L) + 185.0 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 51.25 mL water for at least a 15-minute wash time in warm (30C) water:
   Human Coronavirus, strain 229E, ATCC VR-740
   Influenza A (H1N1) virus, strain A/PR/8/34, ATCC VR-1469
   Rhinovirus type 37, strain 151-1, ATCC VR-1147

   These claims **are supported** by the applicant's data.

8. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry in-wash disinfectant additive for top loading machines when used with a laundry detergent against the following virus using the following dilution rate.

   12.45 mL test substance (62.4g/L) + 133.5 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 137.41 mL water for at least 18-minute wash time in hot (45C) water:
   Influenza A (H1N1) virus, strain A/PR/8/34, ATCC VR-1469

   These claims **are supported** by the applicant's data.

9. The proposed label claim is **not acceptable** regarding the use of the product, Capricorn, as a laundry in-wash disinfectant additive for top loading machines when used a certain laundry detergent against the following virus using the following dilution rate.

   12.45 mL test substance (62.4g/L) + 133.5 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 137.41 mL water for at least 18-minute was time in hot (45C) water:

   Rhinovirus type 37, strain 151-1, ATCC VR-1147

The claims should be **removed** from the proposed label, including from the organism table on page 30.

10. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry in-wash sanitizer additive for HE machines when used with a laundry detergent against the following organisms using the following dilution rate.

    8.58 mL test substance (62.4g/L) + 185.0 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 51.25 mL water for 15-minute wash time in warm (30C) water:
    *Klebsiella pneumoniae* (ATCC 4352)

    17.15 mL test substance (62.4g/L) + 185.0 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 42.66 mL water for 15-minute wash time in warm (30C) water:
    *Staphylococcus aureus* (ATCC 6538)

    These claims **are supported** by the applicant's data.

11. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry in-wash sanitizer for top loading machines when used with a laundry detergent against the following organisms using the following dilution rate.

    12.45 mL test substance (62.4g/L) + 133.5 mL detergent (Arm & Hammer Clean Burst Detergent Lot HH6244 3 0417) + 137.41 mL water for at least 18-minute was time in hot (45C) water:
    *Klebsiella pneumoniae* (ATCC 4352)
    *Staphylococcus aureus* (ATCC 6538)

    These claims **are supported** by the applicant's data.

12. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a carpet sanitizer against the following organisms using a dilution of 62.4 g of product in 1 L of water and a 5-minute contact time.

    *Enterobacter aerogenes* (ATCC 13048)
    *Staphylococcus aureus* (ATCC 6538)

    These claims **are supported** by the applicant's data.

13. On page 1, replace "Disinfector" with "Disinfectant".

14. For directions for use for in-wash laundry disinfection and sanitization additive (pages 3-6), the dilution type should be 2X, instead of 1X, representing the dosage of 62.4g/L that was tested. Referring to the table for Testing and Dilution Type, 2X dilution type is equivalent to 236 grams Product/gallon of water, which means for every 1 gallon of water, the amount of 236 grams of product should be added to washing. Registrant should revise Table 9 and Table 12 accordingly.

    Therefore, in pages 3-6, instructions should identify scoops or pouches and specify the use of appropriate # of pouches to account for 236 grams of product/gallon of water. The instructions to "Add # {Insert *#scoops/pouches/caps to at least equal the dose used in efficacy testing for bacteria to support claims for bacteria and virus HE laundry disinfection}* [scoops] [pouches] [caps] [of product] [of powder] [into] [to] [washing machine]..." are too ambiguous.

These instruction headings should describe the uses as an additive and not as a detergent so as not to discourage users to disregard using a detergent in their laundering routine.

15. On page 18, the HIV statement should be placed under the use-directions for hard, non-porous surface disinfection (page 7), since efficacy testing against the virus was performed to substantiate this use application. Placing it anywhere else would be confusing for users.

16. On page 14, 17, 20, and 22, remove the words "antibacterial protection". This claim implies continuous protection against bacteria, which is not supported by residual data. Registrant should also note that the claim for "all around the house" should not be used to describe disinfection or sanitization.

17. On page 18, remove "[and disinfected]" from the claim "[This product] will help [you] keep your surfaces clean [and disinfected]". The product may be able to keep the surfaces clean, but keeping the surfaces disinfected implies a residual and prolong efficacy beyond the contact time(s), which was not supported by data.

18. On pages 18, 21 and 22, registrant should qualify claims regarding the spread of cold and flu viruses to include "on treated surfaces".

19. Under Hard Non-Porous Surface Sanitizing Claim, registrant should qualify claim #8 and #9 to "Cleans and sanitizes [in One Step] when use directions for sanitizer are followed" and "Cleans, deodorizes, and sanitizes in one step when use directions for sanitizer are followed".
The same claims should be qualified under Soft Surface [and] [Carpet] Sanitizer Claims on page 20 with claims #11 and #12.

20. Remove all "99.99%" text or revise to read "99.9%" throughout the label. While a 4-log (99.99%) reduction is allowed for viruses with data showing a 4-log kill, only a 3-log reduction (99.9%) claim is allowed for other disinfection and sanitization claims.

21. Throughout the label (e.g., pages 19, 20, 23), registrant should remove "hidden bacteria". The term is misleading and implies a greater efficacy than proven by data.

22. On page 20, 21 and 22, registrant should revise all cross contamination claims to "Can help prevent cross contamination between laundry treated in the same wash load." On page 22, the claim "Helps prevent the spread of cold and flu viruses" should also be revised to "Helps prevent the spread of cold and flu viruses between laundry treated in the same wash load".

23. On page 22, remove the claim for "Eliminates [99.9% of] germs* [that ordinary additives [can't] [don't]]". Comparative statements cannot be made unless it is made against the registrant's own product.

24. Under Laundry Disinfection Claims for Presoak and Final Soak on page 21, registrant should remove "soft surfaces" from claims #37 and #38 from this section. Soft spot surface claims were substantiated by data tested using 62.4g/L dilution rate, while presoak laundry disinfectant was tested with 62.4g/2L, which is more diluted than the dilution rate for soft spot surface sanitizer and therefore may not show the same efficacy for general soft surfaces.

25. Under Laundry HE In-Wash Disinfection on page 22, remove claim "Kills [99.9% of] [99.99% of] [Escherichia coli O157:H7 (E. coli)) [and) [Salmonella enterica] [other organisms]". Data for laundry HE in-wash disinfection for *E. coli* O157:H7 and *Salmonella enterica* were not submitted for review.

26. Under Laundry HE and Top Loader In-Wash Sanitization, remove all claims for viruses, germs, and germflighter technology. Claims against viruses and germs are not allowed to describe sanitization.

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

**MEMORANDUM**

8/7/2017

**SUBJECT:** Product Chemistry Review for **Capricorn** EPA Reg. No.: **10772-23**

**FROM:** Narayanan Parthasarathy
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

**THRU:** Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

**TO:** Zeno Bain, PM Team 33 / Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: **Church & Dwight Inc**
Action code: **A570**
Agency Due Date: **8/21/2017**
DP No.: **440026**
Submission No.: **1003308**
E-Sub No.:
Classification: EP
Process: **Integrated system**
Pesticide type: **Disinfectant**

| Formulation from label | | | |
|---|---|---|---|
| PC code(s) | CAS #(s) | Active Ingredient(s) | % weight |
| 128860 | 15630-89-4 | Sodium Percarbonate | 18.50% |
| 004115 | 10543-57-4 | Tetraacetylethylenediamine | 4.44% |
| | | Other Ingredients | 77.06% |
| | | Total | 100.00% |
| Comments/Molecular Structure | | | |

## I. BACKGROUND

On behalf of the **Registrant, Church & Dwight Inc**, the **Consultant, Scientific & Regulatory Consultant, Inc** has submitted an **minor formulation amendment** for their product: **Capricorn EPA Reg. No. 10772-23**.

## II. RELEVANT DOCUMENTS

| | RECEIVED | N/A |
|---|---|---|
| EPA FORM 8570-27 – Formulator's Exemption Statement | ☒ | ☐ |
| EPA FORM 8570-35 – Data Matrix | ☒ | ☐ |
| Cover letter (3/29/2017)and E-mail 7/5/2017 | ☒ | ☐ |
| Transmittal document | ☒ | ☐ |
| Proposed CSF BASIC, (7/5/2017) and Alt CSFs#1-12 (7/5/2017). | ☒ | ☐ |
| Previously Approved Label, (8/15/2016) | ☒ | ☐ |
| Certification for Pilot Fragrance Notification Program (Previously submitted) | ☒ | ☐ |
| | ☐ | ☐ |
| *REFERENCED: CSF* BASIC , (5/17/2016) | -- | |
| Comments: | | |

## III. FINDINGS

a. Product Formulation:

| | TGAI | MUP | EUP | Food use | Non-food use |
|---|---|---|---|---|---|
| Non-integrated | ☐ | ☐ | ☐ | ☐ | ☒ |
| Integrated | ☐ | ☐ | ☒ | | |

| Active Ingredients(s) | Nominal | Upper limit | Lower limit |
|---|---|---|---|
| Sodium Percarbonate | 18.50% | 20.35% | 17.58% |
| Tetraacetylethylenediamine | 4.44% | 4.88% | 4.00% |
| | | | |

| | YES | NO | N/A |
|---|---|---|---|
| 1. The certified limits of all ingredients are within 40 CFR standard certified limits. | ☐ | ☒ | |
| 2. Wider certified limits were requested and rationale was accepted. | ☒ | ☐ | |
| 3. The nominal concentration(s) of the active ingredient is in agreement with the label. | ☒ | ☐ | |
| 4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data. | ☒ | ☐ | |
| 5. All inert ingredients are approved for non-food use pesticide formulations. | ☐ | ☒ | ☐ |
| 6. The impurities present >0.1% are identified. | ☐ | ☐ | ☒ |
| 7. Impurities of toxicological significance have an upper certified limit. | ☐ | ☐ | ☒ |

b. Product Label:

| | Yes | NO | N/A |
|---|---|---|---|
| *The formula contains one of the following*: | | | |
| 1. 10% or more of petroleum distillate | ☐ | ☒ | ☐ |
| 2. 1.0% or more of methyl alcohol | ☐ | ☒ | ☐ |
| 3. Sodium nitrite at any level | ☐ | ☒ | ☐ |
| 4. A toxic list 1 inert at any level | ☐ | ☒ | ☐ |
| 5. Arsenic in any form | ☐ | ☒ | ☐ |
| 6. If yes to 1-5, then the inert ingredient list contains a relevant footnote | ☐ | ☐ | ☒ |
| 7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label | ☐ | ☐ | ☒ |
| 8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses. | ☐ | ☐ | ☒ |
| 9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit. | ☐ | ☐ | ☒ |

**IV. Additional Findings**

1) **Proposed revised Basic CSF (7/5/17) & Alternate CSF #1 (7/5/17) are identical.**
2) **The registrant is proposing wider certified limits for the AIs and justification is provided.**
3) **Alternate CSFs #3-12 contain an uncleared inert ingredient.**
4) **MRID #50209701: Volume 1- The registrant had provided studies to address Product Chemistry Group A 830.1550, 830.1600, 830.1620, 830.1650 and 830.1750 Guidelines.**
5) **The registrant had provided Certificate of Analysis of AIs of two lots as shown below:**

| Active Ingredient | Lot #1 | Lot #2 |
|---|---|---|
| Sodium Percarbonate | 20.21% | 20.37% |
| Tetraacetylethylene diamine | 4.78% | 4.63% |

V. Conclusion

1) Proposed revised Basic CSF (7/5/17) and Alternate CSF#2 are acceptable and supersede previous formulations.

2) Proposed Alternate CSFs #1, 3-12 (7/5/17) are not acceptable.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

## MEMORANDUM

8/1/2017

**SUBJECT:** **Acute Toxicity Review** for **Capricorn,** EPA Reg. No.: **10772-23**

**FROM:** Narayanan Parthasarathy
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

**THRU:** Jenny Tao, Senior Scientist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

**TO:** Zeno Bain, PM Team 33 / Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

| | | |
|---|---|---|
| Registrant: **Church & Dwight Co Inc** | | |
| Decision No.: **527916** | Submission No.: **1003308** | E-Sub No.: |
| DP No.: **440028** | Action Code: **A570** | |
| MRID No(s).: **50209702-50209707** | | |

| Formulation from label | | | |
|---|---|---|---|
| PC code(s) | CAS #(s) | Active Ingredient(s) | % weight |
| 128860 | 15630-89-4 | Sodium Percarbonate | 18.50% |
| 004115 | 10543-57-4 | Tetraacetylethylenediamine | 4.44% |
| | | Other Ingredients | 76.66% |
| | | Total | 100.00% |

## I. BACKGROUND

On behalf of **the Registrant, Church & Dwight Co Inc, the Consultant, Scientific & Regulatory Consultants, Inc.**, has submitted an **application to support an amendment** for their **product: *Capricorn*, EPA Reg. No. 10772-23**. In the amendment, the registrant proposed changes in certified limits of the Basic Confidential Statement of Formulation (CSF; 3/24/2017) based on storage stability. To support the amendment of the Basic CSF, the registrant has submitted the acute toxicity studies, MRIDs 50209703-50209707, to address the acute oral, acute dermal, and acute inhalation toxicity, primary skin irritation, and skin sensitization of the amended formulation. A waiver was requested for primary eye irritation (MRID # 50209702) and was accepted for the original non-amended formulation of the product. This antimicrobial is formulated as end-use, integrated, non-food use disinfectant.

## II. RELEVANT DOCUMENTS

| | RECEIVED | N/A |
|---|---|---|
| EPA FORM 8570-35 – Data Matrix (3/29/2017) | ☒ | ☐ |
| Cover letter (3/29/2017) | ☒ | ☐ |
| Transmittal document | ☒ | ☐ |
| Basic CSF, (7/5/2017) | ☒ | ☐ |
| Proposed label, (3/29/2017) | ☒ | ☐ |
| | ☐ | ☐ |
| Acute Oral Toxicity Study (OSCPP 870.1100) | ☒ | ☐ |
| Acute Dermal Toxicity Study (OSCPP 870.1200) | ☒ | ☐ |
| Acute Inhalation Toxicity Study (OSCPP 870.1300) | ☒ | ☐ |
| Primary Eye Irritation Study (OSCPP 870.2400) (Waiver) | ☒ | ☐ |
| Primary Skin Irritation Study (OSCPP 870.2500) | ☒ | ☐ |
| Dermal Sensitization Study (OSCPP 870.2600) | ☒ | ☐ |

## III. FINDINGS/RECOMMENDATIONS

1) The acute toxicity profile of *Capricorn*, EPA Reg. No. 10772-23, remains unchanged as previously reviewed (D432546; 6/7/2016):

| Study | MRID | Toxicity Category | Status |
|---|---|---|---|
| Acute Oral Toxicity | 49795311 | III | Acceptable |
| Acute Dermal Toxicity | 49795312 | IV | Acceptable |
| Acute Inhalation Toxicity | 49795313 | IV | Acceptable |
| Primary Eye Irritation | 49795314 | I | Waived |
| Primary Skin Irritation | 49795315 | IV | Acceptable |
| Dermal Sensitization | 49795316 | Nonsensitizer | Acceptable |

## VI. PRODUCT LABELING

1) The precautionary labeling and first aid statements for *Capricarn*, EPA Reg. No. 10772-23 remains the same as the original formulation.

## Northern, Terria

**From:** Northern, Terria
**Sent:** Thursday, August 03, 2017 6:10 PM
**To:** 'dswain@srcconsultants.com'
**Cc:** OPP AD Ombudsman; Bain, Zeno
**Subject:** EPA Completed Action 10772-23
**Attachments:** 10772-23-20170803 Predecisional.pdf; 10772-23_D440031_ChurchDwightCo_Capricorn.pdf

Hello David –

I wanted to give you an early start on the required label revisions for the proposed amendment. I am attaching the Agency's pre decisional determination letter, along with the efficacy review for Capricorn. Currently our toxicologist is on sick leave, but will return to the office on Monday and complete the Toxicology and Chemistry review. Note additional label changes may be required after the tox review is received.

As of today the Agency has not received the requested documentation per my email on July 13, 2017. The Alternate CSFs #3-12 will not be reviewed as trade name of one inert ingredients had not yet been approved for pesticide formulation. We are proceeding in reviewing the revised Basic CSF & Alternate CSFs #1-2 (3/24/2017).

Please contact me directly if you have any questions or comments.

Thanks!

*Terria Northern*
**Registration Risk Manager**
**Environmental Protection Agency**
**1200 Penn. Ave., NW (7510P)**
**Washington, DC 20460**
**#703-347-0265**

**Street address: 2777 Crystal Drive**
**1 Potomac Yard South**
**Arlington, VA**

# TECHNICAL SCREEN

| | |
|---|---|
| **EPA Reg#/File Symbol**: 10772-23 | **E-Sub #**: |
| **DP Barcode**: D440031 | **Submission #**: 1003308 |
| **Product name**: Capricorn | **Registrant**: Church & Dwight Co., Inc. |
| **Reviewer's name**: Sophie Nguyen | **Risk Manager:** Seiichi Murasaki/Zebora Johnson |
| **Completion due date**: 6/5/17 | **Completion Date**:6/5/17 |

**Formulation type**: Liquid [] ; Towelettes []; Spray []; Solid [x]; Textile[]; Aerosol []; Other_____

| Sterilant:[] | Sporicide:[] | Disinfect:[x] | TB:[] | Fungicide:[] | Virucide:[x] | NFC Sanit: [x] | FC Sanit:[] |
|---|---|---|---|---|---|---|---|

**MRID(s)**: 50209708 – 50209728 (21 studies)

| PC Code(s) | Active Ingredient Names | % wt (label) | %LCL |
|---|---|---|---|
| 004115 | Tetraacetylethylenediamine (TAED) | 4.44 | 4.00 |
| 128860 | Sodium percarbonate | **18.90***<br>*CSF change | 17.58<br>(@1%: 17.75%) |

| Product Lot(s) | Tested Concentration(s) | Tested at LCL |
|---|---|---|
| 4562-132 | 3.99% TAED | Yes[x] No[] |
| | 17.69% Sodium percarbonate | Yes[x] No[] |
| 4699-40 | 3.97% TAED | Yes[x] No[] |
| | 17.41% Sodium percarbonate | Yes[x] No[] |
| 4779-9 | 4.00% TAED | Yes[x] No[] |
| | 17.48% Sodium percarbonate | Yes[x] No[] |
| 4779-124 | 3.86% TAED | Yes[x] No[] |
| | 17.15% Sodium percarbonate | Yes[x] No[] |
| 4779-126 | 3.77% TAED | Yes[x] No[] |
| | 17.15% Sodium percarbonate | Yes[x] No[] |
| 4779-127 | 3.86% TAED | Yes[x] No[] |
| | 16.92% Sodium percarbonate | Yes[x] No[] |
| 4779-80 | 3.93% TAED | Yes[x] No[] |
| | 17.67% Sodium percarbonate | Yes[x] No[] |
| 4779-86 | 4.01% TAED | Yes[x] No[] |
| | 17.75% Sodium percarbonate | Yes[x] No[] |
| 4779-87 | 4.04% TAED | Yes[x] No[] |
| | 17.42% Sodium percarbonate | Yes[x] No[] |

| **Tested: RTU [] Diluted [x]** | **Label Claims:** |
|---|---|
| Hard surface disinfectant – additional: 9 min. (62.4g/1L) | Hard surface disinfectant – additional: 10 min contact time (62.4g/L) |
| Hard, NFC sanitizer: 4.5 min., (62.4g/2L) | Hard, NFC surface sanitizer: 5 min. contact time (62.4g/2L) |
| Soft surface sanitizer: 4.5 min., (62.4g/L) | Soft surface sanitizer: 5 min. contact time (62.4g/L) |
| Laundry pre-soak disinfectant – fungicidal: 29.5 – 30 min., (62.4g/L) | Laundry pre-soak & final rinse disinfectant – fungicidal: 30 min. immersion (62.4g/2L) |
| Laundry pre-soak sanitizer: 9.5 min (62.4/2L), 4.5 min. (62.4/L) | Laundry pre-soak sanitizer: 10 min. immersion (62.4g/2L) |
| Laundry disinfectant: 15 and 15.5 min. (4:1), 18 min. (10:1) | HE/Front loader laundry disinfectant: 16 min. contact time (15 min. for viruses). Top loader virucidal: 18 min. contact time |
| Laundry sanitizer: 15 min. (4:1), 18 min. (10:1) | HE/Front loader laundry sanitizer: 15 min. contact time<br>Top loader laundry sanitizer: 18 min. contact time |
| Carpet sanitizer: 4.5 – 4.55 min. (62.4/L) | Carpet sanitizer: 5 min. contact time (62.4g/L) |
| **Certificate of Analysis:** Yes[x] No[] | **Performed by testing Lab:** Yes[x] No[] |
| **Test Lab**: Accuratus Lab Services | |

**Comments**: The registrant is requesting to amend the product label for Capricorn, a concentrated solid product to be used when diluted as instructed as a laundry pre-soak or post-soak disinfectant and sanitizer and hard surface disinfectant and sanitizer for use in homes, schools, hospitals, office buildings, etc. The registrant is requesting to add laundry in-wash disinfectant and sanitizer claims to include bactericidal and virucidal claims for HE and top loader machines and to add carpet sanitization claims. The registrant is also seeking to add various organisms and contact times to existing uses.

**The product is cleared at the efficacy technical screen.**

Print Form

*Please read instructions on reverse before completing form.*

Form Approved. OMB No. 2070-0060. Approval expires 2-28-

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

| | | |
|---|---|---|
| 1. Company/Product Number<br>10772-23 | 2. EPA Product Manager<br>Seiichi Murasaki | 3. Proposed Classification<br>☑ None ☐ Restricted |
| 4. Company/Product (Name)<br>Capricorn | PM#<br>33 | |
| 5. Name and Address of Applicant *(Include ZIP Code)*<br>Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd. Ewing, NJ 08628<br>☐ *Check if this is a new address* | 6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:<br>EPA Reg. No. _____<br>Product Name _____ | |

## Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

This submission is for an amendment with data and thus qualifies for PRIA code A570 with a 4 month review period and PRIA fee of $3,831. New efficacy, chemistry, and toxicity data is submitted.
Payment has been made on-line and proof is attached with Agency tracker 75206120137

## Section - III

1. Material This Product Will Be Packaged In:

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes<br>☑ No | ☐ Yes<br>☑ No | ☐ Yes<br>☑ No | ☐ Metal<br>☑ Plastic<br>☐ Glass<br>☐ Paper<br>☐ Other (Specify) _____ |
| * *Certification must be submitted* | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☑ Label ☐ Container | Various. | ☑ On Label<br>☐ On Labeling accompaning product |

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☑ Paper glued ☐ Stenciled ☐ Other _____

## Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| David Swain | Agent for Church & Dwight Co., Inc. | (260) 244-6270 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

| | |
|---|---|
| 2. Signature | 3. Title Agent for Church & Dwight Co., Inc. |
| 4. Typed Name David Swain | 5. Date 03/29/2017 |

DOCUMENTUM

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Co

March 29, 2017

Mr. Seiichi Murasaki, PM-33
Document Processing Desk (APPL)
Office of Pesticide Programs (7S04P)
U.S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard, 2777 S Crystal Drive
Arlington, VA 22202

**SUBJECT:** **Capricorn**
**EPA Reg. No. 10772-23**

Dear Mr. Murasaki:

On behalf of Church & Dwight Co., Inc. (Church & Dwight), we enclose a PRIA amendment for the above referenced product. Scientific & Regulatory Consultants, Inc. is the agent of record for Church & Dwight. This submission qualifies for PRIA code A570 with a 4 month review period and PRIA fee of $3,831. Proof of payment via www.pay.gov is attached to the application.

**Product Chemistry**

This amendment revises the nominal active ingredient level of sodium percarbonate from 18.50% to 18.90%. Additionally, we are requesting expanding the certified limits of sodium percarbonate to +/- 7% instead of the previously approved +/- 5%. The ongoing storage stability study which was a condition of registration has indicated the wider limits for sodium percarbonate will be required. The study is currently in progress and will be submitted by the required deadline of 18 months from the initial registration date of August 26, 2016, or February 26, 2018.

In addition to revised certified limits, a number of alternate formulations are being submitted. These alternate formulations include an alternate EPA registered source of TAED from the same supplier as the approved source. The alternate source is a more pure source of TAED and is also an EPA registered source. Also, a number of new inert ingredients are proposed in alternate formulations. These ingredients and the corresponding concentrations are outlined in the enclosed alternate CSFs and in Volume 1 of the submitted data.

**Acute Toxicity**

To support the expanded limits of sodium percarbonate a new acute toxicity battery of testing has been completed with the exception of primary eye irritation which was Category I with the initial approved Confidential Statement of Formula certified limits and nominal amount of sodium percarbonate. The new acute toxicity testing with a test sample at the upper range of the certified limits of both active ingredients was identical to the original Capricorn formulation. Therefore, precautions and first aid statements for the new CSF certified limits remain the same as previously approved.

The Certificates of Analysis for the test sample lots are enclosed in Volume 2, Acute Toxicity Discussion Volume. The revised certified limit statement and other Part A Product Chemistry changes are included

201 W. Van Buren St.
Columbia City, IN 46725
www.srcconsultants.com
P: 260.244.6270
F: 260.244.6273

DOCUMENTUM

in Volume 1. The new acute toxicity testing final reports are enclosed in Volume 3-7. The test sample lots were names Capricorn-12C and Capricorn-13C and they are identical to the enclosed proposed basic CSF.

**Efficacy**

Relevant efficacy studies are submitted to allow the product label to exhibit new claims for laundry in-wash disinfection and sanitization for HE washing machines and sanitization and virucidal action for top loader laundry washing machines. The parameters of testing for HE versus top loader were different and these are reflected in the Directions for Use on the enclosed label. Efficacy studies are also submitted for additional bacteria and fungi for hard surface non-food contact surface disinfection, hard surface non-food contact surface sanitization, soft surface sanitization and laundry pre-soak or post-soak disinfection and sanitization. Finally, an efficacy study for carpet sanitizer is submitted which corresponds to the protocol which was approved by the Agency on June 29, 2016 with EPA Protocol Identifier: 10772PA1.

We look forward to a timely review of this submission. If you need any clarification or issues arise during the review of this information, please contact me immediately via phone (260-244-6270) or email (dswain@srcconsultants.com) for resolution.

Sincerely,

David Swain
Agent for Church & Dwight Co., Inc.

March 29, 2017

Mr. Seiichi Murasaki, PM-33
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard, 2777 S Crystal Drive
Arlington, VA 22202

**SUBJECT: Capricorn**
**EPA Reg. No. 10772-23**

Dear Mr. Murasaki:

On behalf of Church & Dwight Co., Inc. (Church & Dwight), we enclose a PRIA amendment for the above referenced product. Scientific & Regulatory Consultants, Inc. is the agent of record for Church & Dwight. This submission qualifies for PRIA code A570 with a 4 month review period and PRIA fee of $3,831. Proof of payment via www.pay.gov is attached to the application.

**Product Chemistry**

This amendment revises the nominal active ingredient level of sodium percarbonate from 18.50% to 18.90%. Additionally, we are requesting expanding the certified limits of sodium percarbonate to +/- 7% instead of the previously approved +/- 5%. The ongoing storage stability study which was a condition of registration has indicated the wider limits for sodium percarbonate will be required. The study is currently in progress and will be submitted by the required deadline of 18 months from the initial registration date of August 26, 2016, or February 26, 2018.

In addition to revised certified limits, a number of alternate formulations are being submitted. These alternate formulations include an alternate EPA registered source of TAED from the same supplier as the approved source. The alternate source is a more pure source of TAED and is also an EPA registered source. Also, a number of new inert ingredients are proposed in alternate formulations. These ingredients and the corresponding concentrations are outlined in the enclosed alternate CSFs and in Volume 1 of the submitted data.

**Acute Toxicity**

To support the expanded limits of sodium percarbonate a new acute toxicity battery of testing has been completed with the exception of primary eye irritation which was Category I with the initial approved Confidential Statement of Formula certified limits and nominal amount of sodium percarbonate. The new acute toxicity testing with a test sample at the upper range of the certified limits of both active ingredients was identical to the original Capricorn formulation. Therefore, precautions and first aid statements for the new CSF certified limits remain the same as previously approved.

The Certificates of Analysis for the test sample lots are enclosed in Volume 2, Acute Toxicity Discussion Volume. The revised certified limit statement and other Part A Product Chemistry changes are included

in Volume 1. The new acute toxicity testing final reports are enclosed in Volume 3-7. The test sample lots were names Capricorn-12C and Capricorn-13C and they are identical to the enclosed proposed basic CSF.

**Efficacy**

Relevant efficacy studies are submitted to allow the product label to exhibit new claims for laundry in-wash disinfection and sanitization for HE washing machines and sanitization and virucidal action for top loader laundry washing machines. The parameters of testing for HE versus top loader were different and these are reflected in the Directions for Use on the enclosed label. Efficacy studies are also submitted for additional bacteria and fungi for hard surface non-food contact surface disinfection, hard surface non-food contact surface sanitization, soft surface sanitization and laundry pre-soak or post-soak disinfection and sanitization. Finally, an efficacy study for carpet sanitizer is submitted which corresponds to the protocol which was approved by the Agency on June 29, 2016 with EPA Protocol Identifier: 10772PA1.

We look forward to a timely review of this submission. If you need any clarification or issues arise during the review of this information, please contact me immediately via phone (260-244-6270) or email (dswain@srcconsultants.com) for resolution.

Sincerely,

David Swain
Agent for Church & Dwight Co., Inc.

## Northern, Terria

**From:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>
**Sent:** Wednesday, May 10, 2017 7:51 AM
**To:** dswain@srcconsultants.com
**Cc:** Hebert, John; Johnson, Zebora
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Thank you, David.

The provided explanation will be useful (especially the confirmation that there is no 18.50% product currently on the market).

Seiichi

**From:** dswain@srcconsultants.com [mailto:dswain@srcconsultants.com]
**Sent:** Tuesday, May 09, 2017 2:37 PM
**To:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>
**Cc:** Hebert, John <Hebert.John@epa.gov>; Johnson, Zebora <Johnson.Zebora@epa.gov>
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Hi Seiichi,

Thanks for checking into the inert ingredient questions for Capricorn (EPA Reg. No. 10772-23).

**Yes, I can explain the reasoning behind the change to the nominal and the upper certified limit of Capricorn with this PRIA amendment.**

As you know from the initial EPA acceptance letter for Capricorn dated 8/26/2016 (attached); the storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) test requirements were made a condition of registration. The active ingredients in Capricorn do not allow for the accelerated temperature version of the test so we are doing a one year shelf study which is ongoing. We have 18 months, or until 4/26/2018 to provide this storage stability study.

The initial readings of this study indicated that the sodium percarbonate active ingredient might need more than the usual +/- 5% around the nominal amount to make it within the certified limits for the 12 month study and to account for any manufacturing variance and analytical method variations. Therefore, we are asking for a slightly wider range. We have requested a +/- 7% range with this amendment. However, we wanted to keep the lower certified limit the same at 17.58% so we would not have to redo all the efficacy studies since they are required to be conducted at the LCL. We just moved the nominal for sodium perborate up (from 18.50% to 18.90%) and the upper certified limit up (from 19.42% to 20.22%) to allow for the wider +/- 7% range. We reran the toxicity studies to show the new upper certified limit would not impact the label precautions from the original ranges.

I think the fact that the toxicity studies came out the same shows that the new nominal and upper limit should be able to reside under the same registration as the original approved formulation for Capricorn.

**Finally, to address your last question, what about the product in the market?** The good thing is that this product has not yet been launched into the market. There is no product out there with the original label with the 18.50% nominal. Church & Dwight only plans to market the product with the new nominal label amount of 18.90% for sodium percarbonate. The product has been registered in the states but the labels will be revised at the states prior to placing this product into market. The current estimated launch date 1st quarter 2019 to ensure all stability tests have been submitted to EPA and accepted and the labels have been accepted by all states.

I hope this answers the questions you had. Please let me know if you have any follow up questions.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
**SERVICE Portal, *a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Murasaki, Seiichi [mailto:Murasaki.Seiichi@epa.gov]
**Sent:** Tuesday, May 09, 2017 1:09 PM
**To:** dswain@srcconsultants.com
**Cc:** Hebert, John; Johnson, Zebora
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Hi, David,

I can't tell yet whether the ingredient composition information has been received – it is still not loaded in our system. Zebora will be managing this amendment. Meanwhile, one concern I have is the proposed change in the nominal concentration of one of the AIs in the product – this is typically not a change that we allow once the product has been registered. Can you provide further explanation/justification for making this change (also addressing the estimated amount of product already on the market)?

Thanks!
Seiichi

**From:** dswain@srcconsultants.com [mailto:dswain@srcconsultants.com]
**Sent:** Monday, May 08, 2017 4:33 PM
**To:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>
**Cc:** Hebert, John <Hebert.John@epa.gov>
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Good afternoon Seiichi,

I hope you are doing well.

I wanted to check on the submission deficiency which was communicated to me for the subject PRIA submission for Capricorn (EPA Reg. No. 10772-23) – Decision# 527916.

My understanding from the registrant is that the suppliers of the two inert ingredients listed on the attached have supplied the required composition to EPA.

Could you confirm you have received the necessary information for these inert ingredients?

Thanks for your help.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
**SERVICE Portal, *a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Napoli, Alexandra [mailto:Napoli.Alexandra@epa.gov]
**Sent:** Monday, April 17, 2017 11:07 AM
**To:** dswain@srcconsultants.com
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Mr. Swain,

Thank you for the update.

Please see the attached updated Inert Clearance Status Form.

Best,
Alexandra

**From:** dswain@srcconsultants.com [mailto:dswain@srcconsultants.com]
**Sent:** Monday, April 17, 2017 10:44 AM
**To:** Napoli, Alexandra <Napoli.Alexandra@epa.gov>
**Cc:** Ashe, Anthony <Ashe.Anthony@epa.gov>
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Hi Alexandra,

Thanks again for the review.

Please find attached the fragrance certifications for the fragrance. They were submitted with our initial approval of this product so I didn't think we had to send them again.

For the [redacted], I am surprised it is not on the EPA trade name list. This ingredient was approved by EPA with our initial CSF dated 2/12/16 which I have attached. The original approval letter for the product listed this CSF as approved. Can you check the list again?

*Inert ingredient information may be entitled to confidential treatment*

*Inert ingredient information may be entitled to confidential treatment*
*Product ingredient source information may be entitled to confidential treatment*

- Basic CSF dated 02/12/2016

If you have any questions, please contact me by phone at (703) 308-8735, or via email at chao.julie@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1

Finally, I am working with the registrant to get the "[redacted]" formulation sent to you by [redacted]. Hope you have to you very soon.

Please let me know if you have any questions.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

**SERVICE Portal,** ***a cloud-based gateway to state registrotion data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Napoli, Alexandra [mailto:Napoli.Alexandra@epa.gov]
**Sent:** Thursday, April 13, 2017 10:45 AM
**To:** dswain@srcconsultants.com
**Cc:** Ashe, Anthony
**Subject:** Submission Deficiency (EPA Reg. No. 10772-23)

Dear Mr. Swain,

My name is Alexandra Napoli and I am a contractor with the EPA. I am contacting you in regards to your submission in support of the product Capricorn (EPA Reg. No. 10772-23). We have found a deficiency with the submission that will need to be addressed:

1. Please see the attached Inert Clearance Status Form

Please send the necessary documents in pdf file form before April 19th so that we may further process your submission. After April 19th, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Best,

Alexandra Napoli
EPA Contractor- Inoventures, LLC
2777 S. Crystal Drive, S-4815
Arlington, VA 22202
(703) 347-8784
napoli.alexandra@epa.gov

## Northern, Terria

**From:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>
**Sent:** Tuesday, June 20, 2017 10:08 AM
**To:** Parthasarathy, Narayanan
**Cc:** Hebert, John; Bain, Zeno; Johnson, Zebora
**Subject:** RE: Capricorn, EPA Reg. No. 10772-23, Decision # 527916

Thanks, Partha! I'll let Tony know they have that option as well.

**From:** Parthasarathy, Narayanan
**Sent:** Tuesday, June 20, 2017 9:08 AM
**To:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>
**Subject:** RE: Capricorn, EPA Reg. No. 10772-23, Decision # 527916

Seiichi:

Thanks for your e-mail.
When we talked last week, I thought I heard you saying that they could fix all of this by expanding the upper certified limits and keeping the lower certified limit and nominal concentrations the same (i.e., allowing a normal LCL and much wider UCL). Since that seemed to be your preference (and also seemed like a win-win, I agreed).

I agree the above.
In that case, the registrant had to revise the proposed CSFs and label.

Thanks

Partha

**From:** Murasaki, Seiichi
**Sent:** Monday, June 19, 2017 4:26 PM
**To:** Parthasarathy, Narayanan <Parthasarathy.Narayanan@epa.gov>
**Cc:** Hebert, John <Hebert.John@epa.gov>; Johnson, Zebora <Johnson.Zebora@epa.gov>
**Subject:** RE: Capricorn, EPA Reg. No. 10772-23, Decision # 527916

Partha,

As you can see from the email that Tony attached (and as we discussed last week), the product is not yet in production and we were OK with allowing the minor change to the nominal. The company's main concern is preserving the LCL at 17.58% (for efficacy) while raising the UCL to 20.22% (for storage stability). I think they must have thought the certified limits must be balanced (i.e., the nominal must fall in the center of the certified limits – in this case, 18.90%).

When we talked last week, I thought I heard you saying that they could fix all of this by expanding the upper certified limits and keeping the lower certified limit and nominal concentrations the same (i.e., allowing a normal LCL and much wider UCL). Since that seemed to be your preference (and also seemed like a win-win, I agreed).

If only one of these options is allowed by Chemistry, could you let me know which one it is? If either of these options are acceptable, could you let me know which is preferred?

Thanks!
Seiichi

**From:** therber@srcconsultants.com [mailto:therber@srcconsultants.com]
**Sent:** Monday, June 19, 2017 2:51 PM
**To:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>; Hebert, John <Hebert.John@epa.gov>; Johnson, Zebora <Johnson.Zebora@epa.gov>
**Cc:** Parthasarathy, Narayanan <Parthasarathy.Narayanan@epa.gov>; dswain@srcconsultants.com
**Subject:** Capricorn, EPA Reg. No. 10772-23, Decision # 527916

Hi Seiichi, John, and Zebora,

I'm following up regarding a conversation I had last week with Narayanan Parthasarathy about the subject product. Narayanan indicated the Agency does not allow revisions to the nominal/labeled level for an active ingredient in an existing pesticide product registration. This change is the main focus of the subject PRIA amendment action currently pending with the Agency.

While uncommon, we are aware changes in nominal AI levels have been allowed in certain circumstances. Attached is prior correspondence my colleague David Swain had with you in early May indicating our rationale for this special request (I'm filling in for David for a few weeks as he's on family leave). We believe the circumstances in this situation support our request to amend the existing registration rather than file an additional one. To require an additional registration does not produce tangible benefits for anyone involved, and would make additional work for everyone. Since David had not heard back from Seiichi we believed the Agency was amenable to allowing the slight change in nominal AI level (pending of course the rest of the revisions in the amendment action were acceptable).

To summarize the request:

- Church & Dwight has requested a slight modification (from 18.50% to 18.90%) for the sodium percarbonate active ingredient in Capricorn, EPA Reg. No. 10772-23.
- This is due to a need for slightly expanded certified limits to achieve 12 months of stability for the formulation.
- We are unable to further expand the limits without changing the nominal in order to preserve the existing efficacy testing already done on the product.

And the rationale for why amending this registration is a) a valid option, and b) more desirable than a new registration:

- Additional toxicity testing was conducted and submitted to the Agency to verify the change in active ingredient concentration would not increase the toxicity profile of the product (It did not).
- The product has never been commercially produced or distributed/offered for sale, as Church & Dwight was waiting to confirm stability. (No risk of consumers obtaining product that degrades)
- The product is already registered in the states. As recently discussed with the Agency in the EPA/CSPA information sharing session, state registrations are an integral part of our regulatory requirements. A new EPA registration also requires new state registrations and incurs discontinuation fees (2 years in most states) even though the existing registration was never sold/distributed.

Please confirm the Agency will continue the review of the current amendment action and is agreeable to this minor change in active ingredient level. If I can offer additional assistance please contact me via email or phone (260.244.6270).

Regards,
Tony

**Tony Herber**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

*Inert ingredient information may be entitled to confidential treatment*
*Product ingredient source information may be entitled to confidential treatment*

**Northern, Terria**

**From:** [redacted]
**Sent:** Wednesday, June 28, 2017 4:39 AM
**To:** Murasaki, Seiichi; Parthasarathy, Narayanan
**Subject:** FW: EPA Church and Dwight product; - Capricorn, EPA Registration No. 10772-23. EAP Clearance for [redacted]
**Attachments:** [redacted]

Dear Seiichi and Parthasarathy
Steven "Sam" Adamy from Church & Dwight has asked us to re-send the below product information on the [redacted] we supply to them.
This information was originally sent to your colleagues Stacey Grigsby and Alexandra Napoli in April (please see below) from [redacted]
Please let me know if you require any additional information
Best Regards
[redacted]

**From:** [redacted]
**Sent:** 21 April 2017 10:06
**To:** Grigsby.Stacey@epa.gov; Napoli.Alexandra@epa.gov
**Cc:** [redacted]
**Subject:** EPA Church and Dwight product; - Capricorn, EPA Registration No. 10772-23. EAP Clearance for [redacted]

Stacey, Napoli,

Church and Dwight have asked for us to provide you with the formulation of the [redacted] used in their formulation, please see the email chain below and attached the requested information.

I trust this will meet your requirement, but if you do need anything further on this, please let me know
[redacted]

*Inert ingredient information may be entitled to confidential treatment*
*Product ingredient source information may be entitled to confidential treatment*

[redacted]

**From:** Adamy, Steve [mailto:Steve.Adamy@churchdwight.com]
**Sent:** 19 April 2017 14:27
**To:** [redacted]
**Cc:** Adamy, Steve <Steve.Adamy@churchdwight.com>
**Subject:** EPA Clearance for [redacted]

[redacted]

[redacted] I received you message about setting up a call, and Thursday (4/20) 9am or Friday (4/21) before 11am would be good for me.

I have another issue that I need to address.

One of the powdered formulas that we are testing (and which relates to the [redacted] recently sent) also contains the [redacted]. We have submitted this formula to the EPA for an antibacterial registration, and the EPA has requested that the formula for the [redacted] be submitted as well.

Would it be possible for [redacted] to submit the formula for [redacted] to the EPA contacts listed below on your company letterhead ? The letter should reference the name of our submitted product "Capricorn" and the EPA Registration No. 10772-23.

The emails of the EPA examiners to whom the formula should be sent are

Alexandra Napoli, Napoli.Alexandra@epa.gov
Stacey Grigsby, Grigsby.Stacey@epa.gov

We have a consultant who works with us, and if you like, I can have him review the letter first to make sure it contains the required information. Or you can submit directly to the EPA.

IF [redacted] has already been added to the EPA Inert ingredient trade name list, then let me know.

Regards,
Sam

Steven T. "Sam" Adamy, Ph.D.

Senior Principal Scientist
Church & Dwight Co., Inc.
steve.adamy@churchdwight.com
609-806-1947 (Ph)
609-683-5092 (Fax)

The information contained in this message may be confidential and/or subject to legal privilege, and is for the use of the intended addressee only. Any unauthorized use, dissemination or copying of the information in this message is strictly prohibited. If you have received this message in error, please notify the sender immediately and delete this message.

**********
This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error please notify the system manager.
**********

## Johnson, Zebora

**From:** dswain@srcconsultants.com
**Sent:** Wednesday, May 10, 2017 8:26 AM
**To:** Murasaki, Seiichi
**Cc:** Hebert, John; Johnson, Zebora
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Good morning Seiichi,

Great, thank you. Please let me know if you need further information while the review moves forward.

Have a great day!

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
**SERVICE Portal**, ***a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Murasaki, Seiichi [mailto:Murasaki.Seiichi@epa.gov]
**Sent:** Wednesday, May 10, 2017 7:51 AM
**To:** dswain@srcconsultants.com
**Cc:** Hebert, John; Johnson, Zebora
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Thank you, David.

The provided explanation will be useful (especially the confirmation that there is no 18.50% product currently on the market).

Seiichi

**From:** dswain@srcconsultants.com [mailto:dswain@srcconsultants.com]
**Sent:** Tuesday, May 09, 2017 2:37 PM
**To:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>
**Cc:** Hebert, John <Hebert.John@epa.gov>; Johnson, Zebora <Johnson.Zebora@epa.gov>
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Hi Seiichi,

Thanks for checking into the inert ingredient questions for Capricorn (EPA Reg. No. 10772-23).

**Yes, I can explain the reasoning behind the change to the nominal and the upper certified limit of Capricorn with this PRIA amendment.**

As you know from the initial EPA acceptance letter for Capricorn dated 8/26/2016 (attached); the storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) test requirements were made a condition of registration. The active ingredients in Capricorn do not allow for the accelerated temperature version of the test so we are doing a one year shelf study which is ongoing. We have 18 months, or until 4/26/2018 to provide this storage stability study.

The initial readings of this study indicated that the sodium percarbonate active ingredient might need more than the usual +/- 5% around the nominal amount to make it within the certified limits for the 12 month study and to account for any manufacturing variance and analytical method variations. Therefore, we are asking for a slightly wider range. We have requested a +/- 7% range with this amendment. However, we wanted to keep the lower certified limit the same at 17.58% so we would not have to redo all the efficacy studies since they are required to be conducted at the LCL. We just moved the nominal for sodium perborate up (from 18.50% to 18.90%) and the upper certified limit up (from 19.42% to 20.22%) to allow for the wider +/- 7% range. We reran the toxicity studies to show the new upper certified limit would not impact the label precautions from the original ranges.

I think the fact that the toxicity studies came out the same shows that the new nominal and upper limit should be able to reside under the same registration as the original approved formulation for Capricorn.

**Finally, to address your last question, what about the product in the market?** The good thing is that this product has not yet been launched into the market. There is no product out there with the original label with the 18.50% nominal. Church & Dwight only plans to market the product with the new nominal label amount of 18.90% for sodium percarbonate. The product has been registered in the states but the labels will be revised at the states prior to placing this product into market. The current estimated launch date 1st quarter 2019 to ensure all stability tests have been submitted to EPA and accepted and the labels have been accepted by all states.

I hope this answers the questions you had. Please let me know if you have any follow up questions.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
**SERVICE Portal, *a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Murasaki, Seiichi [mailto:Murasaki.Seiichi@epa.gov]
**Sent:** Tuesday, May 09, 2017 1:09 PM
**To:** dswain@srcconsultants.com
**Cc:** Hebert, John; Johnson, Zebora
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Hi, David,

I can't tell yet whether the ingredient composition information has been received – it is still not loaded in our system. Zebora will be managing this amendment. Meanwhile, one concern I have is the proposed change in the nominal concentration of one of the AIs in the product – this is typically not a change that we allow once the product has been registered. Can you provide further explanation/justification for making this change (also addressing the estimated amount of product already on the market)?

Thanks!
Seiichi

**From:** dswain@srcconsultants.com [mailto:dswain@srcconsultants.com]
**Sent:** Monday, May 08, 2017 4:33 PM
**To:** Murasaki, Seiichi <Murasaki.Seiichi@epa.gov>
**Cc:** Hebert, John <Hebert.John@epa.gov>
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Good afternoon Seiichi,

I hope you are doing well.

I wanted to check on the submission deficiency which was communicated to me for the subject PRIA submission for Capricorn (EPA Reg. No. 10772-23) – Decision# 527916.

My understanding from the registrant is that the suppliers of the two inert ingredients listed on the attached have supplied the required composition to EPA.

Could you confirm you have received the necessary information for these inert ingredients?

Thanks for your help.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
**SERVICE Portal, *a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Napoli, Alexandra [mailto:Napoli.Alexandra@epa.gov]
**Sent:** Monday, April 17, 2017 11:07 AM
**To:** dswain@srcconsultants.com
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Mr. Swain,

Thank you for the update.

Please see the attached updated Inert Clearance Status Form.

Best,
Alexandra

**From:** dswain@srcconsultants.com [mailto:dswain@srcconsultants.com]
**Sent:** Monday, April 17, 2017 10:44 AM
**To:** Napoli, Alexandra <Napoli.Alexandra@epa.gov>
**Cc:** Ashe, Anthony <Ashe.Anthony@epa.gov>
**Subject:** RE: Submission Deficiency (EPA Reg. No. 10772-23)

Hi Alexandra,

Thanks again for the review.

Please find attached the fragrance certifications for the fragrance. They were submitted with our initial approval of this product so I didn't think we had to send them again.

For the [redacted], I am surprised it is not on the EPA trade name list. This ingredient was approved by EPA with our initial CSF dated 2/12/16 which I have attached. The original approval letter for the product listed this CSF as approved. Can you check the list again?

- Basic CSF dated 02/12/2016

If you have any questions, please contact me by phone at (703) 308-8735, or via email at chao.julie@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1

Finally, I am working with the registrant to get the "[redacted]" formulation sent to you by [redacted] Hope you have to you very soon.

Please let me know if you have any questions.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

*Inert ingredient information may be entitled to confidential treatment*
*Product ingredient source information may be entitled to confidential treatment*

SERVICE Portal, ***a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Napoli, Alexandra [mailto:Napoli.Alexandra@epa.gov]
**Sent:** Thursday, April 13, 2017 10:45 AM
**To:** dswain@srcconsultants.com
**Cc:** Ashe, Anthony
**Subject:** Submission Deficiency (EPA Reg. No. 10772-23)

Dear Mr. Swain,

My name is Alexandra Napoli and I am a contractor with the EPA. I am contacting you in regards to your submission in support of the product Capricorn (EPA Reg. No. 10772-23). We have found a deficiency with the submission that will need to be addressed:

1. Please see the attached Inert Clearance Status Form

Please send the necessary documents in pdf file form before April 19th so that we may further process your submission. After April 19th, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Best,

Alexandra Napoli
EPA Contractor- Inoventures, LLC
2777 S. Crystal Drive, S-4815
Arlington, VA 22202
(703) 347-8784
napoli.alexandra@epa.gov

## Murasaki, Seiichi

**From:** dswain@srcconsultants.com
**Sent:** Friday, April 28, 2017 3:01 PM
**To:** Murasaki, Seiichi
**Cc:** Hebert, John
**Subject:** Additional CSFs for Capricorn (EPA Reg. No. 10772-23)
**Attachments:** ATT00001.txt; 07l CSF Capricorn Alt11 042817a F.pdf; 07m CSF Capricorn Alt12 042817a F.pdf

Good afternoon Seiichi,

Hope you have had a nice week.

I am not sure if it is too late, however, Church & Dwight asked if they could add two additional CSF alternate versions to the PRIA amendment currently under review.

It is for Decision# 527916 and have a PRIA date of 21 August 2017.

I have attached the two additional CSFs, Alternate #11 and Alternate #12.

Please let me know if you have any question or if I should submit these in a different way. I also have the SDS for the inert ingredient that makes these CSFs different than the others if you need it.

Thank you and have a nice weekend.

Best regards,

**David Swain**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

**SERVICE Portal, *a cloud-based gateway to state registration data.***
***http://www.srcconsultants.com/services/service-portal***

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

Root MRID **50209700**

**Capricorn**
**EPA File Symbol 10772-23**

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

   Scientific & Regulatory Consultants, Inc.
   201 West Van Buren Street
   Columbia City, IN 46725

   AGENT FOR:
   Church & Dwight Co., Inc.
   500 Charles Ewing Blvd.
   Ewing, NJ 08628

2. Regulatory action in support of which this package is submitted:
   REGISTRATION: PRIA Code A570, PRIA Fee $3,831

3. Transmittal date:

   March 29, 2017

4. Administrative materials:

   A) Cover letter
   B) Proof of PRIA payment via pay.gov Agency tracker #75206120137
   C) Application (8570-1)
   D) Certification with Respect to Citation of Data (8570-34)
   E) Data matrix (8570-35) End Use Product (EPA and Public)
   F) Formulator's Exemption Statement – TAED (8570-27)
   G) Confidential statement of formula (8570-4) (Basic and 10 Alternates)
   H) Proposed product label

5. Vol. 1 Product Chemistry (MRID 50209701)
   OCSPP 830.1550-1800- Product Chemistry - Identity and Composition

7. Vol. 2 Toxicity (MRID 50209702)
   Acute Toxicity Discussion Volume

8. Vol. 3 Toxicity (MRID 50209703)
   OCSPP 870.1100- Acute Oral Toxicity (UDP) in Rats (20454-16)

9. Vol. 4 Toxicity (MRID 50209704)
   OCSPP 870.1200- Acute Dermal Toxicity in Rats (20487-16)

10. Vol. 5 Toxicity (MRID 50209705)
OCSPP 870.1300- Acute Inhalation Toxicity in Rats (20455-16)

11. Vol. 6 Toxicity (MRID 50209706)
OCSPP 870.2500- Acute Dermal Irritation in Rabbits (20619-16)

12. Vol. 7 Toxicity (MRID 50209707)
OCSPP 870.2600- Skin Sensitization in Guinea Pigs (20457-16)

13. Vol. 8 Efficacy (MRID 50209708)
Efficacy Discussion Volume

14. Vol. 9 Efficacy (MRID 50209709)
OCSPP 810.2200- AOAC Use-Dilution Method – *Klebsiella pneumoniae* (A19754)

15. Vol. 10 Efficacy (MRID 50209710)
OCSPP 810.2300- 5tandard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Pseudomonos aeruginosa* (A19766)

16. Vol. 11 Efficacy (MRID 50209711)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Salmonella enterico* (A19768)

17. Vol. 12 Efficacy (MRID 50209712)
OCSPP 810.2400- Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces – *Pseudomanas aeruginosa* (A19901)

18. Vol. 13 Efficacy (MRID 50209713)
OCSPP 810.2200 - Fungicidal Use-Dilution Method – *Trichophyton mentagrophytes* (A20050)

19. Vol. 14 Efficacy (MRID 50209714)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Pseudomonas aeruginoso* (A19763)

20. Vol. 15 Efficacy (MRID 50209715)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Salmanella enterico* (A19762)

21. Vol. 16 Efficacy (MRID 50209716)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Klebsiello pneumoniae, Staphylococcus aureus* (A19796)

22. Vol. 17 Efficacy (MRID 50209717)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Escherichia coli* O157:H7 (A19793)

23. Vol. 18 Efficacy (MRID 50209718)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – Pseudomonas *aeruginosa* (A19794)

24. Vol. 19 Efficacy (MRID 50209719)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Salmonella enterica* (A19795)

25. Vol. 20 Efficacy (MRID 50209720)
OCSPP 810.2400- Standard Test Method for the Evaluation of Laundry Disinfectants - *Klebsiella pneumoniae, Staphylococcus aureus* (A22530) – {HE}

26. Vol. 21 Efficacy (MRID 50209721)
OCSPP 810.2400– Virucidal Efficacy of a Laundry Additive - Human Coronavirus (A22316) {HE}

27. Vol. 22 Efficacy (MRID 50209722)
OCSPP 810.2400– Virucidal Efficacy of a Laundry Additive - Influenza A (H1N1) virus (A22317) {HE}

28. Vol. 23 Efficacy (MRID 50209723)
OCSPP 810.2400– Virucidal Efficacy of a Laundry Additive - Rhinovirus type 37 (A22318) {HE}

29. Vol. 24 Efficacy (MRID 50209724)
OCSPP 810.2400– Virucidal Efficacy of a Laundry Additive - Influenza A (H1N1) virus (A22464) {Top Loader}

30. Vol. 25 Efficacy (MRID 50209725)
OCSPP 810.2400– Virucidal Efficacy of a Laundry Additive - Rhinovirus type 37 (A22536) {Top Loader}

31. Vol. 26 Efficacy (MRID 50209726)
OCSPP 810.2400- Standard Test Method for the Evaluation of Laundry Sanitizers - *Klebsiella pneumoniae, Staphylococcus aureus* (A22333) – {HE}

32. Vol. 27 Efficacy (MRID 50209727)
OCSPP 810.2400- Standard Test Method for the Evaluation of Laundry Sanitizers - *Klebsiella pneumoniae, Staphylococcus aureus* (A22601) – {Top Loader}

33. Vol. 28 Efficacy (MRID 50209728)
EPA Carpet Sanitizer methodology- Carpet Sanitizer – *Staphylococcus aureus, Enterobacter aerogenes* (A21720)

Company Official: David Swain

Company Name: Agent for Church & Dwight Co., Inc.

Company Contact: David Swain
Phone: (260) 244-6270
Email: dswain@srcconsultants.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 13, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SCIENTIFIC & REGULATORY CONSULTANTS, INC.
CHURCH & DWIGHT CO., INC.
201 W. VAN BUREN ST
COLUMBIA CITY, IN 46725

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 29-MAR-17. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 5, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-527916
EPA File Symbol or Registration Number: 10772-23
Product Name: CAPRICORN
EPA Receipt Date: 29-Mar-2017
EPA Company Number: 10772
Company Name: CHURCH & DWIGHT CO., INC.

DAVID SWAIN
LANDIS INTERNATIONAL, INC.
CHURCH & DWIGHT CO., INC.
500 CHARLES EWING BLVD
EWING, NJ 08628

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;REQUIRING DATA REVIEW;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

**dswain@srcconsultants.com**

**From:** notification@pay.gov
**Sent:** Thursday, March 16, 2017 2:57 PM
**To:** dswain@srcconsultants.com
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 261A3LI4
Agency Tracking ID: 75206120137
Transaction Type: Sale
Transaction Date: 03/16/2017 02:57:21 PM EDT

Account Holder Name: Steven T Adamy

Transaction Amount: $3,831.00
Card Type: AmericanExpress
Card Number: **********1001

Registration Number: 10772-23
Company Name: Church Dwight Co., Inc.
Company Number: 10772
Action Code: A570

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



DOCUMENTUM

## Chao, Julie

**From:** dswain@srcconsultants.com
**Sent:** Monday, August 22, 2016 3:31 PM
**To:** Chao, Julie; rjones@srcconsultants.com
**Subject:** RE: EPA Completed Action: 10772-EG Pre-Decisional Determination
**Attachments:** removed.txt; EPA Capricorn Label Changes Revised 081916d.pdf; Capricorn Master Label_ 8.22.16 Clean.pdf; Capricorn Master Label_8.22.16 Mark Up.pdf

Hi Julie,

Hope you had a nice weekend.

On behalf of Church & Dwight, please find attached a revised Capricorn label showing changes ("Mark up"), a clean label with all changes accepted ("Clean") and a chart showing how Church % Dwight is responding to each label change stipulated in the EPA general letter and the science DFRs.

We have made a majority of the required changes. There are five specific cells in the chart with explanations for why changes were not made.

Please NOTE – Church & Dwight initially failed to include one ABN to the front panel with the original submission. This additional ABN has been added to the list on page one and it shown as a revision on the "mark up" label.

We hope our responses will provide information which will make the attached label acceptable.

We look forward to continued discussion on the label and trust the PRIA date of August 30th will be met.

Let me know if you have further questions and have a nice afternoon. Thank you.

Best regards,

SERVICE
*Introducing* SERVICE Portal, *a cloud-based gateway to state registration data.*
*http://www.srcconsultants.com/services/service-portal*

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

**From:** Chao, Julie [mailto:Chao.Julie@epa.gov]
**Sent:** Friday, August 19, 2016 9:20 AM
**To:** rjones@srcconsultants.com
**Cc:** dswain@srcconsultants.com
**Subject:** RE: EPA Completed Action: 10772-EG Pre-Decisional Determination

Terrific, thanks very much Rhonda and David.

You both have a great weekend too!

Best,
Julie

**From:** rjones@srcconsultants.com [mailto:rjones@srcconsultants.com]
**Sent:** Friday, August 19, 2016 9:19 AM
**To:** Chao, Julie <Chao.Julie@epa.gov>
**Cc:** dswain@srcconsultants.com
**Subject:** RE: EPA Completed Action: 10772-EG Pre-Decisional Determination

Julie,

Thank you for accepting the laundry disinfection studies and the colds claim. We do have an Amendment submission ready to go with additional data we withheld due to the size of the initial submission though it does not contain testing on Corona or RSV. I will discuss with CHD on our Monday call testing one of these viruses to gauge interest. David hopes to send over all the other correction responses later today.

Have a great weekend!

Rhonda

CELEBRATING 20 YEARS 1996-2016
**Rhonda Jones, RM(NRM)**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
*Introducing* SERVICE Portal, *a cloud-based gateway to state registration data.*
*http://www.srcconsultants.com/services/service-portal*

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

---

**From:** Chao, Julie [mailto:Chao.Julie@epa.gov]
**Sent:** Friday, August 19, 2016 8:19 AM
**To:** rjones@srcconsultants.com
**Cc:** dswain@srcconsultants.com
**Subject:** RE: EPA Completed Action: 10772-EG Pre-Decisional Determination

Hi Rhonda,

Please see the attached **revised** efficacy review. The laundry pre-soak claims will be accepted. The efficacy team also appreciated some of the other minor typos that you pointed out, and it looks like they fixed those.

Regarding cold claims: the efficacy team reiterated that two of the three "cold" viruses are required to support a general cold virus claim. However, I don't know that this is being consistently carried out. So based on the acceptable rhinovirus data and the fact that rhinovirus is in fact associated with a large percentage of colds, I am willing to consider accepting a general cold virus claim at this time. Can you let me know if Church and Dwight plans to pursue additional efficacy claims in the future? If so, I would like them to consider conducting additional data on at least one of the other viruses as part of any future efficacy submission.

Thanks,
Julie
++++++++++++++++++++++++

| EPA Comment Number | EPA Comment | CD Response |
|---|---|---|
| 1 - General Letter | Throughout the label, please number the marketing claims. | Revised per Agency Direction |
| 2 - General Letter | Throughout the label, surfaces like "countertops" and "counters" need to be qualified as "non-food contact" or "bathroom," as the product is not for use on food contact surfaces. General claims about "kitchen" surfaces must also be qualified as "kitchen floors" or "non-food contact kitchen surfaces." These need to be qualified in the site/surface tables too, and any graphics must not depict food contact sites without a qualifier note "non-food contact surfaces only." | Sites/Surfaces not revised. Competitive products such as:<br><br>- Peroxide Multi Surface Cleaner and Disinfectant (EPA Reg. No. 1677-238)<br>- Baboon (EPA Reg. No. 4822-591)<br>- Sterilex Ultra Disinfectant Cleaner Solution 1 (EPA Reg. No. 63761-8)<br>- PROXI Home General Disinfectant Cleaner Spray (EPA Reg. No. 85837-4)<br><br>have these type of kitchen and counter surfaces but have not been required to qualify with "non-food contact".<br><br>EPA has not published a guidance/policy on this and has not consistently required it of other Registrants. We are entering a small, competitive marketplace and it is critical that we have parity with other currently marketed registrations. We are happy to make these changes to the label once a policy is posted and all registrations are required to revise their labels accordingly. |
| 3 - General Letter | Throughout the label, "cross-contamination" claims must be qualified to read, "cross-contamination between [or across] treated surfaces." | Revised per Agency Direction - Add "on treated surfaces" to these two claims. (page 12 and 15) |
| 4 - General Letter | On page 2, per the acute toxicity data review, add a Note to Physician under the First Aid section. | Revised per Agency Direction |
| 5 - General Letter | On page 5, the storage and disposal statements should be updated per PRN 2007-4 and Chapter 13 of the Label Review Manual. Typical statements would read: "Store in original container in areas inaccessible to children and pets. Keep securely closed. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain." | Revised per Agency Direction |
| 6 - General Letter | On page 9, there is a claim "Cleans x [countertops][floors][square feet][area]." Please qualify "countertops" to read "non-food contact countertops" or "bathroom countertops," as the product is not for food contact use. | See reponse to #2 - General Letter above. |
| 7 - General Letter | On page 10, remove the claim "Free of chemical residue." No data have been submitted to demonstrate residue levels on treated surfaces, and this is considered an implied safety claim. | Revised per Agency Directions |
| 8 - General Letter | On page 10, there is a claim "Go ahead [use around the house on floors][and counters]." Please qualify "counters" to read "non-food contact counters" or "bathroom counters," as the product is not for food contact use. | See reponse to #2 - General Letter above. |
| 9 - General Letter | On page 14, delete the claim "Kills...bacteria for a healthy home [environment]." The phrase "healthy home [environment]" implies impact on the health status of people in contact with the treated sites (a claim regulated under FFDCA), and is not permitted. | Revise to say "Kills [99.9% of] [99.99% of] bacteria on home healthcare surfaces" |
| 9 - Efficacy DER | On the proposed label, registrant must include the dilution of product in water that has up to 100 ppm Calcium carbonate, which accurately represents the hardness of the water used for testing. Regular tap water contains more than 100 ppm of hard water and cannot be used to dilute the product. | Historically EPA has allowed companies to state "dilute with water" by testing with DI or distilled water per 810.2000. We have proactively tested with 100ppm hard water as EPA has begun discussing the desire to have a minimum hardness (draft 810.2000 (2015)) and other regulatory bodies like Canada suggest 100ppm hard water. EPA should not penalize this product by disallowing dilution with "water" on the label when we have proactively tested this product with 100ppm hard water, while all other marketed products continue to state "water" though they have only been tested with deionized or distilled water. We will revise our label to state the 100ppm hardness limit when EPA publishes a final guideline and requires all registered products to update labeling. EPA has not published a guidance/policy on this and has not consistently required it of other Registrants. We are entering a small, competitive marketplace and it is critical that we have parity with other currently marketed registrations. We are happy to make these changes to the label once a policy is posted and all registrations are required to revise their labels accordingly. |
| 10 - Efficacy DER | On the proposed label, registrant must add pre-cleaning instructions to all application uses on hard, non-porous surfaces (i.e. disinfectant, sanitizer and mildewstat). Registrant must also remove "one-step" claims from these uses. Product was not tested using at least 5% organic soil load for hard, non-porous surface disinfection. | Revised in disinfection section. Removed the one-step claim in the disinfection section; kept it in other sections where soil was used. |
| 11 - Efficacy DER | On page 3 of the proposed label, under Laundry Sanitization, registrant must specifically instruct users to prepare the solution accordingly using the accurate doses of product in the required amount of water (as tested) for laundry immersion before adding the treated load to the washing machine. The contact time and amount of water to dilute the product generated from washing machines are difficult to measure and monitor if presoak sanitization were to be done inside the washing machines. | Revised per Agency Direcctions - Delete language for soaking in washing machine. |
| 12 - Efficacy DER | On the proposed label, registrant must remove all claims against cold viruses and claims concerning cold prevention. Agency's criteria for this claim requires effectiveness against 2 of the 3 cold-associated viruses, which are Rhinovirus, Coronavirus, and Respiratory Syncytial virus. | Agency will allow "cold" |

OK JAC

OK JAC

OK JAC

ok JAC

OK JAC

| | | | |
|---|---|---|---|
| 13 - Efficacy DER | On page 4 and 15 under soft surface sanitization, the term "spot" should be removed from the brackets as it is not optional. | Revise per Agency Directions | ✓ |
| 14 - Efficacy DER | On the proposed label, registrant must remove all claims against "black mold". The microorganisms tested are not considered black mold-associated microorganisms. | Revise per Agency Directions "black mold" removed. | ✓ |
| 15 - Efficacy DER | On page 7 of the proposed label, under "Marketing Claims", registrant must remove the claim "ready to use". | Revise per Agency Directions - not a ready to use product. | ✓ |
| 16 - Efficacy DER | On the proposed labe , registrant must remove all claims concerning "antibacterial protection". | Remains on revised label. The word "protection" has historically been allowed (e.g. Products without registration requirements are allowed to use this term, e.g. Treated Article Policy.) Therefore, if products not registered such as Exempt Treated Articles are allowed to use the term "protection"; a registered product such as Capricorn should also be allowed to use it on labeling. | ✓ ok JAC |
| 17 - Efficacy DER | On page 12 and 15 of the proposed label, registrant must specify the claim concerning "cross contamination". Registrant must specify the claim to, "Can help prevent cross-contamination between treated surfaces by [household] bacteria." | Add "on treated surfaces" to these two claims. (page 12 and 15) This matches the change we made for Phoenix and Hydra. | ✓ |
| 18 - Efficacy DER | On page 13 of the proposed label, registrant must remove the brackets from the word "surfaces" from the claim, "[This product] will help [you] keep your [surfaces] clean [and disinfected]". This term is not optional. | Revise per Agency Directions | ✓ |
| 19 - Efficacy DER | Throughout the proposed 'abe , remove the "99.99%" claims from multiple locations under the hard, non-porous disinfection section. | Remains on the revised label. The "99.99%" claims are all specific to the bacteria disinfection claims on the label. The 99.99% claim has been historically allowed for products which passed the disinfection test based on the dried carrier count requirements which range from a 4 -6 log / carrier minimum requirement for bacteria and fungi. | ✓ ok JAC |
| 20 - Efficacy DER | On page 14 of the proposed label, registrant must remove "more than" from the claim "Kills more than 99.9% of bacteria and viruses". | Revise per Agency Directions. Claim removed. | ✓ |
| 21 - Efficacy DER | On page 21, Table 8: Testing and Dilution Type, Fungi must be removed from the Type of Organism column. The name, "Mold and mildew", is more appropriate according to Agency's criteria. | Revise per Agency Directions | ✓ |
| 22 - Efficacy DER | On the proposed label, registrant must qualify all of the "virus", "virucide", and "virucidal" claims with an asterisk or other symbols to refer the claims mentioned to the viruses tested. | Revise per Agency Directions | ✓ |
| 23 - Efficacy DER | On the proposed label, registrant must remove all claims against "fungi", "fungus" and "fungal spores". Product was not tested against the Agency-required microorganism to qualify for the claims. | Capricorn was tested on A. niger spores in the EPA Hard Surface Mildew Fungistatic Test Method and on A. niger and P. variable spores in the EPA Fabric Mildew Fungistatic Test (EPA Product Performance Guidelines - Subdivision G 93 -15 and 93-30). These terms are appropriate and accurate in this context and mirror EPA's terminology in the Guidelines. We have been careful not to make or imply fungicidal action on this label though Capricorn has passed the test and we will be submitting an amendment in September to add this claim. | ✓ ok JAC |
| Toxicity DER | Note to Physician "Probable mucosal damage may contraindicate the use of gastric lavage" must be added to the label because the product is Toxicity Category I for eye irritation. | Revise per Agency Directions | ✓ |
| Toxicity DER | Revise First Aid section to match Toxicity DER | Revise per Agency Directions | ✓ |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Capricorn

{Alternate Brand Names}

OXICLEAN™ Antibacterial Cleaner

OXICLEAN™ Antibacterial Laundry Additive

OXICLEAN™ Antibacterial [Chlorine]Bleach Alternative

OXICLEAN™ White Revive Laundry Stain Remover [with Disinfection]

OXICLEAN™ Color Safe Disinfection

KABOOM™ Plus Disinfex [Toilet Bowl Cleanser]

OXICLEAN Antibacterial Versatile Stain Remover & Disinfectant [Kills 99.9% of Bacteria & Viruses*]

**Active Ingredient:**

| | |
|---|---|
| Sodium Percarbonate | 18.50% |
| Tetraacetylethylenediamine | 4.44% |
| Other ingredients | 77.06% |
| Total: | 100.00% |

**FRONT PANEL:**

**DANGER**
KEEP OUT OF REACH OF CHILDREN

**See back panel for First Aid and additional Precautionary Labeling.**
EPA Reg. No. #10772-XX

EPA Establishment #XXXXX-XX-XXX, #XXXXX-XX-XXX

Manufactured [by] [for]:
Church & Dwight Co., Inc.
500 Charles Ewing Blvd.
Ewing, NJ 08628

Net contents:
1.7 LB (0.77kg)
2.0 LB (0.90kg)
2.5 LB (1.13kg)
2.6 LB (1.17kg)
3.0 LB (1.36kg)
4.0 LB (1.81kg)
4.5 LB (2.04kg)
5.0 LB (2.26kg)
6.5 LB (2.94kg)
10.0 LB (4.53kg)
10.5 LB (4.76kg)
11.0 LB (4.98kg)
13.5 LB (6.123kg)

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

*{NOTE TO REVIEWER: This product meets the EPA's criteria of Toxicity Category 1 for the eye route of exposure, Toxicity Category 3 for oral route of exposure and Toxicity Category 4 for all other routes of exposure. Therefore a Signal Word, Precautionary Language and First Aid Statements are required in accordance with EPA Label Review Manual: Chapter 7. The Precautionary Statements and First Aid Statements below are mandatory and will appear on the container labeling. The skin and inhalation first aid statements below are aptional as the corresponding acute toxicity studies were Toxicity Category 4.}*

**BACK PANEL:**

**PRECAUTIONARY STATEMENTS: Hazardous to Humans and Domestic Animals**

**Danger.** Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**FIRST AID. If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. **If swallowed:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person. [**If on skin:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.][**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.] Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, call the National Pesticides Information Center at 1-800-858-7378. For emergencies, call the poison control center 1-800-222-1222. **Note to Physician** - Probable mucosal damage may contraindicate the use of gastric lavage

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label.

[[1]] Always ensure powder is fully dissolved.

[[2] [Always test {product] [powder] on an inconspicuous area first.]

[[3] [Follow manufacturer's instructions for cleaning.]

[[4] [Do not use on] [wool] [wool blends], [silk], [silk blends], [leather], [or on] [fabrics labeled dry clean only.] [Not for use on] [jewelry], [latex paints], [woven baskets], [unpainted wicker]. [jute], [teak], {or] [unfinished wood]. [Metal must not be soaked and must be rinsed immediately and thoroughly.] [Not for use on] [rust], [dried paint], [or bleach damage].]

[[5] [Treat stains while fresh. Do not place fabric that has not been thoroughly rinsed into dryer.]]

[[6] [Some stains require repeated or longer treatments.] [Adding more [powder] [product] than directed increases the risk of color loss.] [Do not rinse or soak overnight.]]

**[Shake container before pouring.]**
**[[Before pouring,] [G][g]ently tap container on a [hard] surface.]**

**LAUNDRY [USE]**

[To] Clean [and] [&] [Remove Stains]: [Soak [1- 6 hours] for best results]
TOP LOADER: Fill washer [drum] with water. Add up to [1] [2] [scoop] [scoops] [cap] [caps] [capful] [capfuls] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. [Add detergent directed.] [Add regular laundry detergent.]
HE WASHER[**]: Add up to [1] [2] [scoop] [scoops] [cap] [caps] [capful] [capfuls] [of product] [of powder] [into] [to] washer [drum] BEFORE adding laundry. [**Do not mix [powder] [product] with detergent in the dispenser.]

**[LAUNDRY] [SANITIZATION] [and] [DISINFECTION]**

[To] Sanitize [Laundry]:
[Pre-soak [Use]:] *{Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}*~~{in washing machine}~~. Immerse laundry for [at least] 10 minutes prior to starting the wash cycle. [Light soils do not require precleaning.] Effective against *{insert laundry sanitization bacteria from Table 7.}*

[To] Disinfect [Laundry]:
[To kill] bacteria and viruses†[:] *{Insert directions far 1X dilution type and applicable measuring device from Table 9 {scoops) ar Table 10 {caps)}* ~~{in washing machine}~~. Immerse laundry for [at least] 15 minutes prior to starting the wash cycle. [Light soils do not require precleaning.] Effective against *{insert laundry disinfection bacteria and/or viruses from Table 7}.*

[Post-Wash [Sanitization/Disinfection] [Use]: For additional sanitization/disinfection, refill washing machine with [clean] water. *{insert directions for "1X" and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}* in washing machine. Immerse laundry for [at least] 10 minutes for sanitization or 15 minutes for disinfection. Rinse thoroughly.]

[Safe for colorfast fabrics][Follow manufacturer's instructions for water temperature and for cleaning garment or item.]

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

## HOUSEHOLD USE

### HARD NON-POROUS [SURFACES]

[To] Clean [and] [&] [Remove Stains]:
[1] *{Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [using a] [cloth] [sponge] [brush] [mop] [or by] [pouring] [solution] directly onto surface.
[3] Let stand 5-30 [minutes] [min]. Scrub as needed.
[4] Rinse thoroughly [with] [cool] [water] [and let air dry].

[[For use on] [Use only on] {Insert hard non-porous surfaces from Table 3 and/or 5}]

[To] Sanitize [Hard Surfaces]:
[1] *{Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 5 minutes.
[3] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop]. [Pre-clean heavily soiled surfaces.] [*Effective against {Insert non-food contact sanitization bacteria from Table 7}.]*

[To] Disinfect [Hard Surfaces]:
[1] Pre-clean surface.
[2] *{Insert directions for "2X" dilutian type and applicable measuring device from Table 9 (scaops) or Table 10 (caps)}.*
[3] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 10 [minutes] [min.] for bacteria and 5 [minutes] [min.] for viruses†.
[4] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop]. [Effective against *{Insert disinfection bacteria and/or viruses from Table 7}.]*

[To] Prevent Mold [and Mildew]:
[1] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet.
[3] Air dry. Repeat [application] every 7 days [to inhibit] [mold] [and mildew] [growth]. [Effective against Aspergillus [A.] niger ~~[(black mold)]~~ [mildew].

### SOFT SURFACES [AND] [&] [FABRICS]

[To] Clean [and] [&] [Remove Stains]:
[1] *{Insert directions for "2X" dilutian type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [only] [enough] solution to saturate [the] stain. Let stand 1-S [minutes] [min].
[3] Blot [stained] [area] [gently] with a [white] [dye-free] cloth. Repeat [steps 2 and 3] until stain is no longer visible.
[4] Rinse [surface] with [clean] water and pat dry.

[To] [Spot] Sanitize [Soft Surfaces]:
[1] *{Insert directions for "2X" dilution type and opplicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Saturate [fabric] surface until it is thoroughly wet. Let stand 5 minutes.
[3] [Blot] [stained] [area] [gently] with a [white] [dye-free] [cloth] [or sponge]. [Pre-clean heavily soiled surfaces.] *[Effective against {Insert soft surface sanitization bacteria from Table 7}.]* [Blot dry with cloth.]

[To] Prevent Mold [and Mildew] [growth] [on Fabric] :
[1] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] [Saturate] [Mop, spray, wipe or sponge on] [fabric] surface until thoroughly wet.

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

[3] Air dry. [Pre-clean heavily soiled surfaces.] Repeat [application] every 28 days [to inhibit] [mold] [and mildew] [growth]. [Effective against Aspergillus [A.] niger ~~{(black mold)}~~ [mildew] and Penicillium [P.] variable.

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1 AIDS Virus] ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids; and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV-1 [associated with AIDS].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface/object to remain wet for 5 minutes for HIV-1 on hard non-porous surfaces. For laundry allow object to pre-soak for 15 minutes for HIV-1.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

***{Residential Containers}***

**STORAGE AND DISPOSAL:**
Store in original container in areas inaccessible to children and pets. Keep securely closed. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.~~Nonrefillable container. Do not contaminate water, food or feed by storage and disposal. Store in original container in areas inaccessible to small children. Keep securely closed. Do not reuse or refill this container. Place [container] in trash or offer for recycling, if available.~~

***{Institutional Containers}***

*{Nonrefillable containers}*

**STORAGE AND DISPOSAL:**
Do not contaminate water, food or feed by storage and disposal.
**PESTICIDE STORAGE:** Store in original container in areas inaccessible to children and pets. Keep securely closed.
**PESTICIDE DISPOSAL:** To avoid waste, use all material in this container according to label directions. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.
**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.~~Clean container promptly after emptying. Triple rinse [or equivalent]. Follow pesticide disposal instructions for rinsate. Then discard in trash or offer for recycling, if available.~~

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Questions or Comments:
[Call]1.XXX.XXX.XXXX
Mon-Fri 9AM-5PM ET

Website:
www.oxiclean.com/XXXXXXX
www.kaboomkaboom.com/XXXXXXX

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

*NOTE: Any claim may appear on either FRONT / BACK panel in bullet / paragraph format*

**Marketing Claims:**

1. [Clean & Simple]
2. -{Complete]
3. -[Complete OXICLEAN™ Clean]
4. [Easy]
5. -[Easy to use]
6. [Everyday Cleaner]
7. [Everyday Use]
8. [Effective]
9. -[$O_2$ Powered]
10. -[Oxygen Powered]
11. -[Modern]
12. -[Multi-Action]
13. -[Multi-Clean]
14. -[Multi-Purpose]
15. -[Multi-Surface]
16. -[Multi-Task]
17. -[Power & Clear]
18. [Simple Power]
19. -[Triple Action]
20. ~~-[Ready to use]~~
21. [Streak-Free]
22. -[Versatile][with Oxygen]
23. -{Beautiful]
24. -{Bright]
25. [Brilliant]
26. [Glistening]
27. -[Shine] formula
28. [Cleaner]
29. [Cleans]
30. [Cleaning]
31. [Degreaser]
32. [Degreases]
33. [Grease releaser]
34. [with Grease Release Action]
35. [Deodorize]
36. -[Deodorizer]
37. [Deodorizes]
38. -[Deodorizing]
39. [Bathroom]
40. [Floor]
41. -[Kitchen][Multi-Purpose] [Cleaner] [Disinfectant] [Deodorant]
42. -[Cleans][Cuts][Cuts through] [Degreases] [Destroys] [Dissolves][Eliminates] [Penetrates] [[Removes][the following] {*Insert one or more items from Table 1*}] [tough] [the toughest] [even the toughest] [stubborn] [everyday] [stains] [with no] [without] [chlorine bleach] [with no] [without] [chlorine bleach]
43. [Effective]
44. -[Effectively]
45. -[Effortlessly]

46. -[Fresh] [Good][Great][Maximum Cleaning Power][Smell][Smelling] [Smells]
47. -[Clean] [Cleans] [Cleaner] [Cleaning]

48. New [!] {*to be used as a claim descriptor only for the first 6 months on shelf*}

49. From OXICLEAN™, your stain removal partners

50. It's from OXICLEAN™, removing stains *{insert stain from Table 1}* for over XX years

51. From the makers of OXICLEAN™, tackles the toughest stains *{insert stain from Table 1}* all around the house [in the home]

52. From OXICLEAN™, tackling the toughest stains *{insert stain from Table 1}* all around the house [in the home] for XX years

53. Leaves surfaces sparkling

54. Clear drying formula for multiple surfaces

55. Clean the OXICLEAN™ way

56. [Clean] with the power of Oxygen

57. Bleach like whitening

58. From couch to counter

59. *{Insert number of loads according to package weight and corresponding value on Table 11}*. [Mix until powder is fully dissolved]{Laundry] [Disinfecting] [Disinfection] Loads

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

**Fragrance Claims**

1. Fresh Scent
2. Fresh Water Splash
3. Fresh Water Sparkle
4. Fresh Water Springs
5. Arctic Chill
6. Arctic Splash
7. Blue Wave
8. Cool Summer Shower
9. Classic Clean
10. Crisp Morning Air
11. Ocean Air
12. Moonlit Ocean
13. Rain Mist
14. Refreshing spring
15. Sparkling Water
16. Summer Dew
17. Waterfall
18. Water Lily

**Packaging Claims**

1. [Bonus]
2. [Bonus x%]
3. [Bonus x oz.]
4. [X% Discount]
5. [X% More Free]
6. [X oz. Free]
7. [X oz. at x oz. Price]
8. [X oz. for the x oz. Price]
9. [X oz. at the Price of x oz.]
10. [X oz. for the Price of x oz.]
11. [More than]
12. [Over]
13. [Great]
14. [Mega]
15. [Super]
16. [Trial]
17. [Value]
18. [Pack]
19. [Refill]
20. [Size]
21. [Money back guarantee]
22. [Satisfaction guaranteed]
23. [Your # 1 choice]
24. [For more stain fighting ideas visit [website]]

**Cleaning Claims**

1. [A] friendly [cleaner] [cleaning]
2. A shining [beautiful] clean you can see/trust
3. All-in-1 [complete] [cleaning] [action]

4. Alternative [chlorine] bleach cleaner
5. [Available in] [Economy] Economical refill
6. Bathrooms, sinks and faucets and floor areas
7. Better than ever on {stains} *{insert stain from Table 1 below}*
8. Bleach-free
9. Bleach power without the damaging effects and chlorine [fumes] [smell]
10. Boost Laundry Cleaning Power
11. Breaks down [and lifts out] tough stains with supercharged OXICLEAN™ Stain Fighters
12. Brightens
13. [Chlorine] Bleach alternative
14. Chlorine bleach alternative cleaner
15. [Chlorine] bleach free
16. Chlorine free
17. Chlorine free bleach
18. [OXICLEAN™] [a clean] you can trust
19. Cleans
20. Cleans bathroom soils
21. Cleans blood
22. Cleans everyday messes
23. Cleans fingerprints
24. Cleans food
25. Cleans mildew [stains] [odor]
26. Cleans rust stains
27. Cleans to a shine
28. Cleans [up] grease and grime
29. Cleans x [countertops] [floors] [square feet] [area]
30. Cleans and shines
31. Cleans [and smells] [great] [fantastic]
32. Cleans non-food contact surfaces
33. Cleans [tough] grease [better than] [ever] [before]
34. Cleans with a [sparkling] [fresh] [floral] [citrus] scent
35. Cleans without leaving a [dull] residue [behind]
36. Clings to surfaces for a powerful clean
37. Color safe
38. Compatible with equipment surfaces *{insert surface/site from Table 3, 5, 6}*
39. [Compatible with -or- Suitable] [for use on] equipment surfaces
40. Compatible with -or- Suitable –or compatible with equipment surfaces for computer surfaces
41. VOC Compliant
42. Confidence in cleaning
43. Contains [just enough] [cleaning] ingredients for [those] everyday touch ups
44. Contains maximum stain fighting power
45. Contains [effective] [fast-acting] [grease cutters] [cleaning agents]
46. Contains no [chlorine] bleach
47. Contains [water] and [active] [oxygen]
48. Controls [pet] [smoke] [cooking] odors [fast] [quickly]
49. Convenient [surface] cleaner *{insert surface/site from lists below}*
50. Convenient [kitchen] [and] [bathroom] surface cleaner *{insert surface/site from lists below}*
51. Customize your cleaning
52. Cuts -and/or- removes grease -and/or grime-and/or- sweat
53. Cuts Tough Grime without Scrubbing

54. Cuts cleaning time
55. Deep down clean
56. Designed -or- Ideal for daily [cleaning] [use]
57. Designed – or – Ideal for in home cleaning
58. Does not contain [chlorine] bleach
59. Does not contain [dyes]
60. Dye free
61. Easy [cleaning]
62. Easy to use [formula] [formulation]
63. [Easily] removes soap scum
64. Easily removes soap scum, hard water stains, and [dirt][grime]
65. Effective [cleaner -or- cleaning] [formula]
66. Effective cleaning [without chlorine bleach]
67. Effectively works on [many] [hard] non-porous surfaces
68. Efficacious cleaner [without compromise]
69. [OXICLEAN™] essential for oxygen clean
70. Foaming action penetrates your toughest messes
71. Foams [and] [bubbles] so you know it's working
72. For a deep down clean
73. For a deep clean
74. For easy cleaning
75. For everyday [use] [usage] [touch-ups]
76. For multiple cleaning [tasks]
77. Free from [chlorine] bleach

~~Free of chemical residue~~

78. Friendly to your [floor] surfaces
79. Friendly to your clothes
80. Get a true clean [with] [this product]
81. Gives you multiple cleaning actions [-] [removes] [eliminates] [cuts through] [stains] *{insert stain from Table 1}* (and] (deodorizes]
82. Go ahead [use around the house on floors] [and counters]
83. Good for use with microfiber cloths
84. Grease cut [-ter] [-ting] formula
85. Groundbreaking formula [is a] cleaner + stain remover + antibacterial protection
86. Help[s] make your room OXICLEAN™ clean
87. Ideal for larger soft surface areas like [couches, throw rugs, curtains] [sanitize and] to remove stains
88. Ideal for larger surface areas like couches, rugs and countertops
89. Ideal for use in gyms -and/or- health clubs-and/or- wellness centers
90. Ideal for use in schools -and/or- offices -and/or- public places
91. Ideal for use on high touch surfaces
92. Just [apply] mixture[,] wipe. rinse [and you're done] [; no scrubbing required!]
93. Knocks out the toughest kid and pet messes, removing stains and odor [on carpet] [in laundry]
94. Knocks out the toughest kid and pet messes, removing stains and odor [fabrics]
95. Labor saving no-rinse formula
96. Leaves a [long-lasting] [fresh] [clean] scent
97. Leaves a [whitening] shine
98. Leaves no [dull] [filmy] [sticky] residue
99. Leaves nothing behind [except] [but] [the] [smell] [of clean] [shine]
100. Leaves [virtually] no [annoying] [chemical] [scum] [residue] [film]
101. Leaves your *{insert surface/site from Table 3, 5, 6}* [fresh] [clean] [and] [fragrant]

102. _____Leaves your *{insert surface/site from Table 3, 5, 6}* [fresh] [clean] [and] [sparkling] [shiny]
103. _____Leaves your *{insert surface/site from Table 3, 5, 6}* [with a] [fresh] [and] [clean] scent
104. _____Lifts out [and breaks down] tough stains with supercharged OXICLEAN™ Stain Fighters
105. _____Light touch-up quick cleaning
106. _____Makes your [floor] cleaning job easier [in the] [kitchen] [and] [bathroom]
107. _____Makes grout and hard surfaces look radiant
108. _____Makes cleaning easier
109. _____Money-saving formula [use everywhere] [use in laundry & to clean surfaces]
110. _____[Multipurpose][Versatile] Cleaner
111. _____No [chlorine] bleach harshness
112. _____No [chlorine] bleach [fumes] [smell]
113. _____No harsh chemical residue
114. _____No harsh chlorine [bleach] fumes -or- smell –or odor-and/or- build-up -and/or- residue
115. _____No mess [cleaner] [cleaning]
116. _____No mixing, measuring, or rinsing required
117. _____No phosphates
118. _____No scrubbing necessary!
119. _____No sorting necessary!
120. _____No [sticky] [tacky] [residue] [film]
121. _____Non-abrasive
122. _____Non-[chlorine] bleach
123. _____Now cleans [tough] grease [better than] [ever] [before]
124. _____Packaging made with [x%] recycled –or recyclable plastic
125. _____Pleasant smell
126. _____Powerful [cleaner] [additive]
127. _____Proof is in the clean
128. _____Quickly deodorizes
129. _____[Quickly] removes dirt and grime
130. _____Radiant shine
131. _____Releases powerful cleaning agents [on contact]
132. _____Releases powerful OXICLEAN™ Stain Fighters [on contact]
133. _____Removes offensive odors from *{insert surface/site from Table 3, 5, 6}*
134. _____Removes [oxidizable] stains
135. _____Removes stains
136. _____Shine[s] like new
137. _____Smell of clean
138. _____Sparkling shine
139. _____Stain remover
140. _____Stains disappear [before your eyes]
141. _____Starts cleaning on contact
142. _____Starts to work before you do [on]
143. _____Starts to work before [you do] [your eyes]
144. _____Strong cleaning
145. _____Strong [effective] cleanser
146. _____Strong effective cleanser [with a] [non-chemical] [fresh] [scent]
147. _____Strong effective cleanser [with a non-chemical scent]
148. _____Suitable for everyday use
149. _____[The] smell of clean
150. _____The smell of [OXICLEAN™] [clean]
151. _____The toughest stains [instantly] disappear

152. [This product] cleans and shines
153. This product's formula cleans and shines
154. This room is OXICLEAN™ clean
155. Tough on grime
156. Tough stains [instantly] disappear
157. Trusted heritage [of] [Oxygen Cleaning]
158. Versatile for all bathroom surfaces
159. Watch [this] [these] stains [start to] [disappear] [dissolve] [breakdown] right before your eyes
160. Watch [this] [the] [tough] [toughest] stains disappear
161. Works great [smells great]

**Stain Claims**

1. Removes -and/or- Cleans the following: *[insert stain(s)/soil(s) from Table 1]*
2. Removes dried on [blood]
3. Removes grease and grime
4. Removes *[insert stain(s)/soil(s) from Table 1]*
5. Removes [tough] *[insert stain(s)/soil(s) from Table 1]*
6. Use it [in the wash or] [as a] pre-treater [with it] to remove more stains

[bracketed text] i. . ptional; *italicized* text and {bracketed text} nformational.

**Deodorizing Claims**

1. Deodorizer
2. Deodorizes
3. Deodorizes food odors [like garlic and onion] [left behind on kitchen surfaces] [after cooking]
4. Eliminates odors [as it cleans]
5. No harsh chlorine [fumes] [smells]
6. No harsh alcohol smell
7. Pleasant odor
8. Removes odors
9. [This product] will deodorize hard, nonporous surfaces from [where obnoxious odors may develop]
10. [This product] will deodorize surfaces in [and] [other] places bacteria growth can cause malodors

**General Antimicrobial Claims**

1. [3-in-1] [clean –s, -er, -ing][deodorize –s, -er, -ing][disinfect –s, -ant, -ing]
2. [3x Cleaning Power] [clean -s][deodorize -s][disinfect -s]
3. 3 [cleaning] actions [in one bottle] [clean –s, -er, -ing] [deodorize -s, -er, -ing] [disinfect -s, -ant, -ing]
4. 3 [cleaning] actions [in one bottle] [remove -s stains] [clean -s] [disinfect –s] [deodorize -s]
5. [4-in-1] [clean–s, -er, -ing][disinfect –s, -ant, -ing][remove -s non-living allergens][sanitize -s hard surfaces][sanitize -s fabric -s]
6. [4x Cleaning Power] [cleans]][disinfects][removes non-living allergens][sanitizes hard surfaces][sanitizes fabrics]
7. [4-in-1] [cleans][disinfects][removes non-living allergens][sanitizes hard surfaces][sanitizes fabrics]
8. 4 [cleaning] actions [in one bottle] [disinfects] [removes non-living allergens] [sanitizes hard surfaces] [sanitizes fabrics]
9. 3-in-1 Bathroom Cleaner [Disinfectant] [Cleaner] [Deodorizer]
10. A convenient way to [clean] [disinfect] [and] [deodorize]
11. -[All-in-1] [cleaner][deodorizer][disinfectant]
12. [All-in-1 Complete] [cleaner/cleans][deodorizer/deodorizes][disinfectant/disinfects]
13. For a better [4-in-1] [kind of] clean [disinfects] [removes non-living allergens] [sanitizes hard surfaces] [sanitizes fabrics]
14. For [a] complete [clean] [cleaning action]
15. [Antibacterial] [Antibacterial Action] [Bactericidal] [Bactericide] [Germicidal*] [Virucidal†]
16. [Disinfect] [Disinfects] [Disinfectant] [Disinfecting]
17. Antibacterial Cleaner cleans and kills bacteria
18. Antibacterial [surface] *{insert surface/site from Table 3, 5, 6}* cleaner
19. Antibacterial [kitchen] [and] [bathroom] surface *{insert surface/site from Table 3, 5, 6}* cleaner
20. Antibacterial 4-in-1 action [disinfects] [removes non-living allergens] [sanitizes hard surfaces] [sanitizes fabrics]
21. Can help prevent cross-contamination on treated surfaces by [household] bacteria
22. Cleans & Disinfects *{insert hard nonporous surfaces from Table 5}*
23. Cleans as it disinfects
24. Cleaner + stain fighting power + antibacterial protection for all around the house
25. Combines [streak-free] cleaning with antibacterial action
26. [Kills][Effective against] [Controls] odor-causing bacteria
27. [Kills][Effective against] [Controls] odor-causing bacteria in the [kitchen] [and] [bathroom]
28. Designed as a general [multipurpose] [multi surface] [versatile] cleaner and disinfectant
29. Disinfection for your [kitchen] [and] [bathroom] [floors]
30. Disinfects [and] [deodorizes]
31. Disinfects [and] [deodorizes] hard, non-porous surfaces
32. [Disinfectant] [Cleaner] [Deodorizer]
33. Helps prevent the spread of cold° and flu‡ viruses†
34. Multi surface [multipurpose] [versatile] cleaner disinfectant

35. Oxygen-based formula cleans and sanitizes
36. Surface cleaner [with antibacterial formula]
37. [This product] deodorizes areas that are hard to keep fresh smelling [or other areas prone to odors caused by microorganisms]
38. [This product] will help {you} keep your {surfaces} clean [and disinfected]
39. Three steps to clean [Disinfectant] [Cleaner] [Deodorizer]
40. Use [only] one product to get a streak-free shine [plus antibacterial action]
41. Deodorizes odors caused by bacteria
42. Kills odor causing bacteria in the kitchen -or- bathroom

**Hard Non-Porous Surface Sanitizing Claims**

1. Sanitization [against bacteria]
2. Oxygen based formula cleans and sanitizes
3. Kills [and] [Sanitizes] 99.9% of bacteria [including] [*Insert 1 or more strains from Table 7 under non-food contact sanitization*]
4. Powers out the toughest stains and bacteria without stripping color
5. Sanitizer [Sanitizes]
6. [5 minute] [One Step] [1 Step] Sanitizer
7. [5 minute] [One Step] [1 Step] Non-Food Contact Sanitizer
8. Cleans and sanitizes [in One Step]
9. Cleans, deodorizes, and sanitizes in one step
10. When you need sanitization!
11. When you need to kill bacteria [in one [easy] step]!
12. Kills 99.9% bacteria [in 5 minutes]!
13. In 5 minutes, 99.9% bacteria are dead!
14. Kills 99.9% {*Insert bacteria from Table 7 list under non-food contact sanitizer*} [in 5 minutes]
15. {Non-Food Contact Sanitizer] Effective against {*Insert bacteria from Table 7 list under non-food contact sanitizer*}
16. Kill bacteria where you need it most
17. Eliminates 99.9% of [household] bacteria in 5 minutes

**Hard Non-Porous Surface Disinfecting Claims**

1. [Chlorine] Bleach-free
2. Broad spectrum [general] [hospital] disinfectant
3. Destroys bacteria on {*insert site from Table 3, 5, 6*}
4. Disinfectant [&] Cleaner
5. Disinfects bathroom bacteria
6. Kills [*insert organism(s) from Table 7*)]
7. Kills bacteria on {*{insert surface/site from Table 3, 5, 6*}
8. Oxygen-based [disinfectant] kills [99.9%] of bacteria/viruses†
9. Oxygen-based [disinfectant] [cleaner] kills [99.9%] of bacteria/viruses/germs*
10. Reduces bacteria on {*{insert surface/site from Table 3, 5, 6*}
11. Kills 99.9% of [bacteria,] [germs*] [virus†] [and], [Influenza A plus H1N1 virus†]
12. Kills [99.9%] [99.99%] of odor causing bacteria
13. Kills [99.9%] of odor causing [germs*] [With Germfighter* Technology]
14. Designed as a general [versatile] [multipurpose] [multi surface] cleaner and disinfectant [/sanitizer]
15. Cuts tough dirt [grease] and grime and kills 99.9% [99.99%] of bacteria [in the bathroom] [on] *{insert surface/site from Table 3, 5, 6}*
16. Cuts tough grease and grime [killing] 99.9% of bacteria [germs*] [in the kitchen] [on] {*insert surface/site from Table 3, 5, 6}*

17. Destroys germs* [bacteria] [that ordinary cleaners {can't] [don't]]
18. Disinfects *{insert surface/site from Table 3, 5, 6}*
19. Disinfects and removes offensive odors from *{insert surface/site from Table 3, 5, 6}*
20. *Disinfects bacteria and viruses† {in {insert location from Table 6}} [on {Insert items from Table 3 or 5}]*
21. Effective against *{Insert organisms from Table 7 under disinfection}*
22. Eliminates 99.9% of bacteria [germs*] [virus†]
23. Eliminates [99.9% of] [99.99% of] [household] bacteria [in] [10 minutes]
24. Eliminates 99.9% of [household] germs* [in] [10 minutes]
25. Eliminates [99.9% of] [99.99% of] bacteria from [kitchen] [and] [bathroom] *{insert surface/site from Table 3, 5, 6}*
26. Eliminates [99.9% of] [99.99% of] bacteria [in] [the] [kitchen] [and] [bathroom]
27. Eliminates [99.9% of] germs* [that ordinary cleaners [can't] [don't]]
28. Eliminates [99.9% of] [99.99% of] of hidden bacteria
29. Eliminates [99.9% of] [99.99% of] [kitchen] [and] [bathroom] bacteria
30. Kills [99.9% of] [99.99% of] bacteria

~~Kills [99.9% of] [99.99% of] bacteria in one step~~

31. Kills [99.9% of] [99.99% of] bacteria and leaves surfaces sparkling
32. Kills [99.9% of] germs*
33. Kills [99.9% of] bacteria and [&] viruses†
34. Kills [99.9% of] [99.99% of] bacteria for a deep down clean
35. Kills [99.9% of] [99.99% of] bacteria ~~for a healthy~~ on home ~~[environment]~~ healthcare surfaces
36. Kills [99.9% of] [99.99% of] [Escherichia coli O157:H7 (E. coli)) [and) [Salmonella enterica] [other organisms] *{insert organism from Table 7 under disinfection}*
37. Kills [99.9% of] germs* [including [the] cold° and flu' viruses†]
38. Kills [99.9% of] [99.99% of] [household] bacteria [in] [10 minutes]
39. Kills [99.9% of] [99.99% of] the following [household] bacteria commonly found in kitchens on hard, non-porous surfaces in 10 minutes:{organisms} *{insert organism from Table 7 under disinfection}*
40. Kills [99.9% of] [99.99% of] the following [household] bacteria commonly found in bathrooms on hard, non-porous surfaces in 10 minutes:{organisms} *{insert organism from Table 7 under disinfection}*
41. Kills [99.9% of] viruses† and [&] bacteria
42. Kills [99.9% of] viruses† and [&] bacteria [including [the] cold° and flu' viruses]
43. Kills bacteria on hard, non-porous [kitchen] [and] [bathroom] surfaces in 10 minutes
44. Kills viruses† on hard, non-porous [kitchen] [and] [bathroom] surfaces in 5 minutes
45. Kills bacteria on hard, non-porous [kitchen] surfaces in 10 minutes
46. Kills viruses† on hard, non-porous [kitchen] surfaces in 5 minutes
47. Kills bacteria commonly found in [the] [kitchen] [and] [bathroom] [in] [10 minutes)
48. Kills bacteria for a deep down clean
49. Kills germs* [that ordinary cleaners] [don't] [can't]
50. Kills germs*
51. Kills [household] bacteria [germs*]
52. Kills [household] bacteria [commonly found in] [bathrooms] [and] [kitchens] [on hard, non-porous surfaces] [in] [10 minutes]
53. Kills [household] bacteria [in] [10 minutes] [commonly found in] [bathrooms] [and] [kitchens] [and on] [floors]
54. Kills [kitchen] [and] [bathroom] germs*
55. Kills [kitchen] [household] bacteria [germs*]
56. ~~Kills more than 99.9% of bacteria and viruses‡~~
57. Kills Viruses†
58. Reduces the amount of bacteria [germs*] on a surface
59. Removes bacteria [germs*]
60. Designed as a general [versatile] [multi-surface] [multipurpose] cleaner and disinfectant

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

*{Qualified "germs" claim: One of the two following footnotes must appear wherever "germs*" or related words (e.g. Germicidal*) is used on label:*

***[Kills] {*insert at least one bacteria and one virus from Table 7*}**
***Insert Table 7**

**Soft Surface Sanitizer Claims**

1. [Oxygen based] Soft Surface Sanitizer [Sanitization]
2. [Oxygen based] Soft Surface {Spot} [Fabric] Sanitizer [Sanitization]
3. Kills 99.9% of bacteria on soft surfaces [fabric] [upholstery] {{*insert one or more items from Table 4*}}
4. Oxygen based formula cleans and {spot} sanitizes soft surfaces [fabric] [upholstery] [{*insert one or more items from Table 4*}]
5. Powers out the toughest stains and bacteria without stripping color in fabrics
6. [5 minutes] [bacteria] [*Insert 1 or more strains from Table **7** under soft surface sanitization]* soft surface sanitization [Sanitizer]
7. [*Insert 1 or more strains from Table 7 under soft surface sanitization]* soft surface {spot} sanitizer
8. Soft Surface [Fabric] Sanitizer [Sanitizes]
9. [5 minutes] [One Step] [1 Step] Soft Surface [Fabric] Sanitizer
10. [5 minutes] [One Step] [1 Step] soft surface sanitizer [for the [*Insert one or more locations from {Table 6}*]]
11. Cleans and sanitizes fabrics [soft surfaces] {soft and hard surfaces] [in One Step]
12. Cleans, deodorizes, and sanitizes fabrics [soft surfaces] and [hard surfaces] in one [easy] step
13. When you need fabric [and surface] sanitization[!]
14. When you need to kill bacteria on soft and hard surfaces[!]
15. Kills 99.9% bacteria [in] [5 minutes]
16. In 5 minutes, 99.9% bacteria are dead on soft surfaces[!]
17. Kills 99.9% {*Insert bacteria from Table 7 list under soft surface sanitizer}* [in] [5 minutes]
18. [Soft Surface Sanitizer] Effective against {*Insert bacteria from Table 7 list under soft surface sanitizer}*
19. Eliminates 99.9% of [household] bacteria on fabric {soft surfaces] in 5 minutes

**Laundry Disinfection**

1. Antibacterial [laundry] additive cleans and kills bacteria [germs*]
2. Can help prevent cross-contamination in laundry on treated surfaces
3. Cleaner + stain fighting power + antibacterial protection for all your laundry needs
4. [Kills][Eliminates]Controls odor-causing bacteria
5. [Kills][Eliminates]Controls odor-causing bacteria in the {laundry]
6. Deodorizes odors causing bacteria
7. Disinfection for all your laundry needs
8. Disinfects [and] {deodorizes]
9. Disinfects your clothes
10. [Disinfecting] [Antibacterial] [laundry] presoak
11. Dissolve and eliminate tough stains
12. Eliminates 99.9% of bacteria [germs*] [virus†] in your laundry
13. Eliminates {99.9% of] [99.99% of] bacteria [in] [15 minutes] {on your clothing]
14. Eliminates 99.9% of germs* [in] [15 minutes] {on] [{*insert surface/site from Table 4}*
15. Eliminates [99.9% of] [99.99% of] bacteria from *{insert surface/site from Table 4}*
16. Eliminates [99.9% of] [99.99% of] bacteria [in] {the] [laundry] [and] [on] [soft surface]
17. Eliminates [99.9% of] germs* [that ordinary additives [can't] [don't]]
18. Eliminates [99.9% of] [99.99% of] of hidden bacteria

19. Eliminates [99.9% of] [99.99% of] bacteria
20. Freshens while killing bacteria [germs*] [virus†]
21. Helps prevent the spread of cold° and flu[i] viruses†
22. Kills odor causing bacteria in the [wash and/or laundry]
23. [Kills] [Eliminates] [Destroys] [99.9% of] [99.99% of] bacteria in your laundry
24. [Kills] [Eliminates] [Destroys] [99.9% of][germs*] in your laundry
25. [Kills] [Eliminates] [Destroys] odor causing bacteria on {*Insert soft surfoce from Table 4 list under soft surfoce sanitizer*}
26. [Kills] [Eliminates] [Destroys] [99.9% of] viruses†, bacteria, and in your laundry [or on {*Insert soft surfoce from Table 4 list under soft surface sanitizer*}
27. Kills [99.9%] of odor causing bacteria [germs*] [With Germfighter* Technology]
28. Kills 99.9% of [bacteria,] [germs*] [virus†] [and], [Influenza A plus H1N1 virus†] in your laundry
29. Kills [99.9% of] germs*
30. Kills [99.9% of] bacteria and [&] viruses†
31. Kills [99.9% of] [99.99% of] bacteria for a deep clean
32. Kills [99.9% of] [99.99% of] [Escherichia coli O157:H7 (E. coli)) [and) [Salmonella enterica] [other organisms] {*insert organism from Toble 7 under disinfection*}
33. Kills [99.9% of] germs* [including [the] cold° and flu[i] viruses†]
34. Kills [99.9% of] [99.99% of] [odor causing] bacteria [in] [15 minutes]
35. Kills [99.9% of] viruses† and [&] bacteria
36. Kills [99.9% of] viruses† and [&] bacteria [including [the] cold° and flu[i] viruses]
37. Kills bacteria [on] [laundry] [and] [soft surfaces] in 15 minutes
38. Kills viruses† [on] [laundry] [and] [soft surfaces] in 15 minutes
39. Kills germs* [that ordinary cleaners] [don't] [can't]
40. Kills germs*
41. Kills [household] bacteria [germs*]
42. Oxygen-based formula cleans and sanitizes
43. [This product] [even] deodorizes areas that are hard to keep smelling fresh [or other areas prone to odors caused by microorganisms]
44. [This product] will help [you] remove stains from your [laundry] and [and disinfect]
45. Versatile for [all colors] [and loads] [use on {*Insert from Table 1,2,3,4,5,6,7 list under soft surface sanitizer*}]

**Hard Surface Non-Porous Mildewstat Claims**

1. Inhibits [the growth of] [mold] [and] [mildew] for [up to] [7 days]
2. Inhibits [the growth of] [mold] [and] [mildew] for [up to] [7] days on hard surfaces
3. [Controls] [Inhibits][Prevents] [the growth of] [mold] [and] [mildew] for [up to] [7] days on hard surfaces
4. [Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] days on hard surfaces]
5. [Controls][Inhibits][Prevents] [the growth of] [mold] [and] [mildew] for [up to] [7] days on {*Insert one or more of the items in Table 3*}
6. [Controls] [Inhibits] [Prevents] [the growth of] [mold] [and] [mildew] on {*Insert one or more of the items in Table 3*}
7. [Controls] [Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] days on hard surfaces] on {*Insert one or more of the items in Table 3*}
8. [Controls] [Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on {*Insert one or more of the items in Table 3*}
9. [Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] days on [hard] [surfaces] on {*Insert one or more of the lacotions in Table 3*}
10. [Controls][Inhibits][Prevents] [the growth of] [mold] [and] [mildew] on [hard surfaces] like {*Insert one or more of the locations in Table 3*}

11. [Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] days on hard surfaces] on *{Insert one or more of the locations in Table 3}*
12. [Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on [hard surfaces] [like] [including] *{Insert one or more of the locations in Table 3}*
13. [Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on hard and [soft] [fabric] surfaces] [like] [including] *{Insert one or more of the locations in Table 3}*
14. [Controls][Inhibits][Prevents] [the growth of] [mold] [and] [mildew] on hard and [soft] [fabric] surfaces]

**Fabric Mildewstat Claims**

1. Fabric Mildewstat [fungistat]
2. [Controls] [Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] [28] days on fabric
3. [Controls][Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] [28] days on fabric]
4. [Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] [28] days on {*Insert one or more of the items in Table 4*}
5. [Controls] [Inhibits] [Prevents] [the growth of mold] [and] [mildew] on *{Insert one or more of the items in Table 4}*
6. [Controls] [Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] {28} days on fabric] on {*Insert one or more of the items in Table 4*}
7. [Controls] [Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on {*Insert one or more of the items in Table 4*}
8. [Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] [28] days on [fabric] [soft surfaces] in {*Insert one or more of the locations in Table* 6}
9. [Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] on [fabric] [soft surfaces] in *{Insert one or more of the locations in Table 6}*
10. [Controls][Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] [28] days on fabric] in *{Insert one or more of the locations in Table 6}*
11. [Controls][Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on [fabric] [soft surfaces] in *{Insert one or more of the locations in Table 6}*

**Non-Pesticidal Allergen Claims**

1. Breaks Down non-living Allergens[!][including {*insert one or more items from Table 2*}][in {*insert one or more locations from Table 6*}][on *{insert one or more items from Table 3 or 5}]*
2. Controls [the most] [common] non-living allergens [including {*insert one or more items from Table 2*}] [in {*insert one or more locations from Table 6*}] [on {*insert one or more items from Table 3 or 5*}]
3. Destroys [Eliminates] non-living Allergens[!][including {*insert one or more items from Table 2*}][in{*insert one or more locations from Table 6*}][on *{insert one or more items from Table 3 or 5}]*
4. Destroys -or- deactivates dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens [found in dust] [in{*insert one or more locations from Table 6*}][on *{insert one or more items from Table 3 or 5}]*
5. [Penetrates and] breaks down dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens [found in dust] [in {*insert one or more locations from Table 6*}] [on {*insert one or more items from Table 3 or 5*}]
6. Reduces dust mite matter -or- particles, cockroach matter –or particles, and pet dander allergens [found in dust]
7. Reduces non-living Allergens[!][in {*insert one or more locations from Table 6*}][on {*insert one or more items from Toble 3 or 5*}]
8. Reduces up to XX% of [inanimate] [non-living] allergens [that become airborne from {*insert one or more items from Table 3, 4 or 5*}], [such as {*insert one or more items from Table 2*}]
9. [This product] kills germs* and destroys non-living allergens [while cleaning hard, nonporous surfaces.]

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

10. [This product] kills germs* on surfaces, controls mold & mildew on fabric, and destroys non-living allergens.
11. [Deodorizes] [Disinfects][controls mold & mildew on fabric], and destroys non-living allergens

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

{Table 1:} Soils / Odors: (Graphic - depicting soil)

| | | | | |
|---|---|---|---|---|
| Baby food | Dirt (greasy dirt) | Hard water stains | Outdoor grime | Tomato / spaghetti sauce |
| Bacon fat | Dust | Heel / scuff marks | Pancake mix | Toothpaste |
| Bathtub rings | Eggs | Juice / wine stains | Pen / Ink mark | Tough soils / stains |
| BBQ Sauce | Fingerprints | Lime scale | Pet odors | |
| Beverage stains | Food odors | Makeup | Pet stains | |
| Blood stains | Food stains | Mildew stains | Smears / smudges | |
| Blueberry | Grass | Mold stains | Smoke / smoking odors | |
| Chocolate syrup | Gravy | Motor Oil | Soap scum | |
| Coffee | Grease (splatter) | Mud | Stains / soils | |
| Cooking odors | Grime | Mustard | Sweat odors | |
| Cosmetic stains | Hair dye | Musty odors | Sweat stains | |
| Crayon / pencil marks | Handprints | Organic soils / stains | Tea | |

{Table 2:} Non-living Allergens:

| | | |
|---|---|---|
| Cat dander | Dog dander | Hair |
| Cockroach debris | Dust mite debris | Pet dander |
| Cockroach matter | Dust mite matter | Pet hair |
| Cockroach particles | Dust mite particles | Pollen particles |

{Table 3:} Hard Non-Porous Surface Types:

| | | |
|---|---|---|
| Chrome | Glazed granite | Sealed Marble |
| Corian® | Glazed porcelain | Silestone® |
| Countertop [surfaces] | Glazed tile | Stainless steel |
| Crystal | Laminate | Vinyl |
| Enamel | Linoleum | |
| Formica® | Plastic laminate | |
| Glazed ceramic | Sealed Fiberglass fixtures | |

{Table 4:} Exteriors [of] Soft Surfaces :

| | | | |
|---|---|---|---|
| Baby carriages | Curtains [Draperies] | Seat cushion [kitchen] | Suitcase [luggage] |
| Baby prams | Cushion [Pillow] | Shoes [canvas] [fabric] | Throw rug |
| Backpack[/School bag] | Dog [Pet] bed | Shoe interior | [Upholstered] booster seat |
| Bathroom mat | Diaper bag | Shower curtain [fabric] | [Upholstered] chairs |
| Bedding [Bedspread] | Duvet cover | Slippers | [Upholstered] couches |
| Box spring [cover] | Gym bag [fabric] | Sneakers [canvas] [fabric] | [Upholstered] furniture |
| Car [seat] [upholstery] | [Upholstered] Highchair seat | Sponges [rags] | Upholstery |
| Clothing | Laundry bag [fabric] | Sport[s] [bag[s]] [equipment] | Window treatments [fabric] |
| Cotton [fabric] purse | Mattress [cover] | Soft [fabric] surfaces | |
| Cots | Mop [/ broom] | Stroller [seats] | |
| Couch [Sofa] | Seat cushion [household] | Stuffed [Plush] toys | |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

{Table 5:} Hard Non-porous Surfaces: (Graphic - depicting use site)

| | | | |
|---|---|---|---|
| Appliance exterior | Fixture [chrome/stainless steel] | Microwave exterior | Shower [stall] [area] |
| Bathtub [tub] | Floor [linoleum] | Non-medical [chrome/stainless steel] | Sink [basin] |
| Bed frame | Floor [glazed ceramic/porcelain tile] | Outdoor patio furniture [non-wood] | Stove [stovetop] |
| Cabinet [non-wood] | Floor [laminate] | Oven [door] | Table [tabletop] [non-wood] |
| Chair [non-wood] | Floor [sealed marble] | Patio door | Telephone |
| Changing table [non-wood] | Floor [vinyl] | Picnic table [non-wood] | Toilet bowl exterior [Urinal] |
| Counter [Countertop] | Garbage [can] [pail] [container] | Plastic laundry [basket] [hamper] | Water fountain |
| Crib [non-wood] | Glazed ceramic tile | Range hood [stove hood] | Window [windowsill] |
| Diaper pail [non-wood] | Glazed porcelain tile | Refrigerator Shelves [drawers] | Vanity top |
| Exhaust [fan] [hood] | Grill [Barbecue] exterior | Sealed granite | |
| Faucet | Highchair [non-food contact area] | Shower [door] [curtain] | |

{Table 6: Use Sites {Graphic - depicting use site}}:

| | | | |
|---|---|---|---|
| Basement | High-touch areas | Nursery | Dining room |
| Bathroom | Home [House] | Outdoor area | Game room |
| Bedroom | Household areas | Storage [area] [room] | Rec room |
| Den [/Study] | Laundry [room] | Lodging establishments | Public transportation Terminals [air/bus/train/car] |
| Family room | Education [schools, colleges, preschools] | Locker rooms etc. | Pet shops |
| Athletic/Recreational facilities [fitness facilities, gyms] | Entertainment [Theaters, Parks, Playgrounds, etc.] | Manufacturing facilities | Retail locations [Grocery stores, Shops, Malls] |
| Automotive interiors [seats, handles, etc.] | Food service establishments [Restaurants] [Commercial Kitchens] | Other commercial facilities | Shower rooms |
| Breakrooms | Government facilities | Offices | Zoos |
| Churches | Hospitality areas [hotel, motels, extended stay, time share] | Office buildings | Cruise ships |
| Commercial laundry | Living room | Tool shed | Hotel [motel] |
| Garage | Mud room | Kitchen | |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

**Table 7: List of Organisms***

**Hard Surface Non-Porous DISINFECTANT**

| Contact Time | Bacteria |
|---|---|
| 10 minutes | *Pseudomanas aeruginoso*[P.][ATCC 15442]<br>*Salmanella enterica* [S.][ATCC 10708]<br>*Staphylacaccus aureus* [(*Staph*)][S][ATCC 6538]<br>*Escherichia coli O157:H7[E.][ATCC43888]* |
| | **Viruses†** |
| 5 minutes | †°Rhinovirus [(type 39)][ATCC VR-340] [Strain 209]<br>†[‡]Influenza A [Pandemic] [(H1N1)] [CDC #2009712192] [A/Mexico/4108/2009]<br>†Herpes Simplex Virus, Type 1 [ATCC VR-733]<br>† Rotavirus [ATCC VR-2018]<br>†† Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus] |

**Hard Surface Non-Food Contact Non-Porous SANITIZER**

| Contact Time | |
|---|---|
| 5 minutes | *Staphylococcus aureus* [(*Staph*)] [S.][ATCC 6538]<br>*Klebsiello pneumonioe [K.][ATCC 4352]*<br>*Escherichia coli O157:H7[E.][ATCC43888]* |

**Hard Surface Non-Porous MILDEWSTAT**

| | |
|---|---|
| 7 day | *Aspergillus niger[A.]*[ATCC 6275] |

**Soft Surface [Fabric] SANITIZER**

| Contact Time | |
|---|---|
| 5 minutes | *Solmonella enterica* [S.][ATCC 10708]<br>*Staphylacoccus aureus* [(*Staph*)] [S.][ATCC 6538]<br>*Klebsiella pneumoniae[K.][ATCC 4352]*<br>*Escherichia coli O157:H7[E.][ATCC43888]* |

**FABRIC MILDEWSTAT**

| | |
|---|---|
| 28 day | *Aspergillus niger[A.]*[ATCC 6275]<br>*Penicillium variable* [P.][ATCC 32333] |

**Laundry Pre-Soak DISINFECTANT**

| Contact Time | Bacteria |
|---|---|
| 15 minutes | *Pseudomanas aeruginosa*[P.][ATCC 15442]<br>*Salmanella enterica* [S.][ATCC 10708]<br>*Staphylococcus aureus* [(*Staph*)][S][ATCC 6538]<br>*Klebsiella pneumoniae[K.][ATCC 4352]*<br>*Escherichia coli O157:H7[E.][ATCC43888]* |
| | **Viruses†** |
| | †°Rhinovirus [(type 39)][ATCC VR-340] [Strain 209]<br>†[‡]Influenza A [Pandemic] [(H1N1)] [CDC #2009712192]<br>†Herpes Simplex Virus, Type 1 [ATCC VR-733]<br>† Rotavirus [ATCC VR-2018]<br>† Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus] |

**Laundry Pre-Soak SANITIZER**

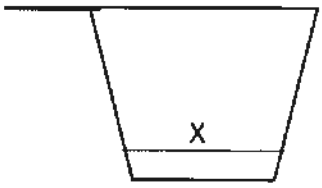
| Contact Time | |
|---|---|
| 10 minutes | *Staphylococcus aureus* [(*Staph*)] [S.][ATCC 6538]<br>*Klebsiella pneumoniae [K.][ATCC 4352]*<br>*Escherichia coli O157:H7[E.][ATCC43888]* |

[Table 8: Testing and Dilution Type]

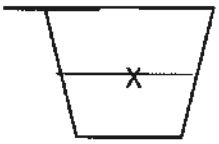
| Testing Type | Type of Organism | Dilution Type | Efficacy Study Dilution Rate | Gallon Conversion |
|---|---|---|---|---|
| Hard Surface Disinfection | Bacteria<br>Viruses-† | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Hard Surface Mildewstat | ~~Fungi~~Mold and Mildew | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Non-Food Contact Sanitization | Bacteria | 1X | 31.2 grams Product / 1 liter water | 118 grams Product / 1 gallon water |
| Soft Surface Sanitization | Bacteria | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Soft Surface Mildewstat | ~~Fungi~~Mold and Mildew | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Laundry Pre-Soak Disinfection | Bacteria<br>Viruses† | 1X | 31.2 grams Product / 1 liter water | 118 grams Product / 1 gallon water |
| Laundry Pre-Soak Sanitization | Bacteria | 1X | 31.2 grams Product / 1 liter water | 118 grams Product / 1 gallon water |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

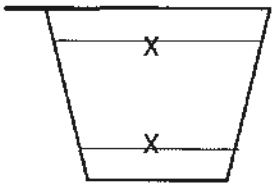
| [Table 9: Scoop Directions for Use Table {[X] can equal any letter or number }]**Scoop Scenario** | **Directions for Use for insertion depending on Measuring Device and Dilution Type** | **Measuring Device** | **Dilution Type** | **grams product per measuring device** | **Total grams product per gallon of water** | **Total grams product per liter of water** |
|---|---|---|---|---|---|---|
| **Scoop X (118 grams)** | | | | | | |
| 1 | "Add 1 scoop of product to 1 gallon of water" | Scoop [X] | 1X | 118 | 118 | 31.2 |
| 2 | "Add 2 scoops of product to 1 gallon of water" | Scoop [X] | 2X | 118 | 236 | 62.4 |
| 3 | "Fill scoop to line [X] and add to 16 ounces of water." | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (59 grams)** | | | | | | |
| 4 | "Add 2 scoops of product to 1 gallon of water" | Scoop [X] | 1X | 59.0 | 118 | 31.2 |
| 5 | "Add 4 scoops of product to 1 gallon of water" | Scoop [X] | 2X | 59.0 | 236 | 62.4 |
| 6 | "Fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (118 grams @ line [X])** | | | | | | |
| 7 | "Fill scoop to line [X] and add to 1 gallon of water" | Scoop [X] Line [X] | 1X | 118 | 118 | 31.2 |
| 8 | "Fill scoop to line [X] 2 times and add to 1 gallon of water" | Scoop [X] Line [X] | 2X | 118 | 236 | 62.4 |
| 9 | "Fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (59 grams @ line [X])** | | | | | | |
| 10 | "Fill scoop to line [X] 2 times and add to 1 gallon of water" | Scoop [X] Line [X] | 1X | 59.0 | 118 | 31.2 |
| 11 | "Fill scoop to line [X] 4 times and add to 1 gallon of water" | Scoop [X] Line [X] | 2X | 59.0 | 236 | 62.4 |
| 12 | "Fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |



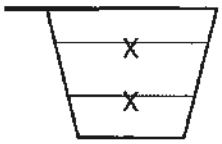

Scoop type X




Scoop type X




Scoop type X

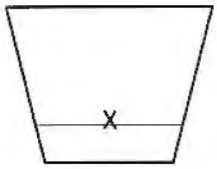



Scoop type X

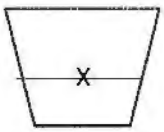
[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

[Table 10: Cap Directions for Use {[X] can equal any letter or number}]

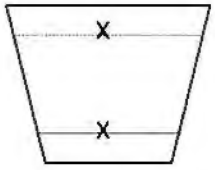
| Cap Scenario | Directions for Use for insertion depending on Measuring Device and Dilution Type | Measuring Device | Dilution Type | grams product per measuring device | Total grams product per gallon of water | Total grams product per liter of water |
|---|---|---|---|---|---|---|
| **Cap [X] (118 grams)** | | | | | | |
| 1 | "Add 1 capful of product to 1 gallon of water" | Cap [X] | 1X | 118 | 118 | 31.2 |
| 2 | "Add 2 capfuls of product to 1 gallon of water" | Cap [X] | 2X | 118 | 236 | 62.4 |
| 3 | "Fill cap to line 'X' and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 4 | "Add 2 capfuls of product to 1 gallon of water" | Cap [X] | 1X | 59.0 | 118 | 31.2 |
| 5 | "Add 4 capfuls of product to 1 gallon of water" | Cap [X] | 2X | 59.0 | 236 | 62.4 |
| 6 | "Fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 7 | "Fill cap to line [X] and add to 1 gallon of water" | Cap [X] Line [X] | 1X | 118 | 118 | 31.2 |
| 8 | "Fill cap to line [X] 2 times and add to 1 gallon of water" | Cap [X] Line [X] | 2X | 118 | 236 | 62.4 |
| 9 | "Fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 10 | "Fill cap to line [X] 2 times and add to 1 gallon of water" | Cap [X] Line [X] | 1X | 59.0 | 118 | 31.2 |
| 11 | "Fill cap to line [X] 4 times and add to 1 gallon of water" | Cap [X] Line [X] | 2X | 59.0 | 236 | 62.4 |
| 12 | "Fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |



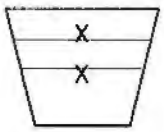

Cap type X




Cap type X




Cap type X




Cap type X

[bracketed text] i. ,tional; *italicized* text and {bracketed text} , informational.

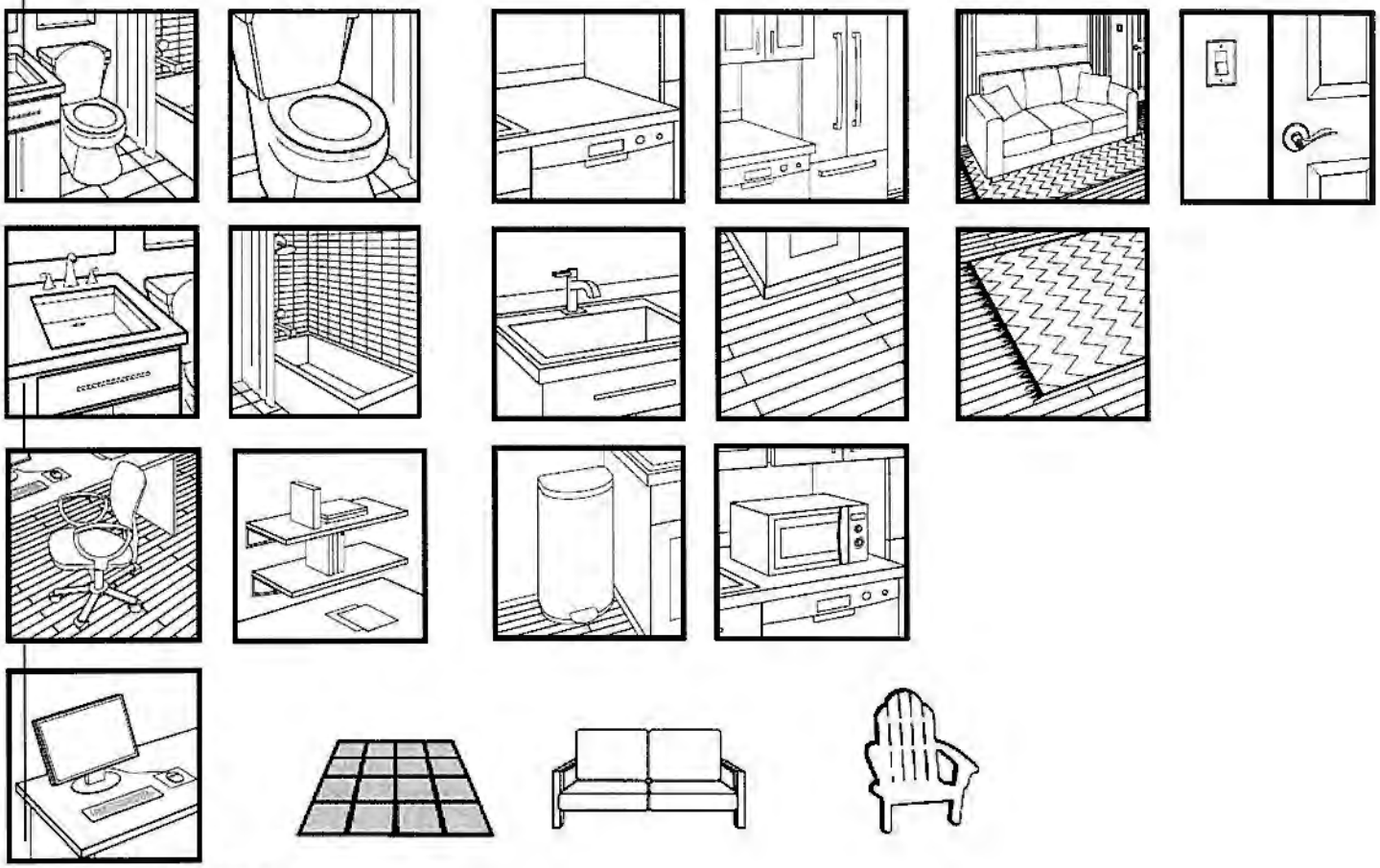
[Table 11: Package dose quantities]

| Content Wt. (lbs.) | Content Mass (kg) | Number of loads (assuming 118 grams in 1 gallon = 1 load) |
|---|---|---|
| 1.7 | 0.77 | 6 |
| 2.5 | 1.13 | 9 |
| 3.0 | 1.36 | 11 |
| 4.5 | 2.04 | 17 |
| 5.0 | 2.27 | 19 |
| 6.5 | 2.95 | 25 |
| 10.0 | 4.54 | 38 |
| 10.5 | 4.76 | 40 |
| 11.0 | 4.99 | 42 |
| 13.5 | 6.12 | 51 |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

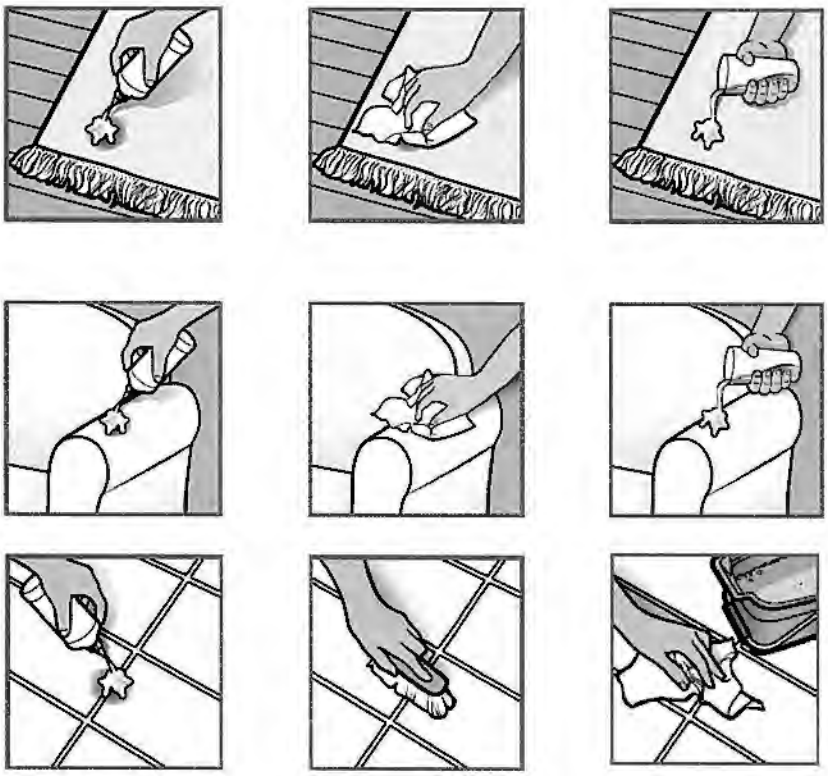
Optional Pictograms- Safety

Optional Pictograms- Locations usage (Bathroom, Kitchen, Living Room, Office, Grout, Soft Surface, Hard Surface)

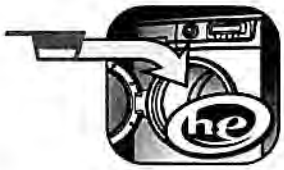


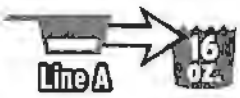
Laundry compatible

Optional Pictograms- Usage



[bracketed text] is optional; *italicized* text and {bracketed text} is informational.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

~~July 29, 2016~~
(Revised 08/18/16)

**MEMORANDUM**

Subject: Efficacy Review for Capricorn,
EPA Reg. File No. 10772-EG,
DP Barcode: D432547

From: Son Nguyen
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

To: Julie Chao, RM33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Church & Dwight Co., Inc.
500 Charles Ewing Blvd.
Ewing, NJ 08628

**Formulation from the Label:**

| Active Ingredient | % by wt. |
|---|---|
| Sodium Percarbonate | 18.50 |
| Tetraacetylethylenediamine | 4.44 |
| OtherIngredients | 77.06 |
| Total | 100.00% |

## I. BACKGROUND

The product, Capricorn (EPA Reg. File #10772-EG) is a new product, designed as a concentrated solid product to be used when diluted as instructed as a laundry pre-soak or post-soak disinfectant and sanitizer and hard surface disinfectant (bactericide, virucide) and sanitizer for use in sites such as homes, schools, hospital and office buildings. The studies were conducted at Accuratus Lab Services, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated March 8, 2016), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), 24 new efficacy studies (MRID Nos. 49795317 through 49795340), and the product's proposed label. Statement of No Data Confidentiality Claims, Compliance Statement and Quality Assurance Unit Summary were included with each study.

Note: On Nov. 10, 2015, the Agency confirmed via email that the contact times for laundry sanitization at 10 minutes and laundry disinfection at 15 minutes are acceptable claims for this product. (Emails attached with submission package).

**Revision 8/18/16: for study with MRID No. 49795331, testing was done based on the current criteria for UDM (2013); therefore, the performance results of 2 positive and 3 positive carriers out of 60 carriers for *Staphylococcus aureus* are acceptable.**

## II. USE DIRECTIONS

The product is designed for use on hard, non-porous surfaces, such as appliance exterior, bathtub [tub], bed frame, cabinet [non-wood], chair [non-wood], changing table [non-wood], counter [countertop], crib [non-wood], diaper pail [non-wood], exhaust [fan] [hood], faucet, fixture [chrome/stainless steel], floor [linoleum], floor [glazed ceramic/porcelain tile], floor [laminate], floor [sealed marble, floor [vinyl], garbage [can] [pail] [container], glazed ceramic tile, glazed porcelain tile, grill [barbecue] exterior, highchair [non-food contact area], microwave exterior, non-medical [chrome/stainless steel], outdoor patio furniture [non-wood], oven [door], patio door, picnic table [non-wood], plastic laundry [basket] [hamper], range hood [stove hood], refrigerator shelves [drawers], sealed granite, shower [door] curtain], shower [stall] [area], sink [basin], stove [stovetop], table [tabletop] [non-wood], telephone, toilet bowl exterior [urinal], water fountain, window [windowsill], vanity top. The product can be used on hard, non-porous surfaces materials, such as chrome, Corian, countertop, crystal, enamel, Formica, glazed ceramic, glazed granite, glazed porcelain, glazed tile, laminate, linoleum, plastic laminate, sealed fiberglass fixtures, sealed marble, Silestone, stainless steel, vinyl. The product is also designed to be used on soft surfaces, such as baby carriages, baby prams, backpack/schoolbag, bathroom mat, bedding [bedspread], box spring [cover], car [seat] [upholstery], clothing, cotton [fabrics] purse, cots, couch [sofa], curtains [draperies], cushion [pillow], dog [pet] bed, diaper bag, duvet cover, gym bag [fabric], [upholstered] highchair seat, laundry bag [fabric], mattress [cover], mop [broom], seat cushion [household], seat cushion [kitchen], shoes [canvas] [fabric], shoe interior, shower curtain [fabric], slippers, sneakers [canvas] [fabrics], sponges [rags], sport(s) [bag(s)] [equipment], soft [fabric] surfaces, stroller [seats], stuffed [plush] toys, suitcase [luggage], throw rug, [upholstered] booster seat, [upholstered] chairs, [upholstered] couches, [upholstered] furniture, upholstery, window treatment [fabric].

Directions on the proposed label provide the following information regarding preparation and use of the product:

Testing and Dilution Type:

| Testing Type | Type of Organis | Dilution Type | Efficacy Study | Gallon Conversion |
|---|---|---|---|---|
| Hard Surface | Bacteria<br>Viruses | 2X | 62.4 grams Product / 1 liter | 236 grams Product / 1 gallon water |
| Hard Surface | Fungi | 2X | 62.4 grams Product / 1 liter | 236 grams Product / 1 gallon water |
| Non-Food Contact | Bacteria | 1X | 31.2 grams Product / 1 liter | 118 grams Product / 1 gallon water |
| Soft Surface | Bacteria | 2X | 62.4 grams Product / 1 liter | 236 grams Product / 1 gallon water |
| Soft Surface | Fungi | 2X | 62.4 grams Product / 1 liter | 236 grams Product / 1 gallon water |
| Laundry Pre-Soak | Bacteria<br>Viruses | 1X | 31.2 grams Product / 1 liter | 118 grams Product / 1 gallon water |
| Laundry Pre-Soak | Bacteria | 1X | 31.2 grams Product / 1 liter | 118 grams Product / 1 gallon water |

**[LAUNDRY] [SANITIZATION] [and] [DISINFECTION]**

[To] Sanitize [Laundry]:
[Pre-soak [Use]:] {Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}[in washing machine]. Immerse laundry for [at least] 10 minutes prior to starting the wash cycle. [Light soils do not require precleaning.]

[To] Disinfect [Laundry]:
[To kill] bacteria and viruses†[:] {Insert directions for 1X dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)} [in washing machine]. Immerse laundry for [at least] 15 minutes prior to starting the wash cycle. [Light soils do not require precleaning.]

**HARD NON-POROUS [SURFACES]**

[To] Sanitize [Hard Surfaces]:
[1] {Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 5 minutes.
[3] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop]. [Pre-clean heavily soiled surfaces.]

[To] Disinfect [Hard Surfaces]: [1] Pre-clean surface.
[2] {Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [3] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 10 [minutes] [min.] for bacteria and 5 [minutes] [min.] for viruses†.
[4] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop].

[To] Prevent Mold [and Mildew]:

[1] {Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet.
[3] Air dry. Repeat [application] every 7 days [to inhibit] [mold] [and mildew] [growth].

**SOFT SURFACES [AND] [&] [FABRICS]**
[To] [Spot] Sanitize [Soft Surfaces]:
[1] {Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] Saturate [fabric] surface until it is thoroughly wet. Let stand 5 minutes.
[3] [Blot] [stained] [area] [gently] with a [white] [dye-free] [cloth] [or sponge]. [Pre-clean heavily soiled surfaces.] [Blot dry with cloth.]

[To] Prevent Mold [and Mildew] [growth] [on Fabric]:
[1] {Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] [Saturate] [Mop, spray, wipe or sponge on] [fabric] surface until thoroughly wet.
[3] Air dry. [Pre-clean heavily soiled surfaces.] Repeat [application] every 28 days [to inhibit] [mold] [and mildew] [growth]. [Effective against Aspergillus [A.] niger [(black mold)] [mildew] and Penicillium [P.] variable.

## III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard, Non-porous Surfaces in Hospital or Medical Environments:
The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (UDM) (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). Sixty carriers must be tested against each of the three batches of the product at lower certified limit(s) (LCL) of the active ingredient(s) against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). For UDM, a mean log density of at least 6.0 (corresponding to a geometric mean density of $1.0 \times 10^6$) and not above 7.0 (corresponding to a geometric mean density of $1.0 \times 10^7$) for both organisms is required. A mean log density <6.0 or >7.0 invalidates the test. For AOAC Germicidal Spray Products Test, a mean log density of at least 5.0 (corresponding to a geometric mean density of $1.0 \times 10^5$) and not above 6.5 (corresponding to a geometric mean density of $3.2 \times 10^6$) for both organisms is required. A mean log density <5.0 or >6.5 invalidates the test. To support products labeled as "disinfectants", killing on 59 out of 60 carriers for germicidal spray testing is required. For AOAC Use-Dilution testing (UDM), conduct three independent tests (i.e., three batches at the LCL tested on three different test days) against the test microbe. The performance standard for *S. aureus* is 0-3 positive carriers out of sixty. The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty. Thus, a total of three tests for *S. aureus* and three tests for *P. aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture media. Contamination of only one carrier (culture tube) is allowed per 60-carrier set; occurrence of more than one contaminated carrier invalidates the test results for both UDM and GST methods. To be deemed an effective product, the product must pass all tests for both microbes. All products should meet the performance standard associated with the method and microbe at ≤ 10 minutes of contact.

Disinfectants for Use on Hard Surface Environments (Additional Microorganisms):
Effectiveness of disinfectants against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. This section addresses efficacy testing for limited, broad-spectrum or hospital disinfectants which bear label claims against bacteria other than *S. enterica* (ATCC10708), *S. aureus* (ATCC 6538) or *P. aeruginosa* (ATCC 15442). The effectiveness of disinfectant against specific bacteria must be determined by AOAC Use-Dilution Method (UDM).

Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. The product should kill all the test microorganisms on all carriers in ≤ten minutes. The minimum carrier count to make the test valid should be 1 x $10^4$ CFU/carrier. For a valid test, no contamination of any carrier is allowed.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least $10^4$ from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Sanitizer Test (for inanimate, non-food contact surfaces):
The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The Agency recommends the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) (Ref. 1). The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. For hard, porous surface label claims use unglazed ceramic tile. For hard, nonporous surface label claims use stainless steel carrier or glass slide. Use 5 test carriers and 3 control carriers. Tests should be performed with each of 3 product samples, representing 3 different product lots, tested at LCL against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least 7.5 x $10^5$ colony forming units per carrier. The performance measure should demonstrate a reduction of ≥99.9% (a 3-log10 reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

Sanitizers (For Non-Food Contact Surfaces; Additional Bacteria):
Effectiveness of sanitizers for non-food contact surfaces against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. In these cases, confirmatory test standards would apply. The effectiveness of sanitizers for non-food contact surfaces against specific bacteria must be determined by the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153). Two product samples, representing 2 different product lots, should be tested against each additional microorganism. Use 5 test carriers and 3 control carriers. The ASTM method states that the inoculum employed should provide a count of at least 7.5 x $10^5$ colony forming units per carrier. The performance measure should demonstrate a reduction of ≥99.9% (a 3-$\log_{10}$ reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

Spot Soft Surface Sanitization:

The study is designed to evaluate the antimicrobial efficacy of sanitizers on pre-cleaned or lightly soiled, non-food contact soft surfaces. For sanitizer products intended for use on soft, non-food contact surfaces, a fabric carrier method is used to generate efficacy data. The test system proposed is a modification of the ASTM approved method for the evaluation of the antimicrobial efficacy of sanitizers on non-food contact surfaces. The method is modified for spray product application. The Agency recommends the use of The American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153-03). Three product samples, representing three different batches, at the LCL should be tested against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). The ASTM method states "an average of at least $7.5 \times 10^5$ organisms must have survived the inoculated control squares for the test to be valid." Two different fabric types should be tested. The fabrics should represent natural fabrics, such as cotton, and synthetic fabrics, such as polyester or rayon. A film of bacterial cells, dried on fabric carriers, is exposed to the test substance for a specified contact time. After exposure, the carriers are transferred to vessel containing neutralizing subculture media and assayed for survivors. Appropriate viability and sterility of organism population and neutralization controls are performed. Carrier type claimed on the label must be consistent with the test system. The test material meets effectiveness requirements of kill an average of at least 99.9% (3 log reduction) of the required organism on the 5 replicate carriers within 5 minutes. Controls must always meet the stipulated criteria.

Hard Surface Mildew Fungistatic Test:
This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 days of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth.

Fabric Mildew Fungistatic Test Method: The test is to be conducted on cotton muslin strips cut 25 by 75 mm from 136 to 203 $g/m^2$ (4 to 6 $oz./yd.^2$) fabric. The strips should be autoclaved sterilized. The product is to be tested against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Soak fabric strips in Nutrient broth for three minutes or until saturated. Remove excess liquid and allow fabric strips to dry before proceeding with application of the test product. Both sides of ten strips for each batch should be spray treated with product. The application specifications including spray distance from nozzle, degree of wetness, draining conditions, and drying procedures should be reported. Equal volumes of well-agitated conidial suspensions of *Aspergillus niger* and *Penicillium variable* using a DeVilbiss atomizer (or equivalent) should be sprayed on both sides of each fabric strip. The fabric samples are suspended in individual 500 mL jars containing 90 mL water and incubated at approximately 28°C with the caps tightened and backed off 1/8 turn to allow for ventilation. Observations are made weekly for four weeks or until treatments fail and abundant growth occurs on all treated strips (at 7, 14, or 21 days). Where no growth is visually evident at the end of the test period, examination at approximately 15X magnification must be conducted to confirm the absence or establish the presence of subvisual growth. The untreated control strips (10 strips) must have a minimum of 50% of their surface area covered with fungal growth after 7 days to consider the test valid. The acceptance criterion requires that all ten treated replicates per batch must be free of fungal growth. The directions for use must specify retreatment every 7, 14, or 21 days, as necessary depending on the length of time that all of the test strips remain free of mildew growth. Labeling of products which do not permit growth after four weeks incubation must specify a retreatment schedule, such as "repeat as

necessary when new growth appears", and should indicate that treatments should be effective for at least 28 days.

Laundry Disinfectant – Pre-Soak Treatment for Use in Hospital or Medical Environments:
The effectiveness of disinfectants as pre-soak treatment for use on soiled fabrics by total immersion in the use solution prior to routine laundry operations in hospital or medical environments must be substantiated by data derived using the AOAC International Use-Dilution Method (Ref.1) (for water soluble powders and liquid products) modified to include 5% organic soil. Sixty carriers must be tested against each of the three batches of the product at the lower certified limit(s) (LCL) of the active ingredient(s) against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). A mean log density of at least 6.0 (corresponding to a geometric mean density of $1.0 \times 10^6$) and not above 7.0 (corresponding to a geometric mean density of $1.0 \times 10^7$) for both organisms is required. A mean log density <6.0 or >7.0 invalidates the test. To support products labeled as "disinfectants", conduct three independent tests (i.e., three batches at the LCL tested on three different test days) against the test microbes. The performance standard for both organisms is 0-1 positive carrier out of sixty. Sixty carriers are required per test, without contamination in the subculture media. Contamination of only one carrier (culture tube) is allowed per 60-carrier set; occurrence of more than one contaminated carrier invalidates the test results. To be deemed an effective product, the product must pass all tests for both microbes. All products should meet the performance standard associated with the method and microbe at ≤ 10 minutes of contact. For additional microorganisms other than those named as the designated test microorganism(s), refer to Disinfectants for Use on Hard Surface Environments (Additional Microorganisms) section above (test with 5% organic soil).

Laundry Sanitizing– Pre-Soak Treatment:
The effectiveness of sanitizers as pre-soak treatment for use on soiled fabrics by total immersion in the use solution prior to routine laundry operations must be substantiated by data derived using the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) modified to include 5% organic soil. Three product samples, representing three different batches, tested at the lower certified limit(s) of the active ingredient(s), should be tested against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (*K. pneumoniae*) (ATCC 4352). *Enterobacter aerogenes* (ATCC 13048) may be substituted for *K. pneumoniae*. Unglazed ceramic tile should be used for the test carrier. Five (5) test carriers and 3 control carriers should be used for each test. According to the ASTM method, "an average of at least $7.5 \times 10^5$ organisms must have survived the inoculated control squares for the test to be valid." The performance standard should demonstrate a reduction of ≥99.9 percent (a 3-$\log_{10}$ reduction) in the number of each test microorganism over the parallel control count in ≤5 minutes. To be deemed an effective product, the product must pass all tests for the indicated microbes. For additional microorganisms other than those named as the designated test microorganism(s), refer to Sanitizers (For Non-Food Contact Surfaces; Additional Bacteria) section above (test with 5% organic soil).

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

## IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY

The active ingredients' concentrations of **Batch No. 4562-132** were reported to be 3.99% TAED and 17.69% Sodium percarbonate, **Batch No. 4562-143** were reported to be 3.91% TAED and 17.29% Sodium percarbonate, **Batch No. 4699-40** were reported to be 3.97% TAED and 17.41% Sodium percarbonate, and **Batch No. 4779-9** were 4.00% TAED and 17.48% Sodium percarbonate. The product's Tetraacetylethylenediamine (TAED) and Sodium percarbonate nominal concentrations are 4.44% and 18.5%, respectively, and the Lower Certified Limits of the product are 4.00% and 17.58%, respectively.

1. **MRID 49795317 "AOAC Use-Dilution Method," Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *and Staphylococcus aureus* (ATCC 6538) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 27, 2016. Project Identification No. A19644.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *and Staphylococcus aureus* (ATCC 6538). Four batches (Batch# 4562-132, Batch# 4562-143, Batch# 4699-40, and Batch# 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.1 (copy provided). The test substances were diluted on different test dates using a dilution of 62.4g/L, defined as 1 pre-weighed packet of test substance plus 1 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 20 minutes. Batch# 4562-132 was tested on 11/18/15, Batch# 4562-143 was tested on 11/18/15 and 01/06/16, and Batch# 4699-40 was tested on 11/23/15. Additional testing using a higher concentration of active was performed on Batch# 4779-9 on 12/21/15. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 19.0-20.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A 10 µL aliquot of a thawed, vortex mixed cryovial of stock organism broth culture was transferred to an initial 10 mL tube of growth medium (Synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, without vortex mixing the *Pseudomonas* culture, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48- 54 hours at 35-37°C. On the day of use, the pellicle was carefully aspirated from the *Pseudomonas aeruginosa* culture by vacuum aspiration. Care was taken to avoid disrupting the pellicle and any visible pellicle on the bottom of the tube was not harvested. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The Pseudomonas culture was visually inspected to ensure no pellicle fragments were present. The *Salmonella enterica* culture was diluted by combining 4.0 mL of test organism suspension with 68.0 mL of sterile growth medium. The *Staphylococcus aureus* culture was diluted by combining 35.0 mL of test organism suspension with 35.0 mL of sterile growth medium. All three test cultures were diluted with synthetic broth. The culture did not include a 5% organic soil load. Sixty (60) stainless steel penicylinders per product lot were inoculated with the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 36.6-36.7°C and at 50.1-53.3% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 9.5 minutes at 19.0-20.5°C. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1%

Sodium Thiosulfate [on test dates 11/18/15, 11/19/15, 11/23/15, and 01/06/16]; Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Sodium Thiosulfate [on test date 12/21/15]). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. On 11/21/15, 11/25/15 and 12/23/15, representative test and positive control subculture tubes showing growth were subcultured to Tryptic Soy Agar + 5% Sheep's blood and incubated at 35-37°C for 1-2 days. The cultures from 11/25/15 were refrigerated at 2-8°C for 3 days. The resultant growth was visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier for *Pseudomonas aeruginosa* (ATCC 15442) is 6.79 $\log_{10}$, for *Salmonella enterica* (ATCC 10708) was 5.84 $\log_{10}$, and for Staphylococcus aureus (ATCC 6538) was 6.53 $\log_{10}$.

Note
Amendment I: The lot numbers were to be amended from Lot 4562-132 (62.4gm dose). Lot 4562-143 (62.4gm dose) and Lot 4562-144 (62.4gm dose) to Lot 4562-132, Lot 4562-143, and Lot 4699-40. The following sentence was to be added to the protocol modification section: Each lot was supplied in a 53.4gm dose.
Amendment II: Additional testing on lot 4779-9, with a higher active concentration closer to the lower certified limits specified on the Confidential Statement of Formula, was to be added to this protocol. Lot 4779-9 was tested for *Staphylococcus aureus* (ATCC 6538) only. All other testing parameters documented in the protocol was to be followed.

There were no protocol deviations.

The assay was set up to be run on 3 separate test dates; 11/18/15, 11/19/15, and 11/23/15. Per Sponsor request, additional testing of *Staphylococcus aureus* with a lot containing a higher active concentration was added to the protocol (see Amendment 2) and tested on 12/14/15. The test from 12/14/15 was invalid because the neutralization confirmation control results did not meet validity criteria. The invalid data from 12/14/15 can be found in Attachment I. The invalid portion of the assay was repeated on 12/21/15. That data is valid and is contained in the body of this report. On 11/19/15, the *Salmonella enterica* portion of the assay was invalid due to the carrier population control being under the minimum requirement. This portion of the assay was repeated on 01/06/15. The invalid data from 11/19/15 can be found in Attachment II. The data from 01/06/15 is considered valid and is contained in the body of this report.

2. **MRID 49795318 "AOAC Use-Dilution Method," Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19755.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Batch# 4562-132 and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.2 (copy provided). The test substances were diluted using a dilution of 62.4g/L, defined as 1 pre-weighed packet of test substance plus 1 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 20 minutes. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 19.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium (synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium

(daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted using sterile growth medium by combining 15.0 mL of test organism suspension with 15.0 mL of sterile growth medium. The culture did not include a 5% organic soil load. Ten (10) stainless steel penicylinders per product lot were inoculated with the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 36.7°C and at 52.9 % relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 9.5 minutes at 19.5°C. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier *Escherichia coli* 0157:H7 (ATCC 43888) was 6.45 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

3. **MRID 49795319 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: 2009-H1N1 Influenza A virus (Novel H1N1) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19752.**

This study was conducted against 2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009 CDC #2009712192. The strain was obtained from the Center for Disease and Control and Prevention (CDC), Atlanta GA. One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. The MDCK (canine kidney) cell line, which exhibits cytopathic effect (CPE) in the presence of 2009-H1N1 Influenza A virus (Novel H1N1), was obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-34) and was used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.FLUA.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 21.0°C in a relative humidity of 35.2% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the

mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 25mM Hepes, 0.2% BSA Fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, and 2µg/mL TPCK-Trypsin. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for 2009-H1N1 Influenza A virus was 5.75 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

4. **MRID 49795320 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Herpes simplex virus type 1 for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19753.**

This study was conducted against Herpes simplex virus type 1, ATCC VR-733, Strain F(1). The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-733). One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. The Vero cells were obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-81) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRG85090815.HSV1.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (22.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone.

The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Herpes simplex virus type 1, ATCC VR-733, Strain F(1) was 4.50 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

5. **MRID 49795321 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Rotavirus for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19771.**

This study was conducted against Rotavirus, ATCC VR-2018, Strain WA. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-2018). One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. Cultures of MA-104 (Rhesus monkey kidney) cells were obtained from American Type Culture Collection, Manassas, VA (ATCC CRL-2378.1) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.ROT.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B, 0.5 µg/mL Trypsin, and 2.0mM L-glutamine. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The inoculum was allowed to adsorb for 60 minutes at 36-38°C in a humidified atmosphere of 5-7% CO2. Following the adsorption period, a 1.0 mL aliquot of the test medium was added to each well of the cell cultures, and the cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus

control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Rotavirus, ATCC VR-2018, Strain WA was 5.00 $log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

6. **MRID 49795322 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Rhinovirus type 39, for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19772.**

This study was conducted against Rhinovirus type 39, ATCC VR-340, Strain 209. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-340). One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. Cultures of WI-38 (human lung) cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-75) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.R39.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 15.5°C in a relative humidity of 55% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was 10% Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Rhinovirus type 39, ATCC VR-340, Strain 209 was 5.00 $log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

The test was originally run on 12/10/15. The dried virus control (DVC) did not achieve 4.0 log growth, as required for a valid study. The assay was re-run on 01/04/16. The assay from 01/04/16 was valid and is included in the body of this report. Invalid data from 12/10/15 can be found in Attachment I.

7. **MRID 49795323 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Human Immunodeficiency virus type 1, for Capricorn, EPA Reg. No. 10772-EG, by Shanen Conway, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016. Project Identification No. A19736.**

This study was conducted against Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$. Five (5) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. The strain was obtained from Advanced Biotechnologies, Inc., Columbia, MD. MT-2 cells (human T-cell leukemia cells) were obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH from Dr. Douglas Richman and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.HIV.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 28.2% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (20.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was RPMI-1640 supplemented with 15% (v/v) heat-inactivated fetal bovine serum (FBS), 2.0 mM L-glutamine and 50 µg/mL gentamicin. Cells in multiwell culture dishes were inoculated in quadruplicate with 200µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/200µL) obtained for Human Immunodeficiency virus type 1 was 5.50 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

8. **MRID 49795324 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab**

**Services. Study completion date – January 11, 2016. Project Identification No. A19683.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (Nos. 4562-132, 4562-143, and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The *Staphylococcus aureus* culture was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. The *Klebsiella pneumoniae* culture was centrifuge concentrated at 3700 RPM for 15 minutes. A total of 21.0 mL of culture was concentrated to 3.00mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile glass 1" x 1" carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 20 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 29% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. On 12/3/15, representative test and positive control subcultures showing growth were visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Staphylococcus aureus* (ATCC 6538) was 1.26 x $10^6$ CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 4.07 x $10^6$ CFU/carrier.

Note
Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4562-144 to Lot 4699-40.

No protocol deviations occurred during this study.

9. **MRID 49795325 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888), for Capricorn, EPA Reg. No. 10772-EG, by Jamie Herzan, B.S.**

**Study conducted at Accuratus Lab Services. Study completion date – January 08, 2016. Project Identification No. A19767.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Nos. 4562-132, and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.2 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The culture was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile glass 1" x 1" carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 21 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 31% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±2 hours. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Escherichia coli* 0157:H7 (ATCC 43888) was 2.04 x $10^5$ CFU/carrier.\

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

10. **MRID 49795326 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 12, 2016. Project Identification No. A19691.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (Nos. 4562-132, 4562-143, and 4699-40) of the product,

Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090915.NFS.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The *Klebsiella pneumoniae* culture was centrifuge concentrated at 3700 RPM for 15 minutes. A total of 25.0 mL of culture was concentrated to 5.00mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Two types of carriers (100% cotton weave fabric and 100% polyester fabric) were prepared and rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Sterile carriers were inoculated with 0.03 mL (30.0 µL) of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated cotton carriers were dried for 20-21 minutes at 35-37°C (35.9-36.1°C) and 40-41% relative humidity with the Petri dish lids intact. The inoculated polyester carriers were dried for 24-26 minutes at 35-37°C (35.9-36°C) and 40% relative humidity with the Petri dish lids intact. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 25-37% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Glass beads were utilized to aid in organism recovery from the modified fabric substrate for testing against *S. aureus*. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. On 12/10/15, representative test and positive control subcultures showing growth were visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control on cotton weave for *Staphylococcus aureus* (ATCC 6538) was 1.20 x $10^6$ CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 3.09 x $10^7$ CFU/carrier. The reported average carrier population control on polyester for *Staphylococcus aureus* (ATCC 6538) was 1.91 x $10^6$ CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 2.82 x $10^7$ CFU/carrier.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

Testing on November 30, 2015 resulted in a carrier population control failure for *Staphylococcus aureus* on 100% plain cotton weave and 100% polyester fabric carriers. Testing of *Staphylococcus aureus* from November 30, 2015 is therefore considered invalid and presented in Attachment I. The neutralization confirmation controls for *Staphylococcus aureus* and the testing for *Klebsiella pneumoniae* performed on November 30, 2015 are considered valid and presented in the body of the report. Testing of Capricorn, Lot 4562-132, Lot 4562-143 and Lot 4699-40 against *Staphylococcus aureus* on 100% plain cotton weave and 100% polyester fabric carriers was repeated on December 8, 2015. Data from this test date is considered valid and presented in the body of the report.

**11. MRID 49795327 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19902.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Nos. 4562-132 and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85112415.NFS.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Two types of carriers (100% cotton weave fabric and 100% polyester fabric) were prepared and rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Sterile carriers were inoculated with 0.03 mL (30.0 µL) of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated carriers were dried for 30 minutes at 35-37°C (36°C) and 40% relative humidity with the Petri dish lids intact. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 16% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Glass beads were utilized to aid in organism recovery from the modified fabric substrate. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. The subcultures were placed at 2-8°C for 2 days prior to examination. Following

incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control on cotton weave for *Escherichia coli* 0157:H7 (ATCC 43888) was 1.74 x $10^5$ CFU/carrier and the reported average carrier population control on polyester for the microorganism was 1.48 x $10^7$ CFU/carrier.

Note
Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4699-40 to Lot 4779-9.

No protocol deviations occurred during this study.

**12. MRID 49795328 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces", Test Organisms: *Salmonella enterica* (ATCC 10708), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 26, 2016. Project Identification No. A19900.**

This study was conducted against *Salmonella enterica* (ATCC 10708). Two batches (Nos. 4562-132 and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85112415.NFS.3 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The culture was centrifuge concentrated at 3510 RPM for 10 minutes. A total of 18.0mL of culture was concentrated to 3.6mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Two types of carriers (100% cotton weave fabric and 100% polyester fabric) were prepared and rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Sterile carriers were inoculated with 0.03 mL (30.0 µL) of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated carriers were dried for 30 minutes at 35-37°C (36.5°C) and 41% relative humidity with the Petri dish lids intact. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (19°C) and 15% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Glass beads were utilized to aid in organism recovery from the modified fabric substrate. Within 30

minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control on cotton weave for *Salmonella enterica* (ATCC 10708) was 1.86 x $10^6$ CFU/carrier and the reported average carrier population control on polyester for the microorganism was 1.10 x $10^7$ CFU/carrier.

Note
Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4699-40 to Lot 4779-9.

No protocol deviations occurred during this study.

**13. MRID 49795329 "EPA Hard Surface Mildew-Fungistatic Test", Test Organisms: *Aspergillus niger* (ATCC 6275), for Capricorn, EPA Reg. No. 10772-EG, by Jamie Herzan, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016. Project Identification No. A19759.**

This study was conducted against *Aspergillus niger* (ATCC 6275). Two batches (Nos. 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090915.MSTAT (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The solution was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The conidial suspension was prepared by inoculating a flask of Sabouraud Agar (Modified) (aka neopeptone agar) and incubating for 7 days at 25-30°C. Following incubation, sterile saline/Triton Solution (0.85% saline + 0.05 Triton X-100) and sterile glass beads were added to the flask. The flask was agitated to remove mycelia/conidia from the agar. The conidia suspension was aspirated from the flask and passed through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The viable cell count was 1.2 x $10^8$ CFU/mL. The suspension was added to a sterile tissue grinder and macerated to break up spore chains at the time of harvesting. The macerated conidial suspension was standardized to contain an approximate target of 5 x $10^6$ conidia per mL by combining 1.00mL of unadjusted culture to 19.0mL of sterile 0.85% Saline. A 1.0mL aliquot of this suspension was added to 20.0mL of sterile Czapek's solution. A 1.00mL aliquot of FBS was added to 19.0mL of prepared Czapek/organism suspension to yield a 5% Fetal Bovine Serum organic soil load. One inch by one inch glazed ceramic tiles were sterilized for ≥2 hours at ≥180°C in a hot air oven and were used as carriers. For each lot of the prepared test substance, the surfaces of 10 carriers were treated by immersing the carriers in the test substance until completely covered. The carriers were removed from the test substance and were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried in Petri dishes at 35-37°C for 12 minutes with the lids ajar. Untreated carriers were placed in sterile Petri dishes (10 carriers total) and dried for 12 minutes at 35-37°C with the lids ajar alongside the test carriers. Following the initial drying period, an atomizer was used to spray the surface of each test carrier and control carrier with the *Aspergillus niger* conidia-Czapek suspension. Approximately 2 sprays were used to apply the test organism. The atomizer was periodically mixed to agitate the culture during inoculation. Carriers contained in Petri dishes were returned to a 35-37°C incubator and dried with the lids slightly ajar for 18 minutes until visibly dry. Each carrier (sprayed side up) was placed onto an individual water agar plate. All plates were incubated for 7 days at 25-30°C in a minimum of 95% relative humidity. The purity control was incubated for 44-76 hours at 25-30°C. All test and control carriers were examined after 7 days of incubation. The absence of fungal growth on all carriers is the criterion for determining the

effectiveness of the test product. No visual growth was evident at the end of the 7 days on test carriers therefore a magnified examination was performed. To be considered a valid test, each untreated control carrier must be at least 50% covered with fungal growth after the 7 days. Controls included sterility, purity, and untreated control carriers. The visual evaluation of control carriers was reported as passing.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**14. MRID 49795330 "Fabric Mildew-Fungistatic Test", Test Organisms: *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333), for Capricorn, EPA Reg. No. 10772-EG, by Matthew Sathe, B.S. Study conducted at Accuratus Lab Services. Study completion date – February 5, 2016. Project Identification No. A19758.**

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333). Two batches (Nos. 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.FMSTAT (copy provided). The test substance was prepared by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The solution was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The *Aspergillus niger* conidial suspension was prepared by inoculating a flask of Sabouraud Agar (Modified) (aka neopeptone agar) and incubating for 7 days at 25-30°C. Following incubation, sterile saline/Triton Solution (0.85% saline + 0.05 Triton X-100) and sterile glass beads were added to the flask. The flask was agitated to remove mycelia/conidia from the agar. The conidia suspension was aspirated from the flask and passed through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The viable cell count was 1.2 x $10^8$ CFU/mL. The conidial suspension was standardized to contain an approximate target of 5 x $10^6$ conidia per mL by combining 1.00mL of unadjusted culture to 19.0mL of sterile 0.85% Saline. The *Penicillium variable* conidial suspension was prepared by inoculating 30 Sabouraud Dextrose agar plates (also known as Emmons agar) and incubating at 25-30°C for 11 days (see Protocol Deviation). Following incubation, 3.0 mL of sterile saline/Triton Solution (0.85% Saline + 0.05 % Triton X-100) was added to each plate harvested. The growth was harvested from the agar surface using a cell scrape. The harvested growth was transferred to a sterile vessel containing sterile beads and was swirled thoroughly. The culture was then filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The conidial count was 9.8 x $10^8$ CFU/mL. The conidial suspension was standardized to contain an approximate target of 5 x $10^6$ condia per mL by combining 1.00 mL of unadjusted culture with 49.0 mL of 0.85% saline. Fabric carriers were cut as approximately 25mm by 75mm strips from 136 to 203g/$m^2$ (4 to 6 oz/$yd^2$) cotton muslin and were autoclave. The sterilized fabric carriers were saturated with sterile glycerol nutrient solution by soaking the carriers for approximately three minutes until saturated. The excess liquid was squeezed out and the fabric carriers were allowed to dry prior to use as carriers. For each lot of the prepared test substance, 10 test carriers were treated by dipping the carriers in the test substance. The carriers were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried in Petri dishes at room temperature (23.3°C) for 37 minutes until dry. Equal volumes (10.0mL) of each well-mixed conidial suspension were combined within a DeVilbiss atomizer. One mL was removed and a 1.00 mL aliquot of FBS was added to 19.0 mL of the combined organism suspension to yield a 5% Fetal Bovine Serum soil load. Both sides of each fabric test carrier strip was lightly sprayed using approximately 6 sprays. The culture was mixed periodically within the atomizer during spraying. The fabric test and control samples were suspended in individual 250 mL French Square bottles containing approximately 10 mL sterile deionized water and incubated at 25-30°C. The caps were tightened and then backed off

approximately 1/8 turn to allow for ventilation. It was ensured that no fabric was touching the water at the time of incubation. The control plates and organic soil load sterility control were incubated for 3 days at 25-30°C. These subcultures were refrigerated for 2 days at 2-8°C prior to examination. Observations were made and recorded every 7 days for four weeks. The presence or absence of observable mold on the test carriers was the criterion for determining the effectiveness of the test product. Where no growth was visually evident at each weekly observation, a magnified examination was conducted to confirm the absence or establish the presence of sub-visual growth. Controls included sterility, purity, initial suspension, and untreated control carrier. The visual evaluation of control carriers was reported as passing. To be considered a valid control, each untreated control carrier must be covered with at least 50% of fungal growth over the total surface area after 7 days of incubation.

Note
*250 mL French square bottles containing 10 mL of deionized water were used to incubate the samples in this study. This is a modification of the method and was performed because of apparatus availability. Despite this modification, samples were incubated in a humid environment as required by the method and can be hooked so that the bottom ends of the attached fabric samples are about 13 mm above the water level as required by the method.*

There were no protocol amendments.

Protocol Deviation:
The protocol states *Penicillium variabile* will be prepared by incubating Sabouraud Dextrose agar plates for 7-10 days. In testing, the *Penicillium variabile* culture was inadvertently incubated for 11 days. Since the culture met the control acceptance criteria outlined in the protocol, this protocol deviation has no impact on the outcome of the study.

**15. MRID 49795331 "AOAC Use-Dilution Method," Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *and Staphylococcus aureus* (ATCC 6538) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016 (Report Amended on January 29, 2016). Project Identification No. A19659.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *and Staphylococcus aureus* (ATCC 6538). Three batches (Batch# 4562-132, Batch# 4562-143, and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.4 (copy provided). The test substances were diluted on different test dates using a dilution of 62.4g/2L, defined as 1 pre-weighed packet of test substance plus 2 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 10 minutes. Batch# 4562-132 was tested on 11/25/15, Batch# 4562-143 was tested on 11/23/15, and Batch# 4699-40 was tested on 11/24/15. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20±1°C (19.5-20.0°C) water bath and allowed to equilibrate for ≥10 minutes prior to testing. A 10 µL aliquot of a thawed, vortex mixed cryovial of stock organism broth culture was transferred to an initial 10 mL tube of growth medium (synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, without vortex mixing the *Pseudomonas* culture, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48- 54 hours at 35-37°C. On the day of use, the pellicle was carefully aspirated from the *Pseudomonas aeruginosa* culture by vacuum aspiration. Care was taken to avoid disrupting the pellicle and any visible pellicle on the bottom of the tube was not harvested. Each test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind

any clumps or debris and was pooled in a sterile vessel and mixed. The Pseudomonas culture was visually inspected to ensure no pellicle fragments were present. The *Salmonella enterica* culture was diluted by combining 4.0 mL of test organism suspension with 68.0 mL of sterile growth medium. The *Staphylococcus aureus* culture was diluted by combining 35.0 mL of test organism suspension with 35.0 mL of sterile growth medium. A 3.5 mL aliquot of FBS was added to 66.5 ml of each prepared culture to yield a 5% fetal bovine serum organic soil load. Sixty (60) stainless steel penicylinders per product lot were immersed for in the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 35-37°C (36.0-36.7°C) and at 50.6-52.5% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 14.5 minutes at 19.5-20.0°C. The carrier was placed into the test substance within ±5 seconds of the exposure time following a calibrated timer. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. On 11/25/15, 11/26/15, and 11/27/15, representative test and positive control subculture tubes showing growth were subcultured to Tryptic Soy Agar + 5% Sheep's blood and incubated at 35-37'°C for 1-2 days. The resultant growth was visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier for *Pseudomonas aeruginosa* (ATCC 15442) is 7.09 $\log_{10}$, for *Salmonella enterica* (ATCC 10708) is 6.07 $\log_{10}$, and for *Staphylococcus aureus* (ATCC 6538) was 6.49 $\log_{10}$.

Note

Protocol Amendments:

Amendment 1: Per Sponsor request, the exposure time will be changed from 15 minutes to 14.5 minutes.

Amendment 2: Per Sponsor request, the following reference will be added to the protocol; U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2400: Disinfectants and Sanitizers for Use on Fabrics and Textiles- Efficacy Data Recommendations, December 21, 2012.

Amendment 3: Per Sponsor request, the lot numbers will be amended from Lot 4562-132 (62.4gm dose). Lot 4562-143 (62.4gm dose) and Lot 4562-144 (62.4gm dose) to Lot 4562-132, Lot 4562- 143, and Lot 4699-40. Per Sponsor request, the following sentence will be added to the protocol modification section: Each lot was supplied in a 62.4gm dose.

Protocol Deviation:

Testing for Capricorn (Lot# 4562-132) originally ran on 11/19/15 was repeated on 11/25/15 due to inadvertently diluting the test substance incorrectly. This deviation has no impact on the overall Intent and purpose of the study.

Testing for Capricorn (Lot# 4562-132) originally ran on 11/19/15 was repeated on 11/25/15 due to inadvertently diluting the test substance incorrectly (see protocol deviation). Data from 11/25/15 is valid and is presented in the report. See Attachment I for invalid data from 11/19/15.

16. **MRID 49795332 "AOAC Use-Dilution Method," Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016 (Report Amended on January 29, 2016). Project Identification No. A19757.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Batch# 4562-132 and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.5 (copy provided). The test substances were diluted using a dilution of 62.4g/2L, defined as 1 pre-weighed packet of test substance plus 2 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 10 minutes. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium (synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted by combining 15.0 mL of test organism suspension with 15.0 mL of sterile growth medium. A 1.5 mL aliquot of FBS was added to 28.5 ml of each prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) stainless steel penicylinders per product lot were immersed in the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 35-37°C (36.7°C) and at 50.2% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 15 minutes at 20.5°C. The carrier was placed into the test substance within ±5 seconds of the exposure time following a calibrated timer. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier *Escherichia coli* 0157:H7 (ATCC 43888) was 6.58 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

17. **MRID 49795333 "AOAC Use-Dilution Method," Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016 (Report Amended on January 29, 2016). Project Identification No. A19756.**

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two batches (Batch# 4562-132 and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab

Services Protocol No. SRC85090815.UD.6 (copy provided). The test substances were diluted using a dilution of 62.4g/2L, defined as 1 pre-weighed packet of test substance plus 2 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 10 minutes. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium (Nutrient broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. A 1.5 mL aliquot of FBS was added to 28.5 ml of each prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) stainless steel penicylinders per product lot were immersed in the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 35-37°C (36.6-36.7°C) and at 52.1% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 15 minutes at 20.0°C. The carrier was placed into the test substance within ±5 seconds of the exposure time following a calibrated timer. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier *Klebsiella pneumoniae* (ATCC 4352) was 7.07 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**18. MRID 49795334 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: 2009-H1N1 Influenza A virus (Novel H1N1) for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – December 31, 2015. Project Identification No. A19760.**

This study was conducted against 2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009 CDC #2009712192. The strain was obtained from the Center for Disease and Control and Prevention (CDC), Atlanta GA. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The MDCK (canine kidney) cell line, which exhibits cytopathic effect (CPE) in the presence of 2009-H1N1 Influenza A virus (Novel H1N1), was obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-34) and was used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.FLUA.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test

substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 26.6% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (20.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures ($10^{-1}$ dilution). To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 2.5 µg/mL TTPCK-trypsin, 25mM Hepes, 0.2% BSA Fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for 2009-H1N1 Influenza A virus was 5.25 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

19. **MRID 49795335 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Herpes simplex virus type 1 for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19761.**

This study was conducted against Herpes simplex virus type 1, ATCC VR-733, Strain F(1). The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-733). The stock virus culture contained 5% fetal bovine serum as the organic soil load. The Vero cells were obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-81) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.HSV1.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 51% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed

through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Herpes simplex virus type 1, ATCC VR-733, Strain F(1) was 5.25 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

The initial assay performed on December 9, 2015, was repeated on January 4, 2016, to recover at least 4 $\log_{10}$ of infectivity from the dried virus control as required for a valid test. See Attachment I for the invalid data. Valid results were obtained from the assay performed on January 4, 2016, and may be found in the body of this report.

**20. MRID 49795336 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Rotavirus for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – December 31 2015. Project Identification No. A19770.**

This study was conducted against Rotavirus, ATCC VR-2018, Strain WA. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-2018). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Cultures of MA-104 (Rhesus monkey kidney) cells were obtained from American Type Culture Collection, Manassas, VA (ATCC CRL-2378.1) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.ROT.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (22.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and

assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B, 0.5 µg/mL Trypsin, and 2.0mM L-glutamine. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The inoculum was allowed to adsorb for 60 minutes at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. Following the adsorption period, a 1.0 mL aliquot of the test medium was added to each well of the cell cultures, and the cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Rotavirus, ATCC VR-2018, Strain WA was 5.75 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**21. MRID 49795337 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Rhinovirus type 39, for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19769.**

This study was conducted against Rhinovirus type 39, ATCC VR-340, Strain 209. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-340). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Cultures of WI-38 (human lung) cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-75) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.R39.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 15.5°C in a relative humidity of 55% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 31-35°C in a humidified

atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Rhinovirus type 39, ATCC VR-340, Strain 209 was 5.25 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

The initial assay performed on December 10, 2015, was repeated on January 4, 2016, to recover at least 4 $\log_{10}$ of infectivity from the dried virus control as required for a valid test and to demonstrate neutralization in the non-virucidal level control. See Attachment I for the invalid data. Valid results were obtained from the assay performed on January 4, 2016, and may be found in the body of this report.

**22. MRID 49795338 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Human Immunodeficiency virus type 1, for Capricorn, EPA Reg. No. 10772-EG, by Shanen Conway, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016. Project Identification No. A19728.**

This study was conducted against Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$. The stock virus culture contained 5% fetal bovine serum as the organic soil load. The strain was obtained from Advanced Biotechnologies, Inc., Columbia, MD. MT-2 cells (human T-cell leukemia cells) were obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH from Dr. Douglas Richman and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.HIV.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.5°C in a relative humidity of 26.5% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (20.5°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was RPMI-1640 supplemented with 15% (v/v) heat-inactivated fetal bovine serum (FBS), 2.0 mM L-glutamine and 50 µg/mL gentamicin. Cells in multiwell culture dishes were inoculated in quadruplicate with 200µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers

are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/200µL) obtained for Human Immunodeficiency virus type 1 was 5.75 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**23. MRID 49795339 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19679.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Four batches (Nos. 4562-132, 4562-143, 4699-40, and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.5 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium (Nutrient broth). A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. For testing performed on 11/30/15, the *Staphylococcus aureus* culture was diluted by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. For testing on 12/15/15, the *Klebsiella pneumoniae* culture was centrifuge concentrated at 3500 RPM for 15 minutes. A total of 25.0 mL of culture was concentrated to 5.00mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile 1" x 1" unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 20 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 25% relative humidity for 9.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. On 12/2/15, representative test and positive control subcultures showing growth were visually examined. Gram stained and biochemically

assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Staphylococcus aureus* (ATCC 6538) was 1.15 x $10^8$ CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 1.51 x $10^6$ CFU/carrier.

Note

Protocol Amendments:

1.
   a. Per Sponsor's request the protocol is amended to change the exposure time the exposure time from 10 minutes to 9.5 minutes.
   b. Per Sponsor's request the protocol is amended to change Lot 4562-144 to Lot 4699-40.

2. Per Sponsor's request the protocol is amended to change Lot 4562-143 to Lot 4779-9 for repeat testing against Klebsiella pneumoniae (ATCC 4352).

Protocol Deviation:

Per the protocol, the Test Culture Titer (TOT) and the Neutralizer Toxicity Treatment (NTT) are to be completed using 25 mL of sterile diluent/neutralizer. The TOT and NTT controls were completed using 30 mL of sterile diluent/neutralizer to make a direct comparison to the test and the amounts used in testing.

Testing performed on November 30, 2015 resulted in a carrier population control failure for *Klebsiella pneumoniae*. Testing against *Klebsiella pneumoniae* (Lot 4562-132, Lot 4562-143 and Lot 4699-40) from November 30, 2015 is therefore considered invalid and presented in Attachment I. The neutralization confirmation controls for *Klebsiella pneumoniae* performed on November 30, 2015 were deemed acceptable and valid and are presented in the body of the report. Testing of *Klebsiella pneumoniae* was repeated on December 15, 2015 against Capricorn Lot 4562-132, Lot 4699-40 and Lot 4779-9 (see Amendment 2). Neutralization confirmation controls for Lot 4779-9 were also performed on December 15, 2015. All testing performed on December 15, 2015 is considered valid and presented in the body of the report.

**24. MRID 49795340 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19749.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Nos. 4562-132, and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.6 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium (Synthetic broth). A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile 1" x 1" unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture using a

calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 20 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 23% relative humidity for 9.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±2 hours. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Escherichia coli* 0157:H7 (ATCC 43888) was 7.41 x $10^5$ CFU/carrier.

Note
Protocol Amendments:
No protocol amendments were required for this study.

Protocol Deviations:

a. Per the protocol, inoculated carriers are to be dried for 20-40 minutes until visibly dry. The carriers were dried for a full 40 minutes, but were still not visibly dry when used in testing.
b. Per the protocol and protocol modifications, the test substance was to be used within 40 minutes following the mixing of the test substance. The test substance was inadvertently used 13-14 minutes after the expiration time.

Testing performed on December 9, 2015 was completed using carriers that were not visibly dry (see Protocol Deviation). Therefore, data from this test date is invalid and presented in Attachment I. Due to the carriers being wet, testing was repeated in its entirety on December 21, 2015. Data from this test date is valid and presented in the body of this report.

## V. RESULTS

### 1. Hard Non-Porous Surface Bactericidal Disinfectant (62.4g/1L):

| Contact Time | MRID No. | Organism | No. Carriers Exhibiting Growth/Total Carriers | | | | Carrier Population ($Log_{10}$ CFU/Carrier) |
|---|---|---|---|---|---|---|---|
| | | | Batch #4562-132 | Batch #4562-143 | Batch #4699-40 | Batch #4779-9 | |
| 9.5 minutes | 49795318 | *Escherichia coli* 0157:H7 (ATCC 43888) | 0/10 | -- | 0/10 | -- | 6.45 |
| | 49795317 | *Pseudomonas aeruginosa* (ATCC 15442) | 0/60 | 0/60 | 2/60 | -- | 6.79 |
| | | *Salmonella enterica* (ATCC 10708) | 0/60 | 0/60 | 0/60 | -- | 5.84 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | *Staphylococcus aureus* (ATCC 6538) | 0/60 | **7/60** | 0/60 | 2/60 | 6.53 |

## 2. Hard Non-Porous Surface Virucidal Disinfectant (62.4g/1L):

| MRID No. | Contact Time | Organism | Results | | |
|---|---|---|---|---|---|
| | | | | Batch #4562-132 | Batch #4699-40 |
| 49795319 | 4.5 minutes | 2009-H1N1 Influenza A Virus (novel H1N1) + 1% FBS | **Description** | **Rep. 1** | **Rep. 1** |
| | | | $10^{-1}$ to $10^{-6}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |
| | | | $Log_{10}$ Reduction | ≥5.25 | ≥5.25 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.75}$** | |
| 49795320 | | Herpes simplex virus type 1 + 1% FBS | $10^{-1}$ to $10^{-4}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.00 | ≥4.00 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{4.50}$** | |
| 49795321 | | Rotavirus + 1% FBS | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity |
| | | | $10^{-2}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ |
| | | | $Log_{10}$ Reduction | ≥3.50 | ≥3.50 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.00}$** | |
| 49795322 | | Rhinovirus type 39 + 1% FBS | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity |
| | | | $10^{-2}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ |
| | | | $Log_{10}$ Reduction | ≥3.50 | ≥3.50 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.00}$** | |
| 49795323 | | Human Immunodeficiency virus type 1 + 5% FBS | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity |
| | | | $10^{-2}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/200µL | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.00 | ≥4.00 |
| | | | **Dried Virus Control ($TCID_{50}$/200µL)** | **$10^{5.50}$** | |

## 3. Hard Non-Porous Non-Food Contact Surface Sanitizer (62.4g/2L):

| Contact Time | MRID No. | Organism | Results | | | Carrier Population CFU/Carrier (Avg. $Log_{10}$) |
|---|---|---|---|---|---|---|
| | | | Batch# | CFU/Carrier (Average $log_{10}$) | Percent Reduction | |
| 4.5 minutes | 49795324 | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | 4562-132 | $6.17 \times 10^2$ (2.79) | >99.9 | $1.26 \times 10^6$ (6.10) |
| | | | 4562-143 | $6.03 \times 10^2$ (2.78) | >99.9 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | 4699-40 | $5.89 \times 10^2$ (2.77) | >99.9 | |
| | | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS | 4562-132 | $<2.51 \times 10^1$ (<1.40) | >99.9 | $4.07 \times 10^6$ (6.61) |
| | | | 4562-143 | $<2.51 \times 10^1$ (<1.40) | >99.9 | |
| | | | 4699-40 | $<2.51 \times 10^1$ (<1.40) | >99.9 | |
| | 49795325 | *Escherichia coli* 0157:H7 (ATCC 43888) + 5% FBS | 4562-132 | $<2.51 \times 10^1$ (<1.40) | >99.9 | $2.04 \times 10^5$ (5.31) |
| | | | 4699-40 | $<2.51 \times 10^1$ (<1.40) | >99.9 | |

**4. Soft, Non-Food Contact Surface Sanitizer (62.4g/L)**

| Contact Time | MRID No. | Organism | Results | | | | |
|---|---|---|---|---|---|---|---|
| | | | | 100% Plain Cotton Weave | | 100% Polyester | |
| | | | Batch# | CFU/Carrier (Average $\log_{10}$) | Percent Reduction | CFU/Carrier (Average $\log_{10}$) | Percent Reduction |
| 4.5 minutes | 49795326 | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | 4562-132 | $3.98 \times 10^2$ (2.60) | >99.9 | $<3.31 \times 10^2$ (2.52) | >99.9 |
| | | | 4562-143 | $1.66 \times 10^2$ (2.22) | >99.9 | $<8.32 \times 10^1$ (1.92) | >99.9 |
| | | | 4699-40 | $<8.71 \times 10^1$ (<1.94) | >99.9 | $<3.80 \times 10^1$ (<1.58) | >99.9 |
| | | **Carrier Population CFU/Carrier (Avg. $\text{Log}_{10}$)** | | **$1.20 \times 10^6$ (6.08)** | | **$1.91 \times 10^6$ (6.28)** | |
| | | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS | 4562-132 | $<2.51 \times 10^1$ (<1.40) | >99.9 | $<2.51 \times 10^1$ (<1.40) | >99.9 |
| | | | 4562-143 | $<2.51 \times 10^1$ (<1.40) | >99.9 | $<2.51 \times 10^1$ (<1.40) | >99.9 |
| | | | 4699-40 | $<2.51 \times 10^1$ (<1.40) | >99.9 | $<2.51 \times 10^1$ (<1.40) | >99.9 |
| | | **Carrier Population CFU/Carrier (Avg. $\text{Log}_{10}$)** | | **$3.09 \times 10^7$ (7.49)** | | **$2.82 \times 10^7$ (7.45)** | |
| | 49795327 | *Escherichia coli* 0157:H7 (ATCC 43888) + 5% FBS | 4562-132 | $<2.51 \times 10^1$ (<1.40) | >99.9 | $<2.51 \times 10^1$ (<1.40) | >99.9 |
| | | | 4779-9 | $<2.51 \times 10^1$ (<1.40) | >99.9 | $<2.51 \times 10^1$ (<1.40) | >99.9 |
| | | **Carrier Population CFU/Carrier (Avg. $\text{Log}_{10}$)** | | **$1.74 \times 10^5$ (5.24)** | | **$1.48 \times 10^7$ (7.71)** | |
| | 49795328 | *Salmonella enterica* (ATCC 10708) + 5% FBS | 4562-132 | $<2.51 \times 10^1$ (<1.40) | >99.9 | $<2.51 \times 10^1$ (<1.40) | >99.9 |
| | | | 4779-9 | $<2.51 \times 10^1$ (<1.40) | >99.9 | $<2.51 \times 10^1$ (<1.40) | >99.9 |
| | | **Carrier Population CFU/Carrier (Avg. $\text{Log}_{10}$)** | | **$1.86 \times 10^6$ (6.27)** | | **$1.10 \times 10^7$ (7.04)** | |

5. **Hard Surface Mildew-Fungistatic (62.4g/L):**

| Contact Time | MRID No. | Organism | Visual Evaluation | | Magnified Evaluation | | *Untreated Carrier Results (Pass/Fail) |
|---|---|---|---|---|---|---|---|
| | | | Batch #4562-132 | Batch #4699-40 | Batch #4562-132 | Batch #4699-40 | |
| Day 7 | 49795329 | *Aspergillus niger* (ATCC 6275) + 5% FBS | 0% coverage on 10 carriers | 0% coverage on 10 carriers | No growth on 10 carriers | No growth on 10 carriers | Pass on 10 carriers |

*To be considered passing, each control carrier must demonstrate ≥50% coverage at Day 7.

6. **Fabric Mildew-Fungistatic (62.4g/L):**

| MRID No. | Organism | Contact Time | Visual Evaluation | | Magnified Evaluation | | *Untreated Carrier Results (Pass/Fail) |
|---|---|---|---|---|---|---|---|
| | | | Batch #4562-132 | Batch #4699-40 | Batch #4562-132 | Batch #4699-40 | |
| 49795330 | *Aspergillus niger* (ATCC 6275) & *Penicillium variabile* (ATCC 32333) + 5% FBS | Day 7 | 0% coverage on 10 carriers | 0% coverage on 10 carriers | No growth on 10 carriers | No growth on 10 carriers | Pass on 10 carriers |
| | | Day 14 | 0% coverage on 10 carriers | 0% coverage on 10 carriers | No growth on 10 carriers | No growth on 10 carriers | Pass on 10 carriers |
| | | Day 21 | 0% coverage on 10 carriers | 0% coverage on 10 carriers | No growth on 10 carriers | No growth on 10 carriers | Pass on 10 carriers |
| | | Day 28 | 0% coverage on 10 carriers | 0% coverage on 10 carriers | No growth on 10 carriers | No growth on 10 carriers | Pass on 10 carriers |

*To be considered passing, each control carrier must demonstrate ≥50% coverage.

7. **Laundry Presoak Bactericide Disinfectant (62.4g/2L):**

| Contact Time | MRID No. | Organism | No. Carriers Exhibiting Growth/Total Carriers | | | Carrier Population ($Log_{10}$ CFU/Carrier) |
|---|---|---|---|---|---|---|
| | | | Batch #4562-132 | Batch #4562-143 | Batch #4699-40 | |
| 14.5 minutes | 49795331 | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | 2/60 | 3/60 | 1/60 | 6.50 |
| | | *Pseudomonas aeruginosa* (ATCC 15442) + 5% FBS | 0/60 | 0/60 | 0/60 | 7.09 |
| | | *Salmonella enterica* (ATCC 10708) + 5% FBS | 0/60 | 1/60 | 0/60 | 6.07 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 15 minutes | 49795332 | *Escherichia coli* 0157:H7 (ATCC 43888) + 5% FBS | 0/60 | -- | 0/60 | 6.58 |
| | 49795333 | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS | 0/60 | -- | 0/60 | 7.07 |

**8. Laundry Presoak Virucide Disinfectant (62.4g/2L):**

| MRID No. | Contact Time | Organism | Results | | |
|---|---|---|---|---|---|
| | | | | Batch #4562-132 | Batch #4699-40 |
| 49795334 | 14.5 minutes | 2009-H1N1 Influenza A Virus (novel H1N1) + 5% FBS | **Description** | **Rep. 1** | **Rep. 1** |
| | | | $10^{-1}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.75 | ≥4.75 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.25}$** | |
| 49795335 | | Herpes simplex virus type 1 + 5% FBS | $10^{-1}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.75 | ≥4.75 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.25}$** | |
| 49795336 | | Rotavirus + 5% FBS | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity |
| | | | $10^{-2}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.25 | ≥4.25 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.75}$** | |
| 49795337 | | Rhinovirus type 39 + 5% FBS | $10^{-1}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.75 | ≥4.75 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.25}$** | |
| 49795338 | | Human Immunodeficiency virus type 1 + 5% FBS | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity |
| | | | $10^{-2}$ to $10^{-6}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/200µL | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.25 | ≥4.25 |
| | | | **Dried Virus Control ($TCID_{50}$/200µL)** | **$10^{5.75}$** | |

**9. Laundry Presoak Sanitizer (62.4g/2L):**

| Contact Time | MRID No. | Organism | Results | | | Carrier Population CFU/Carrier (Avg. $Log_{10}$) |
|---|---|---|---|---|---|---|
| | | | Batch# | CFU/Carrier (Average $log_{10}$) | Percent Reduction | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 9.5 minutes | 49795339 | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >99.9 | 1.15 x $10^6$ (6.06) |
| | | | 4562-143 | <3.02 x $10^1$ (<1.48) | >99.9 | |
| | | | 4699-40 | <3.47 x $10^1$ (<1.54) | >99.9 | |
| | | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >99.9 | 1.51 x $10^6$ (6.18) |
| | | | 4699-40 | <3.02 x $10^1$ (<1.48) | >99.9 | |
| | | | 4779-9 | <3.02 x $10^1$ (<1.48) | >99.9 | |
| | 49795340 | *Escherichia coli* 0157:H7 (ATCC 43888) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >99.9 | 7.41 x $10^5$ (5.87) |
| | | | 4699-40 | <3.02 x $10^1$ (<1.48) | >99.9 | |

## VI. CONCLUSION

1. The submitted efficacy data **support** the use of the product, Capricorn, as a disinfectant with bactericidal activity against the following microorganisms tested without a 5% organic soil load on hard, non-porous surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness for a 9.5 minute contact time.

   MRID 49795317 *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538)
   MRID 49795318 *Escherichia coli* 0157:H7 (ATCC 43888)

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of the product, Capricorn, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness for a 4.5 minute contact time.

   Cultures included 1% fetal bovine serum as organic soil load:
   MRID 49795319 2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009 CDC #2009712192
   MRID 49795320 Herpes simplex virus type 1, ATCC VR-733, Strain F(1)
   MRID 49795321 Rotavirus, ATCC VR-2018, Strain WA
   MRID 49795322 Rhinovirus type 39, ATCC VR-340, Strain 209

   Cultures included 5% fetal bovine serum as organic soil load:
   MRID 49795323 Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$

   Recoverable virus titer of at least 4 $log_{10}$ were achieved for the required product lots. Complete inactivation (no growth) was demonstrated in all dilutions tested. When cytotoxicity is evident, at least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

3. The submitted efficacy data **support** the use of the product, Capricorn, as a non-food contact sanitizer against the following microorganisms, tested with 5% fetal bovine serum as organic soil load, on hard, non-porous surfaces when diluted using 62.4g of product in 2L of water of up to 100ppm hardness for a 4.5 minute contact time.

   MRID 49795324 *Staphylococcus aureus* (ATCC 6538)
   *Klebsiella pneumoniae* (ATCC 4352)
   MRID 49795325 *Escherichia coli* 0157:H7 (ATCC 43888)

   Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

4. The submitted efficacy data **support** the use of the product, Capricorn, as a non-food contact sanitizer against the following microorganisms, tested with 5% fetal bovine serum as organic soil load, on soft surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness for a 4.5 minute contact time (using plain cotton weave and polyester as the types of carriers).

   MRID 49795326 *Staphylococcus aureus* (ATCC 6538)
   *Klebsiella pneumoniae* (ATCC 4352)
   MRID 49795327 *Escherichia coli* 0157:H7 (ATCC 43888)
   MRID 49795328 *Salmonella enterica* (ATCC 10708)

   Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

5. The submitted efficacy data **support** the use of the product, Capricorn, as a mildew-fungistat against the following microorganisms, tested with 5% fetal bovine serum as an organic soil load, on hard, non-porous surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness after 7 days of incubation.

   MRID 49795329 *Aspergillus niger* (ATCC 6275)

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Purity controls were reported as pure. Sterility controls did not show growth.

6. The submitted efficacy data **support** the use of the product, Capricorn, as a mildew-fungistat against the following microorganisms, tested with 5% fetal bovine serum as an organic soil load, on fabrics when diluted using 62.4g of product in 1L of water of up to 100ppm hardness after 7, 14, 21, and 28 days of incubation.

   MRID 49795330 *Aspergillus niger* (ATCC 6275),
   *Penicillium variabile* (ATCC 32333)

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Purity controls were reported as pure. Sterility controls did not show growth.

7. The submitted efficacy data **support** the use of the product, Capricorn, as a laundry presoak disinfectant with bactericidal activity against the following microorganisms, tested with 5% fetal bovine serum as an organic soil load, on stainless steel penicylinders when diluted using 62.4g of product in 2L of water of up to 100ppm hardness.

   In 14.5 minute contact time:
   MRID 49795331 *Pseudomonas aeruginosa* (ATCC 15442),
   *Salmonella enterica* (ATCC 10708),
   *Staphylococcus aureus* (ATCC 6538)

   In 15 minute contact time:
   MRID 49795332 *Escherichia coli* 0157:H7 (ATCC 43888)
   MRID 49795333 *Klebsiella pneumoniae* (ATCC 4352)

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

   **Revision 8/18/16: for study with MRID No. 49795331, testing was done based on the current criteria for UDM (2013); therefore, the performance results of 2 positive and 3 positive carriers out of 60 carriers for *Staphylococcus aureus* are acceptable.**

8. The submitted efficacy data below **support** the use of the product, Capricorn, as a laundry presoak disinfectant with virucidal activity against the following microorganisms, tested with 5% fetal bovine serum as an organic soil load, on glass petri dish surfaces when diluted using 62.4g of product in 2L of water of up to 100ppm hardness for a 14.5 minute contact time.

   MRID 49795334 2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009 CDC #2009712192
   MRID 49795335 Herpes simplex virus type 1, ATCC VR-733, Strain F(1)
   MRID 49795336 Rotavirus, ATCC VR-2018, Strain WA
   MRID 49795337 Rhinovirus type 39, ATCC VR-340, Strain 209
   MRID 49795338 Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$

   Recoverable virus titer of at least 4 $\log_{10}$ were achieved for the required product lots. Complete inactivation (no growth) was demonstrated in all dilutions tested. When cytotoxicity is evident, at least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

9. The submitted efficacy data **support** the use of the product, Capricorn, as a presoak sanitizer against the following microorganisms, tested with 5% fetal bovine serum as organic soil load, on unglazed ceramic tiles when diluted using 62.4g of product in 2L of water of up to 100ppm hardness for a 4.5 minute contact time.

   MRID 49795339 *Staphylococcus aureus* (ATCC 6538)
   *Klebsiella pneumoniae* (ATCC 4352)
   MRID 49795340 *Escherichia coli* 0157:H7 (ATCC 43888)

Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

## VII. LABEL RECOMMENDATIONS

Dilution of product is acceptable with deionized water or water with up to 100ppm hardness.

1. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a disinfectant with bactericidal activity against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 10-minute contact time with pre-cleaning instructions.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):
   *Pseudomonas aeruginosa* (ATCC 15442),
   *Salmonella enterica* (ATCC 10708),
   *Staphylococcus aureus* (ATCC 6538)
   *Escherichia coli* 0157:H7 (ATCC 43888)

   These claims **are supported** by the applicant's data

2. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a disinfectant with virucidal activity against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 5-minute contact time with pre-cleaning instructions.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):
   2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009
   Herpes simplex virus type 1, ATCC VR-733, Strain F(1)
   Rotavirus, ATCC VR-2018, Strain WA
   Rhinovirus type 39, ATCC VR-340, Strain 209
   Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$

   These claims **are supported** by the applicant's data.

3. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a non-food contact sanitizer against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 5-minute contact time.

   31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):
   *Staphylococcus aureus* (ATCC 6538),
   *Klebsiella pneumoniae* (ATCC 4352),
   *Escherichia coli* 0157:H7 (ATCC 43888)

   These claims **are supported** by the applicant's data.

4. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a non-food contact sanitizer against the following organisms for use on soft (fabric) surfaces using the following dilution rate in a 5-minute contact time.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):
   *Staphylococcus aureus* (ATCC 6538),

*Klebsiella pneumoniae* (ATCC 4352),
*Escherichia coli* 0157:H7 (ATCC 43888),
*Salmonella enterica* (ATCC 10708)

These claims **are supported** by the applicant's data.

5. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a mildewstat against the following organisms for use on soft (fabric) surfaces using the following dilution rate for a 28-day contact period.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):
   *Aspergillus niger* (ATCC 6275)

   These claims **are supported** by the applicant's data.

6. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a mildewstat against the following organisms for use on hard, non-porous surfaces using the following dilution rate for a 7-day contact period.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):
   *Aspergillus niger* (ATCC 6275),
   *Penicillium variabile* (ATCC 32333)

   These claims **are supported** by the applicant's data.

7. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry presoak disinfectant against the following organisms for use in laundry using the following dilution rate by total immersion application for a 15-minute contact time.

   31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):
   *Pseudomonas aeruginosa* (ATCC 15442),
   *Salmonella enterica* (ATCC 10708),
   *Staphylococcus aureus* (ATCC 6538),
   *Escherichia coli* 0157:H7 (ATCC 43888),
   *Klebsiella pneumoniae* (ATCC 4352),
   2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009,
   Herpes simplex virus type 1, ATCC VR-733, Strain F(1),
   Rotavirus, ATCC VR-2018, Strain WA,
   Rhinovirus type 39, ATCC VR-340, Strain 209,
   Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$

   These claims **are supported** by the applicant's data.

8. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry presoak sanitizer against the following organisms for use in laundry using the following dilution rate by total immersion application for a 10-minute contact time.

   31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):
   *Staphylococcus aureus* (ATCC 6538)
   *Klebsiella pneumoniae* (ATCC 4352)
   *Escherichia coli* 0157:H7 (ATCC 43888)

   These claims **are supported** by the applicant's data.

9. On the proposed label, registrant must include the dilution of product in water that has up to 100 ppm Calcium carbonate, which accurately represents the hardness of the water used for testing. Regular tap water contains more than 100 ppm of hard water and cannot be used to dilute the product.

10. On the proposed label, registrant must add pre-cleaning instructions to all application uses on hard, non-porous surfaces (i.e. disinfectant, sanitizer and mildewstat). Registrant must also remove "one-step" claims from these uses. Product was not tested using at least 5% organic soil load for hard, non-porous surface disinfection.

11. On page 3 of the proposed label, under Laundry Sanitization, registrant must specifically instruct users to prepare the solution accordingly using the accurate doses of product in the required amount of water (as tested) for laundry immersion before adding the treated load to the washing machine. The contact time and amount of water to dilute the product generated from washing machines are difficult to measure and monitor if presoak sanitization were to be done inside the washing machines.

12. On the proposed label, registrant must remove all claims against cold viruses and claims concerning cold prevention. Agency's criteria for this claim requires effectiveness against 2 of the 3 cold-associated viruses, which are Rhinovirus, Coronavirus, and Respiratory Syncytial virus.

13. On page 4 and 15 under soft surface sanitization use directions and claims, the terms "spot" must be removed from the brackets as it is not optional.

14. On the proposed label, registrant must remove all claims against "black mold". The microorganisms tested are not considered black mold-associated microorganisms.

15. On page 7 of the proposed label, under "Marketing Claims", registrant must remove the claim "ready to use".

16. On the proposed label, registrant must remove all claims concerning "antibacterial protection".

17. On page 12 and 15 of the proposed label, registrant must specify the claims concerning "cross-contamination" to "Can help reduce cross-contamination <u>between treated surfaces</u>..."

18. On page 13 of the proposed label, registrant must remove the brackets from the word "surfaces" from the claim, "[This product] will help [you] keep your [surfaces] clean [and disinfected]". This term is not optional.

19. Throughout the proposed label, remove the "99.99%" claims from multiple locations under the disinfection sections.

20. On page 14 of the proposed label, registrant must remove "more than" from the claim "Kills more than 99.9% of bacteria and viruses".

21. On page 21, Table 8: Testing and Dilution Type, Fungi must be removed from the Type of Organism column. The name, "Mold and mildew", is more appropriate according to Agency's criteria.

22. On the proposed label, registrant must qualify all of the "virus", "virucide", and "virucidal" claims with an asterisk or other symbols to refer the claims mentioned to the viruses tested.

23. On the proposed label, registrant must remove all claims against "fungi", "fungus" and "fungal spores". Product was not tested against the Agency-required microorganism to qualify for the claims.

## Chao, Julie

**From:** Nguyen, Son
**Sent:** Thursday, August 18, 2016 3:44 PM
**To:** Chao, Julie
**Cc:** Perry, Mark
**Subject:** RE: EPA Completed Action: 10772-EG Pre-Decisional Determination

Julie,

I posted the revised review on Documentum. In addition to allowing presoak laundry disinfection claims, I also fixed label recommendation #'s 13, 17, and 19 to reflect minor changes. Let me know if you have any questions.

https://prismdocs.epa.gov/prism/drl/objectId/0901efd18049694b

Thanks,
*Sophie*
Son Nguyen, Biologist
U.S. Environmental Protection Agency
OCSPP, OPP, AD, PSB
(703) 347-8319

**From:** Chao, Julie
**Sent:** Thursday, August 18, 2016 7:16 AM
**To:** Perry, Mark <Perry.Mark@epa.gov>; Nguyen, Son <Nguyen.Son@epa.gov>
**Subject:** FW: EPA Completed Action: 10772-EG Pre-Decisional Determination

Hi Mark and Sophie,

One additional question on "cold virus" from SRC on Capricorn, 10772-EG.

Let me know if it would be helpful for the three of us to sit down and discuss.

Thanks very much,
Julie

**From:** rjones@srcconsultants.com [mailto:rjones@srcconsultants.com]
**Sent:** Wednesday, August 17, 2016 6:34 PM
**To:** Chao, Julie <Chao.Julie@epa.gov>
**Cc:** dswain@srcconsultants.com
**Subject:** RE: EPA Completed Action: 10772-EG Pre-Decisional Determination

Julie,

We are working on this label with the client and wanted to confirm if you have heard back from the Efficacy Team. I also want to push back on the "cold virus" labeling comment requiring additional data. The EPA has always allowed "colds" claims to be supported by Rhinovirus only. Where products were not effective against Rhinovirus, EPA has allowed us to test RSV and Coronavirus instead of Rhinovirus. I am not aware of EPA publishing a new policy to require the testing of 2 cold viruses to make such claims. Please confirm this is also an oversight.

Rhonda

SERVICE
*Introducing* SERVICE Portal, *a cloud-based gateway to state registration data.*
*http://www.srcconsultants.com/services/service-portal*

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy

**From:** rjones@srcconsultants.com
**Sent:** Monday, August 15, 2016 3:58 PM
**To:** Chao, Julie (Chao.Julie@epa.gov)
**Cc:** dswain@srcconsultants.com
**Subject:** RE: EPA Completed Action: 10772-EG Pre-Decisional Determination
**Importance:** High

Julie,

We are working with Church & Dwight to begin the response/revision process. I wanted to quickly get back with you with regard to the Laundry Disinfection efficacy studies as I hope we can quickly reverse that rejection of data.

The laundry bactericidal and fungicidal studies were conducted using the AOAC Use Dilution Method (UDM) per 810.2400. The Efficacy Review has applied the performance criteria of 0-1 positive tube/60 per the 810.2400 (2012) in error. However, it is my understanding from the attached Nov. 2013 EPA UDM Performance Revision Guidance as well as discussions with the Efficacy Team that the new UDM criteria found in the Guide would be applied to these studies as long as they were conducted on 3 separate dates, which the reviewer has noted was done. I believe this is an oversight as the 810's have not been updated to reflect this Guidance yet. I also note that the Agency Standards on page 10 of the pdf state testing on 3 separate days is required which is only required by the 2013 Guide yet the criteria was not updated to add the new performance criteria found in the 2013 Guide.

As this has significant label revision consequences as well as commercial consequences, I would like to clear this up quickly first. Thanks for your assistance in taking a second look at this item.

Rhonda

CELEBRATING 20 YEARS 1996-2016
**Rhonda Jones, RM(NRM)**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE
*Introducing* SERVICE Portal, *a cloud-based gateway to state registration data.*
*http://www.srcconsultants.com/services/service-portal*

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy

**From:** Chao, Julie [mailto:Chao.Julie@epa.gov]
**Sent:** Monday, August 15, 2016 11:00 AM
**To:** dswain@srcconsultants.com
**Cc:** OPP AD Ombudsman
**Subject:** EPA Completed Action: 10772-EG Pre-Decisional Determination

Hi David,

Please see the attached pre-decisional determination letter for 10772-EG. Let me know if you'd like to discuss. I'll be back in the office tomorrow.

Thank you,
Julie
++++++++++++++++++++++++++
Julie Chao, MA, MSPH
Product Manager 33
Risk Management Branch 1
Antimicrobials Division
Office of Pesticide Programs
703.308-8735 (phone)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 15, 2016

David Swain
Representative for Church & Dwight Company, Inc.
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street
Columbia City, IN 46725

Subject: Pre-Decisional Determination
Product Name: Capricorn
EPA File Symbol: 10772-EG
EPA Decision No.: 514854
Application Date: March 8, 2016

Dear Mr. Swain:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified in the attached document, as well as in the attached science reviews (efficacy, acute toxicity, product chemistry).

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

(a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
(b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
(c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact me at (703) 308-8735 or chao.julie@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Attachments: Agency Label Comments
Efficacy Review dated July 29, 2016
Acute Toxicity Review dated June 7, 2016
Product Chemistry Review dated April 27, 2016

**Label Comments for 10772-EG**

**Note that additional label comments are included in the efficacy and acute toxicity data reviews.**

1. Throughout the label, please number the marketing claims.

2. Throughout the label, surfaces like "countertops" and "counters" need to be qualified as "non-food contact" or "bathroom," as the product is not for use on food contact surfaces. General claims about "kitchen" surfaces must also be qualified as "kitchen floors" or "non-food contact kitchen surfaces." These need to be qualified in the site/surface tables too, and any graphics must not depict food contact sites without a qualifier note "non-food contact surfaces only."

3. Throughout the label, "cross-contamination" claims must be qualified to read, "cross-contamination between [or across] treated surfaces."

4. On page 2, per the acute toxicity data review, add a Note to Physician under the First Aid section.

5. On page 5, the storage and disposal statements should be updated per PRN 2007-4 and Chapter 13 of the Label Review Manual. Typical statements would read: "Store in original container in areas inaccessible to children and pets. Keep securely closed. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain."

6. On page 9, there is a claim "Cleans x [countertops][floors][square feet][area]." Please qualify "countertops" to read "non-food contact countertops" or "bathroom countertops," as the product is not for food contact use.

7. On page 10, remove the claim "Free of chemical residue." No data have been submitted to demonstrate residue levels on treated surfaces, and this is considered an implied safety claim.

8. On page 10, there is a claim "Go ahead [use around the house on floors][and counters]." Please qualify "counters" to read "non-food contact counters" or "bathroom counters," as the product is not for food contact use.

9. On page 14, delete the claim "Kills...bacteria for a healthy home [environment]." The phrase "healthy home [environment]" implies impact on the health status of people in contact with the treated sites (a claim regulated under FFDCA), and is not permitted.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 29, 2016

**MEMORANDUM**

Subject: Efficacy Review for Capricorn, EPA Reg. File No. 10772-EG, DP Barcode: D432547

From: Son Nguyen
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

To: Julie Chao, RM33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Church & Dwight Co., Inc.
500 Charles Ewing Blvd.
Ewing, NJ 08628

**Formulation from the Label:**

| Active Ingredient | % by wt. |
|---|---|
| Sodium Percarbonate | 18.50 |
| Tetraacetylethylenediamine | 4.44 |
| OtherIngredients | 77.06 |
| Total | 100.00% |

## I. BACKGROUND

The product, Capricorn (EPA Reg. File #10772-EG) is a new product, designed as a concentrated solid product to be used when diluted as instructed as a laundry pre-soak or post-soak disinfectant and sanitizer and hard surface disinfectant (bactericide, virucide) and sanitizer for use in sites such as homes, schools, hospital and office buildings. The studies were conducted at Accuratus Lab Services, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated March 8, 2016), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), 24 new efficacy studies (MRID Nos. 49795317 through 49795340), and the product's proposed label. Statement of No Data Confidentiality Claims, Compliance Statement and Quality Assurance Unit Summary were included with each study.

Note: On Nov. 10, 2015, the Agency confirmed via email that the contact times for laundry sanitization at 10 minutes and laundry disinfection at 15 minutes are acceptable claims for this product. (Emails attached with submission package).

## II. USE DIRECTIONS

The product is designed for use on hard, non-porous surfaces, such as appliance exterior, bathtub [tub], bed frame, cabinet [non-wood], chair [non-wood], changing table [non-wood], counter [countertop], crib [non-wood], diaper pail [non-wood], exhaust [fan] [hood], faucet, fixture [chrome/stainless steel], floor [linoleum], floor [glazed ceramic/porcelain tile], floor [laminate], floor [sealed marble, floor [vinyl], garbage [can] [pail] [container], glazed ceramic tile, glazed porcelain tile, grill [barbecue] exterior, highchair [non-food contact area], microwave exterior, non-medical [chrome/stainless steel], outdoor patio furniture [non-wood], oven [door], patio door, picnic table [non-wood], plastic laundry [basket] [hamper], range hood [stove hood], refrigerator shelves [drawers], sealed granite, shower [door] curtain], shower [stall] [area], sink [basin], stove [stovetop], table [tabletop] [non-wood], telephone, toilet bowl exterior [urinal], water fountain, window [windowsill], vanity top. The product can be used on hard, non-porous surfaces materials, such as chrome, Corian, countertop, crystal, enamel, Formica, glazed ceramic, glazed granite, glazed porcelain, glazed tile, laminate, linoleum, plastic laminate, sealed fiberglass fixtures, sealed marble, Silestone, stainless steel, vinyl. The product is also designed to be used on soft surfaces, such as baby carriages, baby prams, backpack/schoolbag, bathroom mat, bedding [bedspread], box spring [cover], car [seat] [upholstery], clothing, cotton [fabrics] purse, cots, couch [sofa], curtains [draperies], cushion [pillow], dog [pet] bed, diaper bag, duvet cover, gym bag [fabric], [upholstered] highchair seat, laundry bag [fabric], mattress [cover], mop [broom], seat cushion [household], seat cushion [kitchen], shoes [canvas] [fabric], shoe interior, shower curtain [fabric], slippers, sneakers [canvas] [fabrics], sponges [rags], sport(s) [bag(s)] [equipment], soft [fabric] surfaces, stroller [seats], stuffed [plush] toys, suitcase [luggage], throw rug, [upholstered] booster seat, [upholstered] chairs, [upholstered] couches, [upholstered] furniture, upholstery, window treatment [fabric].

Directions on the proposed label provide the following information regarding preparation and use of the product:

Testing and Dilution Type:

| Testing Type | Type of Organis | Dilution Type | Efficacy Study | Gallon Conversion |
|---|---|---|---|---|
| Hard Surface | Bacteria<br>Viruses | 2X | 62.4 grams Product / 1 liter | 236 grams Product / 1 gallon water |
| Hard Surface | Fungi | 2X | 62.4 grams Product / 1 liter | 236 grams Product / 1 gallon water |
| Non-Food Contact | Bacteria | 1X | 31.2 grams Product / 1 liter | 118 grams Product / 1 gallon water |
| Soft Surface | Bacteria | 2X | 62.4 grams Product / 1 liter | 236 grams Product / 1 gallon water |
| Soft Surface | Fungi | 2X | 62.4 grams Product / 1 liter | 236 grams Product / 1 gallon water |
| Laundry Pre-Soak | Bacteria<br>Viruses | 1X | 31.2 grams Product / 1 liter | 118 grams Product / 1 gallon water |
| Laundry Pre-Soak | Bacteria | 1X | 31.2 grams Product / 1 liter | 118 grams Product / 1 gallon water |

**[LAUNDRY] [SANITIZATION] [and] [DISINFECTION]**
[To] Sanitize [Laundry]:
[Pre-soak [Use]:] {Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}[in washing machine]. Immerse laundry for [at least] 10 minutes prior to starting the wash cycle. [Light soils do not require precleaning.]

[To] Disinfect [Laundry]:
[To kill] bacteria and viruses†[:] {Insert directions for 1X dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)} [in washing machine]. Immerse laundry for [at least] 15 minutes prior to starting the wash cycle. [Light soils do not require precleaning.]

**HARD NON-POROUS [SURFACES]**
[To] Sanitize [Hard Surfaces]:
[1] {Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 5 minutes.
[3] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop]. [Pre-clean heavily soiled surfaces.]

[To] Disinfect [Hard Surfaces]: [1] Pre-clean surface.
[2] {Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [3] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 10 [minutes] [min.] for bacteria and 5 [minutes] [min.] for viruses†.
[4] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop].

[To] Prevent Mold [and Mildew]:
[1] {Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet.
[3] Air dry. Repeat [application] every 7 days [to inhibit] [mold] [and mildew] [growth].

**SOFT SURFACES [AND] [&] [FABRICS]**
[To] [Spot] Sanitize [Soft Surfaces]:
[1] {Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] Saturate [fabric] surface until it is thoroughly wet. Let stand 5 minutes.
[3] [Blot] [stained] [area] [gently] with a [white] [dye-free] [cloth] [or sponge]. [Pre-clean heavily soiled surfaces.] [Blot dry with cloth.]

[To] Prevent Mold [and Mildew] [growth] [on Fabric]:
[1] {Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}. [2] [Saturate] [Mop, spray, wipe or sponge on] [fabric] surface until thoroughly wet.
[3] Air dry. [Pre-clean heavily soiled surfaces.] Repeat [application] every 28 days [to inhibit] [mold] [and mildew] [growth]. [Effective against Aspergillus [A.] niger [(black mold)] [mildew] and Penicillium [P.] variable.

## III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard, Non-porous Surfaces in Hospital or Medical Environments:
The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (UDM) (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). Sixty carriers must be tested against each of the three batches of the product at lower certified limit(s) (LCL) of the active ingredient(s) against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). For UDM, a mean log density of at least 6.0 (corresponding to a geometric mean density of $1.0 \times 10^6$) and not above 7.0 (corresponding to a geometric mean density of $1.0 \times 10^7$) for both organisms is required. A mean log density <6.0 or >7.0 invalidates the test. For AOAC Germicidal Spray Products Test, a mean log density of at least 5.0 (corresponding to a geometric mean density of $1.0 \times 10^5$) and not above 6.5 (corresponding to a geometric mean density of $3.2 \times 10^6$) for both organisms is required. A mean log density <5.0 or >6.5 invalidates the test. To support products labeled as "disinfectants", killing on 59 out of 60 carriers for germicidal spray testing is required. For AOAC Use-Dilution testing (UDM), conduct three independent tests (i.e., three batches at the LCL tested on three different test days) against the test microbe. The performance standard for *S. aureus* is 0-3 positive carriers out of sixty. The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty. Thus, a total of three tests for *S. aureus* and three tests for *P. aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture media. Contamination of only one carrier (culture tube) is allowed per 60-carrier set; occurrence of more than one contaminated carrier invalidates the test results for both UDM and GST methods. To be deemed an effective product, the product must pass all tests for both microbes. All products should meet the performance standard associated with the method and microbe at ≤ 10 minutes of contact.

Disinfectants for Use on Hard Surface Environments (Additional Microorganisms):
Effectiveness of disinfectants against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. This section addresses efficacy testing for limited, broad-spectrum or hospital disinfectants which bear label claims against bacteria other than *S. enterica* (ATCC10708), *S. aureus* (ATCC 6538) or *P. aeruginosa* (ATCC 15442). The effectiveness of disinfectant against specific bacteria must be determined by AOAC Use-Dilution Method (UDM). Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. The product should kill all the test microorganisms on all carriers in ≤ten minutes. The minimum carrier count to make the test valid should be $1 \times 10^4$ CFU/carrier. For a valid test, no contamination of any carrier is allowed.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least $10^4$ from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Sanitizer Test (for inanimate, non-food contact surfaces):
The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The Agency recommends the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) (Ref. 1). The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. For hard, porous surface label claims use unglazed ceramic tile. For hard, nonporous surface label claims use stainless steel carrier or glass slide. Use 5 test carriers and 3 control carriers. Tests should be performed with each of 3 product samples, representing 3 different product lots, tested at LCL against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least $7.5 \times 10^5$ colony forming units per carrier. The performance measure should demonstrate a reduction of ≥99.9% (a 3-log10 reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

Sanitizers (For Non-Food Contact Surfaces; Additional Bacteria):
Effectiveness of sanitizers for non-food contact surfaces against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. In these cases, confirmatory test standards would apply. The effectiveness of sanitizers for non-food contact surfaces against specific bacteria must be determined by the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153). Two product samples, representing 2 different product lots, should be tested against each additional microorganism. Use 5 test carriers and 3 control carriers. The ASTM method states that the inoculum employed should provide a count of at least $7.5 \times 10^5$ colony forming units per carrier. The performance measure should demonstrate a reduction of ≥99.9% (a 3-$\log_{10}$ reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

Spot Soft Surface Sanitization:
The study is designed to evaluate the antimicrobial efficacy of sanitizers on pre-cleaned or lightly soiled, non-food contact soft surfaces. For sanitizer products intended for use on soft, non-food contact surfaces, a fabric carrier method is used to generate efficacy data. The test system proposed is a modification of the ASTM approved method for the evaluation of the antimicrobial

efficacy of sanitizers on non-food contact surfaces. The method is modified for spray product application. The Agency recommends the use of The American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153-03). Three product samples, representing three different batches, at the LCL should be tested against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). The ASTM method states "an average of at least 7.5 x $10^5$ organisms must have survived the inoculated control squares for the test to be valid." Two different fabric types should be tested. The fabrics should represent natural fabrics, such as cotton, and synthetic fabrics, such as polyester or rayon. A film of bacterial cells, dried on fabric carriers, is exposed to the test substance for a specified contact time. After exposure, the carriers are transferred to vessel containing neutralizing subculture media and assayed for survivors. Appropriate viability and sterility of organism population and neutralization controls are performed. Carrier type claimed on the label must be consistent with the test system. The test material meets effectiveness requirements of kill an average of at least 99.9% (3 log reduction) of the required organism on the 5 replicate carriers within 5 minutes. Controls must always meet the stipulated criteria.

Hard Surface Mildew Fungistatic Test:
This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 days of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth.

Fabric Mildew Fungistatic Test Method: The test is to be conducted on cotton muslin strips cut 25 by 75 mm from 136 to 203 g/$m^2$ (4 to 6 oz./yd.$^2$) fabric. The strips should be autoclaved sterilized. The product is to be tested against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Soak fabric strips in Nutrient broth for three minutes or until saturated. Remove excess liquid and allow fabric strips to dry before proceeding with application of the test product. Both sides of ten strips for each batch should be spray treated with product. The application specifications including spray distance from nozzle, degree of wetness, draining conditions, and drying procedures should be reported. Equal volumes of well-agitated conidial suspensions of *Aspergillus niger* and *Penicillium variable* using a DeVilbiss atomizer (or equivalent) should be sprayed on both sides of each fabric strip. The fabric samples are suspended in individual 500 mL jars containing 90 mL water and incubated at approximately 28°C with the caps tightened and backed off 1/8 turn to allow for ventilation. Observations are made weekly for four weeks or until treatments fail and abundant growth occurs on all treated strips (at 7, 14, or 21 days). Where no growth is visually evident at the end of the test period, examination at approximately 15X magnification must be conducted to confirm the absence or establish the presence of subvisual growth. The untreated control strips (10 strips) must have a minimum of 50% of their surface area covered with fungal growth after 7 days to consider the test valid. The acceptance criterion requires that all ten treated replicates per batch must be free of fungal growth. The directions for use must specify retreatment every 7, 14, or 21 days, as necessary depending on the length of time that all of the test strips remain free of mildew growth. Labeling of products which do not permit growth after four weeks incubation must specify a retreatment schedule, such as "repeat as necessary when new growth appears", and should indicate that treatments should be effective for at least 28 days.

Laundry Disinfectant – Pre-Soak Treatment for Use in Hospital or Medical Environments:
The effectiveness of disinfectants as pre-soak treatment for use on soiled fabrics by total immersion in the use solution prior to routine laundry operations in hospital or medical environments must be substantiated by data derived using the AOAC International Use-Dilution Method (Ref.1) (for water soluble powders and liquid products) modified to include 5% organic soil. Sixty carriers must be tested against each of the three batches of the product at the lower certified limit(s) (LCL) of the active ingredient(s) against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). A mean log density of at least 6.0 (corresponding to a geometric mean density of $1.0 \times 10^6$) and not above 7.0 (corresponding to a geometric mean density of $1.0 \times 10^7$) for both organisms is required. A mean log density <6.0 or >7.0 invalidates the test. To support products labeled as "disinfectants", conduct three independent tests (i.e., three batches at the LCL tested on three different test days) against the test microbes. The performance standard for both organisms is 0-1 positive carrier out of sixty. Sixty carriers are required per test, without contamination in the subculture media. Contamination of only one carrier (culture tube) is allowed per 60-carrier set; occurrence of more than one contaminated carrier invalidates the test results. To be deemed an effective product, the product must pass all tests for both microbes. All products should meet the performance standard associated with the method and microbe at ≤ 10 minutes of contact. For additional microorganisms other than those named as the designated test microorganism(s), refer to Disinfectants for Use on Hard Surface Environments (Additional Microorganisms) section above (test with 5% organic soil).

Laundry Sanitizing– Pre-Soak Treatment:
The effectiveness of sanitizers as pre-soak treatment for use on soiled fabrics by total immersion in the use solution prior to routine laundry operations must be substantiated by data derived using the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) modified to include 5% organic soil. Three product samples, representing three different batches, tested at the lower certified limit(s) of the active ingredient(s), should be tested against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (*K. pneumoniae*) (ATCC 4352). *Enterobacter aerogenes* (ATCC 13048) may be substituted for *K. pneumoniae*. Unglazed ceramic tile should be used for the test carrier. Five (5) test carriers and 3 control carriers should be used for each test. According to the ASTM method, "an average of at least $7.5 \times 10^5$ organisms must have survived the inoculated control squares for the test to be valid." The performance standard should demonstrate a reduction of ≥99.9 percent (a 3-$\log_{10}$ reduction) in the number of each test microorganism over the parallel control count in ≤5 minutes. To be deemed an effective product, the product must pass all tests for the indicated microbes. For additional microorganisms other than those named as the designated test microorganism(s), refer to Sanitizers (For Non-Food Contact Surfaces; Additional Bacteria) section above (test with 5% organic soil).

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

## IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY

The active ingredients' concentrations of **Batch No. 4562-132** were reported to be 3.99% TAED and 17.69% Sodium percarbonate, **Batch No. 4562-143** were reported to be 3.91% TAED and 17.29% Sodium percarbonate, **Batch No. 4699-40** were reported to be 3.97% TAED and 17.41% Sodium percarbonate, and **Batch No. 4779-9** were 4.00% TAED and 17.48% Sodium

percarbonate. The product's Tetraacetylethylenediamine (TAED) and Sodium percarbonate nominal concentrations are 4.44% and 18.5%, respectively, and the Lower Certified Limits of the product are 4.00% and 17.58%, respectively.

1. **MRID 49795317 "AOAC Use-Dilution Method," Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *and Staphylococcus aureus* (ATCC 6538) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 27, 2016. Project Identification No. A19644.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *and Staphylococcus aureus* (ATCC 6538). Four batches (Batch# 4562-132, Batch# 4562-143, Batch# 4699-40, and Batch# 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.1 (copy provided). The test substances were diluted on different test dates using a dilution of 62.4g/L, defined as 1 pre-weighed packet of test substance plus 1 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 20 minutes. Batch# 4562-132 was tested on 11/18/15, Batch# 4562-143 was tested on 11/18/15 and 01/06/16, and Batch# 4699-40 was tested on 11/23/15. Additional testing using a higher concentration of active was performed on Batch# 4779-9 on 12/21/15. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 19.0-20.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A 10 µL aliquot of a thawed, vortex mixed cryovial of stock organism broth culture was transferred to an initial 10 mL tube of growth medium (Synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, without vortex mixing the *Pseudomonas* culture, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48- 54 hours at 35-37°C. On the day of use, the pellicle was carefully aspirated from the *Pseudomonas aeruginosa* culture by vacuum aspiration. Care was taken to avoid disrupting the pellicle and any visible pellicle on the bottom of the tube was not harvested. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The Pseudomonas culture was visually inspected to ensure no pellicle fragments were present. The *Salmonella enterica* culture was diluted by combining 4.0 mL of test organism suspension with 68.0 mL of sterile growth medium. The *Staphylococcus aureus* culture was diluted by combining 35.0 mL of test organism suspension with 35.0 mL of sterile growth medium. All three test cultures were diluted with synthetic broth. The culture did not include a 5% organic soil load. Sixty (60) stainless steel penicylinders per product lot were inoculated with the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 36.6-36.7°C and at 50.1-53.3% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 9.5 minutes at 19.0-20.5°C. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate [on test dates 11/18/15, 11/19/15, 11/23/15, and 01/06/16]; Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Sodium Thiosulfate [on test date 12/21/15]). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. On

11/21/15, 11/25/15 and 12/23/15, representative test and positive control subculture tubes showing growth were subcultured to Tryptic Soy Agar + 5% Sheep's blood and incubated at 35-37°C for 1-2 days. The cultures from 11/25/15 were refrigerated at 2-8°C for 3 days. The resultant growth was visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier for *Pseudomonas aeruginosa* (ATCC 15442) is 6.79 $\log_{10}$, for *Salmonella enterica* (ATCC 10708) was 5.84 $\log_{10}$, and for Staphylococcus aureus (ATCC 6538) was 6.53 $\log_{10}$.

Note
Amendment I: The lot numbers were to be amended from Lot 4562-132 (62.4gm dose). Lot 4562-143 (62.4gm dose) and Lot 4562-144 (62.4gm dose) to Lot 4562-132, Lot 4562-143, and Lot 4699-40. The following sentence was to be added to the protocol modification section: Each lot was supplied in a 53.4gm dose.
Amendment II: Additional testing on lot 4779-9, with a higher active concentration closer to the lower certified limits specified on the Confidential Statement of Formula, was to be added to this protocol. Lot 4779-9 was tested for *Staphylococcus aureus* (ATCC 6538) only. All other testing parameters documented in the protocol was to be followed.

There were no protocol deviations.

The assay was set up to be run on 3 separate test dates; 11/18/15, 11/19/15, and 11/23/15. Per Sponsor request, additional testing of *Staphylococcus aureus* with a lot containing a higher active concentration was added to the protocol (see Amendment 2) and tested on 12/14/15. **The test from 12/14/15 was invalid because the neutralization confirmation control results did not meet validity criteria**. The invalid data from 12/14/15 can be found in Attachment I. The invalid portion of the assay was repeated on 12/21/15. That data is valid and is contained in the body of this report. **On 11/19/15, the *Salmonella enterica* portion of the assay was invalid due to the carrier population control being under the minimum requirement**. This portion of the assay was repeated on 01/06/15. The invalid data from 11/19/15 can be found in Attachment II. The data from 01/06/15 is considered valid and is contained in the body of this report.

2. **MRID 49795318 "AOAC Use-Dilution Method," Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19755.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Batch# 4562-132 and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.2 (copy provided). The test substances were diluted using a dilution of 62.4g/L, defined as 1 pre-weighed packet of test substance plus 1 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 20 minutes. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 19.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium (synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted using sterile growth medium by

combining 15.0 mL of test organism suspension with 15.0 mL of sterile growth medium. The culture did not include a 5% organic soil load. Ten (10) stainless steel penicylinders per product lot were inoculated with the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 36.7°C and at 52.9 % relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 9.5 minutes at 19.5°C. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier *Escherichia coli* 0157:H7 (ATCC 43888) was 6.45 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

3. **MRID 49795319 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: 2009-H1N1 Influenza A virus (Novel H1N1) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19752.**

This study was conducted against 2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009 CDC #2009712192. The strain was obtained from the Center for Disease and Control and Prevention (CDC), Atlanta GA. One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. The MDCK (canine kidney) cell line, which exhibits cytopathic effect (CPE) in the presence of 2009-H1N1 Influenza A virus (Novel H1N1), was obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-34) and was used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.FLUA.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 21.0°C in a relative humidity of 35.2% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium

(MEM) supplemented with 25mM Hepes, 0.2% BSA Fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, and 2µg/mL TPCK-Trypsin. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for 2009-H1N1 Influenza A virus was 5.75 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

4. **MRID 49795320 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Herpes simplex virus type 1 for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19753.**

This study was conducted against Herpes simplex virus type 1, ATCC VR-733, Strain F(1). The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-733). One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. The Vero cells were obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-81) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRG85090815.HSV1.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (22.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity

($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Herpes simplex virus type 1, ATCC VR-733, Strain F(1) was 4.50 $log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

5. **MRID 49795321 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Rotavirus for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 04, 2016. Project Identification No. A19771.**

This study was conducted against Rotavirus, ATCC VR-2018, Strain WA. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-2018). One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. Cultures of MA-104 (Rhesus monkey kidney) cells were obtained from American Type Culture Collection, Manassas, VA (ATCC CRL-2378.1) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.ROT.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B, 0.5 µg/mL Trypsin, and 2.0mM L-glutamine. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The inoculum was allowed to adsorb for 60 minutes at 36-38°C in a humidified atmosphere of 5-7% CO2. Following the adsorption period, a 1.0 mL aliquot of the test medium was added to each well of the cell cultures, and the cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Rotavirus, ATCC VR-2018, Strain WA was 5.00 $log_{10}$.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

6. **MRID 49795322 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Rhinovirus type 39, for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19772.**

This study was conducted against Rhinovirus type 39, ATCC VR-340, Strain 209. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-340). One (1) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. Cultures of WI-38 (human lung) cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-75) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.R39.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 15.5°C in a relative humidity of 55% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was 10% Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Rhinovirus type 39, ATCC VR-340, Strain 209 was 5.00 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

The test was originally run on 12/10/15. **The dried virus control (DVC) did not achieve 4.0 log growth**, as required for a valid study. The assay was re-run on 01/04/16. The assay from 01/04/16 was valid and is included in the body of this report. Invalid data from 12/10/15 can be found in Attachment I.

7. **MRID 49795323 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Human Immunodeficiency virus type 1, for Capricorn, EPA Reg. No. 10772-EG, by Shanen Conway, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016. Project Identification No. A19736.**

This study was conducted against Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$. Five (5) percent fetal bovine serum was added to the prepared culture to achieve an organic soil load. The strain was obtained from Advanced Biotechnologies, Inc., Columbia, MD. MT-2 cells (human T-cell leukemia cells) were obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH from Dr. Douglas Richman and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.HIV.1 (copy provided). Both lots were tested at a 62.4g/L dilution defined as 1 pre-weighted packet of test substance + 1 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 20 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 28.2% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 4.5 minutes at room temperature (20.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was RPMI-1640 supplemented with 15% (v/v) heat-inactivated fetal bovine serum (FBS), 2.0 mM L-glutamine and 50 µg/mL gentamicin. Cells in multiwell culture dishes were inoculated in quadruplicate with 200µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/200µL) obtained for Human Immunodeficiency virus type 1 was 5.50 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

8. **MRID 49795324 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 11, 2016. Project Identification No. A19683.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (Nos. 4562-132, 4562-143, and 4699-40) of the product,

Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The *Staphylococcus aureus* culture was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. The *Klebsiella pneumoniae* culture was centrifuge concentrated at 3700 RPM for 15 minutes. A total of 21.0 mL of culture was concentrated to 3.00mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile glass 1" x 1" carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 20 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 29% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. On 12/3/15, representative test and positive control subcultures showing growth were visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Staphylococcus aureus* (ATCC 6538) was 1.26 x $10^6$ CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 4.07 x $10^6$ CFU/carrier.

Note
Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4562-144 to Lot 4699-40.

No protocol deviations occurred during this study.

9. **MRID 49795325 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888), for Capricorn, EPA Reg. No. 10772-EG, by Jamie Herzan, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 08, 2016. Project Identification No. A19767.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Nos. 4562-132, and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services

Protocol No. SRC85090815.NFS.2 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The culture was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile glass 1" x 1" carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 21 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 31% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±2 hours. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Escherichia coli* 0157:H7 (ATCC 43888) was 2.04 x $10^5$ CFU/carrier.\

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**10. MRID 49795326 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 12, 2016. Project Identification No. A19691.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (Nos. 4562-132, 4562-143, and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090915.NFS.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an

initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The *Klebsiella pneumoniae* culture was centrifuge concentrated at 3700 RPM for 15 minutes. A total of 25.0 mL of culture was concentrated to 5.00mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Two types of carriers (100% cotton weave fabric and 100% polyester fabric) were prepared and rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Sterile carriers were inoculated with 0.03 mL (30.0 µL) of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated cotton carriers were dried for 20-21 minutes at 35-37°C (35.9-36.1°C) and 40-41% relative humidity with the Petri dish lids intact. The inoculated polyester carriers were dried for 24-26 minutes at 35-37°C (35.9-36°C) and 40% relative humidity with the Petri dish lids intact. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 25-37% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Glass beads were utilized to aid in organism recovery from the modified fabric substrate for testing against *S. aureus*. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. On 12/10/15, representative test and positive control subcultures showing growth were visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control on cotton weave for *Staphylococcus aureus* (ATCC 6538) was 1.20 x $10^6$ CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 3.09 x $10^7$ CFU/carrier. The reported average carrier population control on polyester for *Staphylococcus aureus* (ATCC 6538) was 1.91 x $10^6$ CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 2.82 x $10^7$ CFU/carrier.

Note

No protocol amendments were required for this study. No protocol deviations occurred during this study.

**Testing on November 30, 2015 resulted in a carrier population control failure for *Staphylococcus aureus* on 100% plain cotton weave and 100% polyester fabric carriers.** Testing of *Staphylococcus aureus* from November 30, 2015 is therefore considered invalid and presented in Attachment I. The neutralization confirmation controls for *Staphylococcus aureus* and the testing for *Klebsiella pneumoniae* performed on November 30, 2015 are considered valid and presented in the body of the report. Testing

of Capricorn, Lot 4562-132, Lot 4562-143 and Lot 4699-40 against *Staphylococcus aureus* on 100% plain cotton weave and 100% polyester fabric carriers was repeated on December 8, 2015. Data from this test date is considered valid and presented in the body of the report.

**11. MRID 49795327 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19902.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Nos. 4562-132 and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85112415.NFS.1 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Two types of carriers (100% cotton weave fabric and 100% polyester fabric) were prepared and rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Sterile carriers were inoculated with 0.03 mL (30.0 µL) of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated carriers were dried for 30 minutes at 35-37°C (36°C) and 40% relative humidity with the Petri dish lids intact. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 16% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Glass beads were utilized to aid in organism recovery from the modified fabric substrate. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control on cotton weave for *Escherichia coli* 0157:H7 (ATCC 43888) was $1.74 \times 10^5$ CFU/carrier and the reported average carrier population control on polyester for the microorganism was $1.48 \times 10^7$ CFU/carrier.

Note
Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4699-40 to Lot 4779-9.

No protocol deviations occurred during this study.

**12. MRID 49795328 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces", Test Organisms: *Salmonella enterica* (ATCC 10708), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 26, 2016. Project Identification No. A19900.**

This study was conducted against *Salmonella enterica* (ATCC 10708). Two batches (Nos. 4562-132 and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85112415.NFS.3 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The culture was centrifuge concentrated at 3510 RPM for 10 minutes. A total of 18.0mL of culture was concentrated to 3.6mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Two types of carriers (100% cotton weave fabric and 100% polyester fabric) were prepared and rinsed by first placing the fabric into boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The carriers were cut from the fabric to a size of approximately 1 inch x 1 inch and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Sterile carriers were inoculated with 0.03 mL (30.0 µL) of culture using a calibrated pipettor distributing the inoculum evenly about the carrier. The inoculated carriers were dried for 30 minutes at 35-37°C (36.5°C) and 41% relative humidity with the Petri dish lids intact. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps. Using staggered intervals, 5.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (19°C) and 15% relative humidity for 4.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Glass beads were utilized to aid in organism recovery from the modified fabric substrate. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control on cotton weave for *Salmonella enterica* (ATCC

10708) was 1.86 x $10^6$ CFU/carrier and the reported average carrier population control on polyester for the microorganism was 1.10 x $10^7$ CFU/carrier.

Note
Protocol Amendment: Per Sponsor's request the protocol is amended to change Lot 4699-40 to Lot 4779-9.

No protocol deviations occurred during this study.

13. **MRID 49795329 "EPA Hard Surface Mildew-Fungistatic Test", Test Organisms: *Aspergillus niger* (ATCC 6275), for Capricorn, EPA Reg. No. 10772-EG, by Jamie Herzan, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016. Project Identification No. A19759.**

This study was conducted against *Aspergillus niger* (ATCC 6275). Two batches (Nos. 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090915.MSTAT (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The solution was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The conidial suspension was prepared by inoculating a flask of Sabouraud Agar (Modified) (aka neopeptone agar) and incubating for 7 days at 25-30°C. Following incubation, sterile saline/Triton Solution (0.85% saline + 0.05 Triton X-100) and sterile glass beads were added to the flask. The flask was agitated to remove mycelia/conidia from the agar. The conidia suspension was aspirated from the flask and passed through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The viable cell count was 1.2 x $10^8$ CFU/mL. The suspension was added to a sterile tissue grinder and macerated to break up spore chains at the time of harvesting. The macerated conidial suspension was standardized to contain an approximate target of 5 x $10^6$ conidia per mL by combining 1.00mL of unadjusted culture to 19.0mL of sterile 0.85% Saline. A 1.0mL aliquot of this suspension was added to 20.0mL of sterile Czapek's solution. A 1.00mL aliquot of FBS was added to 19.0mL of prepared Czapek/organism suspension to yield a 5% Fetal Bovine Serum organic soil load. One inch by one inch glazed ceramic tiles were sterilized for ≥2 hours at ≥180°C in a hot air oven and were used as carriers. For each lot of the prepared test substance, the surfaces of 10 carriers were treated by immersing the carriers in the test substance until completely covered. The carriers were removed from the test substance and were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried in Petri dishes at 35-37°C for 12 minutes with the lids ajar. Untreated carriers were placed in sterile Petri dishes (10 carriers total) and dried for 12 minutes at 35-37°C with the lids ajar alongside the test carriers. Following the initial drying period, an atomizer was used to spray the surface of each test carrier and control carrier with the *Aspergillus niger* conidia-Czapek suspension. Approximately 2 sprays were used to apply the test organism. The atomizer was periodically mixed to agitate the culture during inoculation. Carriers contained in Petri dishes were returned to a 35-37°C incubator and dried with the lids slightly ajar for 18 minutes until visibly dry. Each carrier (sprayed side up) was placed onto an individual water agar plate. All plates were incubated for 7 days at 25-30°C in a minimum of 95% relative humidity. The purity control was incubated for 44-76 hours at 25-30°C. All test and control carriers were examined after 7 days of incubation. The absence of fungal growth on all carriers is the criterion for determining the effectiveness of the test product. No visual growth was evident at the end of the 7 days on test carriers therefore a magnified examination was performed. To be considered a valid test, each untreated control carrier must be at least 50% covered with fungal growth after the 7 days. Controls included sterility, purity, and untreated control carriers. The visual evaluation of control carriers was reported as passing.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**14. MRID 49795330 "Fabric Mildew-Fungistatic Test", Test Organisms: *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333), for Capricorn, EPA Reg. No. 10772-EG, by Matthew Sathe, B.S. Study conducted at Accuratus Lab Services. Study completion date – February 5, 2016. Project Identification No. A19758.**

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333). Two batches (Nos. 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.FMSTAT (copy provided). The test substance was prepared by adding one pre-weighed dose (62.4g) of powder to 1L of 100 ppm AOAC Synthetic Hard Water. The solution was allowed to stir until all the powder was evenly dispersed by not longer than 20 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The *Aspergillus niger* conidial suspension was prepared by inoculating a flask of Sabouraud Agar (Modified) (aka neopeptone agar) and incubating for 7 days at 25-30°C. Following incubation, sterile saline/Triton Solution (0.85% saline + 0.05 Triton X-100) and sterile glass beads were added to the flask. The flask was agitated to remove mycelia/conidia from the agar. The conidia suspension was aspirated from the flask and passed through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The viable cell count was 1.2 x $10^8$ CFU/mL. The conidial suspension was standardized to contain an approximate target of 5 x $10^6$ conidia per mL by combining 1.00mL of unadjusted culture to 19.0mL of sterile 0.85% Saline. The *Penicillium variable* conidial suspension was prepared by inoculating 30 Sabouraud Dextrose agar plates (also known as Emmons agar) and incubating at 25-30"C for 11 days (see Protocol Deviation). Following incubation, 3.0 mL of sterile saline/Triton Solution (0.85% Saline + 0.05 % Triton X-100) was added to each plate harvested. The growth was harvested from the agar surface using a cell scrape. The harvested growth was transferred to a sterile vessel containing sterile beads and was swirled thoroughly. The culture was then filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The conidial count was 9.8 x $10^8$ CFU/mL. The conidial suspension was standardized to contain an approximate target of 5 x $10^6$ condia per mL by combining 1.00 mL of unadjusted culture with 49.0 mL of 0.85% saline. Fabric carriers were cut as approximately 25mm by 75mm strips from 136 to 203g/$m^2$ (4 to 6 oz/$yd^2$) cotton muslin and were autoclave. The sterilized fabric carriers were saturated with sterile glycerol nutrient solution by soaking the carriers for approximately three minutes until saturated. The excess liquid was squeezed out and the fabric carriers were allowed to dry prior to use as carriers. For each lot of the prepared test substance, 10 test carriers were treated by dipping the carriers in the test substance. The carriers were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried in Petri dishes at room temperature (23.3°C) for 37 minutes until dry. Equal volumes (10.0mL) of each well-mixed conidial suspension were combined within a DeVilbiss atomizer. One mL was removed and a 1.00 mL aliquot of FBS was added to 19.0 mL of the combined organism suspension to yield a 5% Fetal Bovine Serum soil load. Both sides of each fabric test carrier strip was lightly sprayed using approximately 6 sprays. The culture was mixed periodically within the atomizer during spraying. The fabric test and control samples were suspended in individual 250 mL French Square bottles containing approximately 10 mL sterile deionized water and incubated at 25-30°C. The caps were tightened and then backed off approximately 1/8 turn to allow for ventilation. It was ensured that no fabric was touching the water at the time of incubation. The control plates and organic soil load sterility control were incubated for 3 days at 25-30°C. These subcultures were refrigerated for 2 days at 2-8°C prior to examination. Observations were made and recorded every 7 days for four weeks. The presence or absence of observable mold on the test carriers was the criterion for determining the effectiveness of the test product. Where no growth was visually evident at each weekly observation, a magnified

examination was conducted to confirm the absence or establish the presence of sub-visual growth. Controls included sterility, purity, initial suspension, and untreated control carrier. The visual evaluation of control carriers was reported as passing. To be considered a valid control, each untreated control carrier must be covered with at least 50% of fungal growth over the total surface area after 7 days of incubation.

Note
*250 mL French square bottles containing 10 mL of deionized water were used to incubate the samples in this study. This is a modification of the method and was performed because of apparatus availability. Despite this modification, samples were incubated in a humid environment as required by the method and can be hooked so that the bottom ends of the attached fabric samples are about 13 mm above the water level as required by the method.*

There were no protocol amendments.

Protocol Deviation:
The protocol states *Penicillium variabile* will be prepared by incubating Sabouraud Dextrose agar plates for 7-10 days. **In testing, the *Penicillium variabile* culture was inadvertently incubated for 11 days.** Since the culture met the control acceptance criteria outlined in the protocol, this protocol deviation has no impact on the outcome of the study.

**15. MRID 49795331 "AOAC Use-Dilution Method," Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *and Staphylococcus aureus* (ATCC 6538) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016 (Report Amended on January 29, 2016). Project Identification No. A19659.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *and Staphylococcus aureus* (ATCC 6538). Three batches (Batch# 4562-132, Batch# 4562-143, and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.4 (copy provided). The test substances were diluted on different test dates using a dilution of 62.4g/2L, defined as 1 pre-weighed packet of test substance plus 2 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 10 minutes. Batch# 4562-132 was tested on 11/25/15, Batch# 4562-143 was tested on 11/23/15, and Batch# 4699-40 was tested on 11/24/15. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20±1°C (19.5-20.0°C) water bath and allowed to equilibrate for ≥10 minutes prior to testing. A 10 µL aliquot of a thawed, vortex mixed cryovial of stock organism broth culture was transferred to an initial 10 mL tube of growth medium (synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, without vortex mixing the *Pseudomonas* culture, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48- 54 hours at 35-37°C. On the day of use, the pellicle was carefully aspirated from the *Pseudomonas aeruginosa* culture by vacuum aspiration. Care was taken to avoid disrupting the pellicle and any visible pellicle on the bottom of the tube was not harvested. Each test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The Pseudomonas culture was visually inspected to ensure no pellicle fragments were present. The *Salmonella enterica* culture was diluted by combining 4.0 mL of test organism suspension with 68.0 mL of sterile growth medium. The *Staphylococcus aureus* culture was diluted by combining 35.0 mL of test organism suspension with 35.0 mL of sterile growth medium. A 3.5 mL aliquot of FBS was added to 66.5 ml of each prepared culture to yield a 5% fetal bovine serum organic soil load. Sixty (60) stainless

steel penicylinders per product lot were immersed for in the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 35-37°C (36.0-36.7°C) and at 50.6-52.5% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 14.5 minutes at 19.5-20.0°C. The carrier was placed into the test substance within ±5 seconds of the exposure time following a calibrated timer. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. On 11/25/15, 11/26/15, and 11/27/15, representative test and positive control subculture tubes showing growth were subcultured to Tryptic Soy Agar + 5% Sheep's blood and incubated at 35-37'°C for 1-2 days. The resultant growth was visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier for *Pseudomonas aeruginosa* (ATCC 15442) is 7.09 $\log_{10}$, for *Salmonella enterica* (ATCC 10708) is 6.07 $\log_{10}$, and for Staphylococcus aureus (ATCC 6538) was 6.49 $\log_{10}$.

Note
Protocol Amendments:
Amendment 1: Per Sponsor request, the exposure time will be changed from 15 minutes to 14.5 minutes.

Amendment 2: Per Sponsor request, the following reference will be added to the protocol; U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2400: Disinfectants and Sanitizers for Use on Fabrics and Textiles- Efficacy Data Recommendations, December 21, 2012.

Amendment 3: Per Sponsor request, the lot numbers will be amended from Lot 4562-132 (62.4gm dose). Lot 4562-143 (62.4gm dose) and Lot 4562-144 (62.4gm dose) to Lot 4562-132, Lot 4562- 143, and Lot 4699-40. Per Sponsor request, the following sentence will be added to the protocol modification section: Each lot was supplied in a 62.4gm dose.

Protocol Deviation:
Testing for Capricorn (Lot# 4562-132) originally ran on 11/19/15 was repeated on 11/25/15 due to inadvertently diluting the test substance incorrectly. This deviation has no impact on the overall Intent and purpose of the study.

**Testing for Capricorn (Lot# 4562-132) originally ran on 11/19/15 was repeated on 11/25/15 due to inadvertently diluting the test substance incorrectly (see protocol deviation)**. Data from 11/25/15 is valid and is presented in the report. See Attachment I for invalid data from 11/19/15.

16. **MRID 49795332 "AOAC Use-Dilution Method," Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016 (Report Amended on January 29, 2016). Project Identification No. A19757.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Batch# 4562-132 and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.5 (copy provided). The test substances were diluted using a dilution of 62.4g/2L, defined as 1 pre-weighed packet of test substance plus 2 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 10 minutes. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium (synthetic broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted by combining 15.0 mL of test organism suspension with 15.0 mL of sterile growth medium. A 1.5 mL aliquot of FBS was added to 28.5 ml of each prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) stainless steel penicylinders per product lot were immersed in the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 35-37°C (36.7°C) and at 50.2% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 15 minutes at 20.5°C. The carrier was placed into the test substance within ±5 seconds of the exposure time following a calibrated timer. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier *Escherichia coli* 0157:H7 (ATCC 43888) was 6.58 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**17. MRID 49795333 "AOAC Use-Dilution Method," Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) for Capricorn, EPA Reg. No. 10772-EG, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016 (Report Amended on January 29, 2016). Project Identification No. A19756.**

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two batches (Batch# 4562-132 and Batch# 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.UD.6 (copy provided). The test substances were diluted using a dilution of 62.4g/2L, defined as 1 pre-weighed packet of test substance plus 2 liter of diluent of 100 ppm AOAC synthetic hard water. The mixture was stirred until the powder was dispersed, but no longer than 10 minutes. Ten (10.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20.5°C water bath and allowed to equilibrate for ≥10 minutes prior to testing. A loopful of stock slant culture was transferred to an

initial 10 mL tube of growth medium (Nutrient broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to sufficient 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. A 1.5 mL aliquot of FBS was added to 28.5 ml of each prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) stainless steel penicylinders per product lot were immersed in the prepared culture suspension for 15±2 minutes at a ratio of one carrier per one mL of culture. The carriers were completely covered by the culture. A maximum of 100 carriers were inoculated per vessel. The inoculated carriers were transferred to sterile Petri dishes matted with filter paper, and no more than 12 carriers were placed in each Petri dish. The carriers were dried for 38 minutes at 35-37°C (36.6-36.7°C) and at 52.1% relative humidity. Carriers were used in the test procedure within 2 hours of drying. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use-dilution. Immediately after placing each test carrier in the test tube, the tube was swirled using approximately 2-3 gentle rotations to release any air bubbles trapped in or on the carrier. The carriers were exposed for 15 minutes at 20.0°C. The carrier was placed into the test substance within ±5 seconds of the exposure time following a calibrated timer. After the exposure time, each medicated carrier was transferred by wire hook at staggered intervals to 10mL of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.1% Sodium Thiosulfate). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier *Klebsiella pneumoniae* (ATCC 4352) was 7.07 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**18. MRID 49795334 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: 2009-H1N1 Influenza A virus (Novel H1N1) for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – December 31, 2015. Project Identification No. A19760.**

This study was conducted against 2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009 CDC #2009712192. The strain was obtained from the Center for Disease and Control and Prevention (CDC), Atlanta GA. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The MDCK (canine kidney) cell line, which exhibits cytopathic effect (CPE) in the presence of 2009-H1N1 Influenza A virus (Novel H1N1), was obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-34) and was used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.FLUA.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 26.6% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (20.0°C). Just prior to the end

of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures ($10^{-1}$ dilution). To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 2.5 µg/mL TTPCK-trypsin, 25mM Hepes, 0.2% BSA Fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for 2009-H1N1 Influenza A virus was 5.25 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**19. MRID 49795335 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Herpes simplex virus type 1 for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19761.**

This study was conducted against Herpes simplex virus type 1, ATCC VR-733, Strain F(1). The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-733). The stock virus culture contained 5% fetal bovine serum as the organic soil load. The Vero cells were obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-81) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.HSV1.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 51% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL

gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Herpes simplex virus type 1, ATCC VR-733, Strain F(1) was 5.25 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**The initial assay performed on December 9, 2015, was repeated on January 4, 2016, to recover at least 4 $\log_{10}$ of infectivity from the dried virus control as required for a valid test**. See Attachment I for the invalid data. Valid results were obtained from the assay performed on January 4, 2016, and may be found in the body of this report.

20. **MRID 49795336 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Rotavirus for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – December 31 2015. Project Identification No. A19770.**

This study was conducted against Rotavirus, ATCC VR-2018, Strain WA. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-2018). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Cultures of MA-104 (Rhesus monkey kidney) cells were obtained from American Type Culture Collection, Manassas, VA (ATCC CRL-2378.1) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.ROT.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.0°C in a relative humidity of 40% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (22.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B, 0.5 µg/mL Trypsin, and 2.0mM L-glutamine. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The inoculum was allowed to adsorb for 60

minutes at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. Following the adsorption period, a 1.0 mL aliquot of the test medium was added to each well of the cell cultures, and the cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Rotavirus, ATCC VR-2018, Strain WA was 5.75 $\log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**21. MRID 49795337 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Rhinovirus type 39, for Capricorn, EPA Reg. No. 10772-EG, by Mary J. Miller, M.T. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19769.**

This study was conducted against Rhinovirus type 39, ATCC VR-340, Strain 209. The strain was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-340). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Cultures of WI-38 (human lung) cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CCL-75) and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.R39.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 15.5°C in a relative humidity of 55% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (21.0°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Cells in multiwell culture dishes were inoculated in quadruplicate with 100µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and

neutralization. The dried virus control (in $TCID_{50}$/100µL) obtained for Rhinovirus type 39, ATCC VR-340, Strain 209 was 5.25 $log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**The initial assay performed on December 10, 2015, was repeated on January 4, 2016, to recover at least 4 $log_{10}$ of infectivity from the dried virus control as required for a valid test and to demonstrate neutralization in the non-virucidal level control**. See Attachment I for the invalid data. Valid results were obtained from the assay performed on January 4, 2016, and may be found in the body of this report.

22. **MRID 49795338 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Test Organisms: Human Immunodeficiency virus type 1, for Capricorn, EPA Reg. No. 10772-EG, by Shanen Conway, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 4, 2016. Project Identification No. A19728.**

This study was conducted against Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$. The stock virus culture contained 5% fetal bovine serum as the organic soil load. The strain was obtained from Advanced Biotechnologies, Inc., Columbia, MD. MT-2 cells (human T-cell leukemia cells) were obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH from Dr. Douglas Richman and were used as the indicator cell line in the infectivity assays. Two batches (Batch# 4562-132 and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.HIV.2 (copy provided). Both lots were tested at a 62.4g/2L dilution defined as 1 pre-weighted packet of test substance + 2 liter of 100 ppm AOAC Synthetic Hard Water. The mixture was stirred for 10 minutes until all of the powder was fully dispersed. The prepared test substance was used within 40 minutes following mixing. Films of virus were prepared by spreading 200µL of virus inoculum uniformly over the bottoms of three separate 100 x 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The virus films were dried at 20.5°C in a relative humidity of 26.5% until visibly dry (20 minutes). For each batch of test substance, one dried virus film were individually exposed to a 2.00mL aliquot of the use dilution of the test substance and held covered for 14.5 minutes at room temperature (20.5°C). Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. To aid in the removal of the cytotoxic effects to the cell cultures the $10^{-1}$ dilution was passed through an additional individual Sephadex column using the syringe plungers prior to titration. The filtrates ($10^{-1}$ dilution) were then titered by 10-fold serial dilution and assayed for infectivity and/or cytotoxicity. The test medium used in this study was RPMI-1640 supplemented with 15% (v/v) heat-inactivated fetal bovine serum (FBS), 2.0 mM L-glutamine and 50 µg/mL gentamicin. Cells in multiwell culture dishes were inoculated in quadruplicate with 200µL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$ in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence of presence of CPE, cytotoxicity, and for viability. Viral and cytotoxicity titers are expressed as $-log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity ($TCD_{50}$), respectively, as calculated by the method of Spearman Karber. Controls included those for input virus control, dried virus control film, cytotoxicity, and neutralization. The dried virus control (in $TCID_{50}$/200µL) obtained for Human Immunodeficiency virus type 1 was 5.75 $log_{10}$.

Note
No protocol amendments were required for this study. No protocol deviations occurred during this study.

**23. MRID 49795339 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19679.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Four batches (Nos. 4562-132, 4562-143, 4699-40, and 4779-9) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.5 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10 µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium (Nutrient broth). A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. For testing performed on 11/30/15, the *Staphylococcus aureus* culture was diluted by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. For testing on 12/15/15, the *Klebsiella pneumoniae* culture was centrifuge concentrated at 3500 RPM for 15 minutes. A total of 25.0 mL of culture was concentrated to 5.00mL. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile 1" x 1" unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 20 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 25% relative humidity for 9.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±4 hours. Following incubation, the subcultures were visually enumerated. On 12/2/15, representative test and positive control subcultures showing growth were visually examined. Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Staphylococcus aureus* (ATCC 6538) was 1.15 x $10^6$ CFU/carrier, and for *Klebsiella pneumoniae* (ATCC 4352) was 1.51 x $10^6$ CFU/carrier.

Note

Protocol Amendments:
1.
   a. Per Sponsor's request the protocol is amended to change the exposure time the exposure time from 10 minutes to 9.5 minutes.
   b. Per Sponsor's request the protocol is amended to change Lot 4562-144 to Lot 4699-40.

2. Per Sponsor's request the protocol is amended to change Lot 4562-143 to Lot 4779-9 for repeat testing against Klebsiella pneumoniae (ATCC 4352).

Protocol Deviation:
Per the protocol, the Test Culture Titer (TOT) and the Neutralizer Toxicity Treatment (NTT) are to be completed using 25 mL of sterile diluent/neutralizer. The TOT and NTT controls were completed using 30 mL of sterile diluent/neutralizer to make a direct comparison to the test and the amounts used in testing.

**Testing performed on November 30, 2015 resulted in a carrier population control failure for *Klebsiella pneumoniae*.** Testing against *Klebsiella pneumoniae* (Lot 4562-132, Lot 4562-143 and Lot 4699-40) from November 30, 2015 is therefore considered invalid and presented in Attachment I. The neutralization confirmation controls for *Klebsiella pneumoniae* performed on November 30, 2015 were deemed acceptable and valid and are presented in the body of the report. Testing of *Klebsiella pneumoniae* was repeated on December 15, 2015 against Capricorn Lot 4562-132, Lot 4699-40 and Lot 4779-9 (see Amendment 2). Neutralization confirmation controls for Lot 4779-9 were also performed on December 15, 2015. All testing performed on December 15, 2015 is considered valid and presented in the body of the report.

**24. MRID 49795340 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable)", Test Organisms: *Escherichia coli* 0157:H7 (ATCC 43888), for Capricorn, EPA Reg. No. 10772-EG, by Maggie Brusky, B.S. Study conducted at Accuratus Lab Services. Study completion date – January 25, 2016. Project Identification No. A19749.**

This study was conducted against *Escherichia coli* 0157:H7 (ATCC 43888). Two batches (Nos. 4562-132, and 4699-40) of the product, Capricorn, were tested using Accuratus Lab Services Protocol No. SRC85090815.NFS.6 (copy provided). Testing was conducted by adding one pre-weighed dose (62.4g) of powder to 2L of 100 ppm AOAC Synthetic Hard Water. The mixture was allowed to stir until all the powder was evenly dispersed by not longer than 10 minutes. The prepared test substance was homogenous and was used within 40 minutes of mixing. The "initial broth suspension" was prepared by inoculating an initial tube (10mL) of culture broth with 5 transfers from the original stock. A minimum of three daily transfers using 1 loopful (10µL) of the initial broth suspension into 10mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium (Synthetic broth). A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The cultures were thoroughly mixed prior to use. A 0.10mL aliquot of FBS was added to 1.90mL of each prepared culture to yield a 5% Fetal Bovine Serum organic soil load. Sterile 1" x 1" unglazed ceramic tile carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3mm of the edges of the carrier. The inoculated carrier were dried for 20 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. A constant humidity chamber was used in place of a desiccating chamber to ensure uniform humidification conditions and to overcome slow re-equilibration of a desiccator after opening. After drying, each of the five test carriers were transferred to individual

sterile 2oz. (60mL) polypropylene jars using sterile forceps with the inoculum facing up. Using staggered intervals, 10.0mL of prepared test substance was transferred to each jar. The liquid completely covered the carrier during exposure. The remaining test carriers were treated using staggered intervals. The carriers were allowed to expose at room temperature (20°C) and 23% relative humidity for 9.5 minutes. Following exposure, 20 mL of neutralizer (Letheen Broth + 3.0% Tween 80 + 0.4% Sodium Lauryl Sulfate + 0.3% Lecithin + 3.0% Saponin + 0.1% Histidine + 0.5% Sodium Thiosulfate + 0.01% Catalase) was transferred to the jars using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery plate medium (Tryptic Soy Agar with 5% Sheep Blood (BAP)). The plates were incubated at 35-37°C for 48±2 hours. Following incubation, the subcultures were visually enumerated. Controls included carrier population control, sterility, purity, neutralization confirmation, and inoculum count. The reported average carrier population control for *Escherichia coli* 0157:H7 (ATCC 43888) was 7.41 x $10^5$ CFU/carrier.

Note
Protocol Amendments:
No protocol amendments were required for this study.

Protocol Deviations:

a. Per the protocol, inoculated carriers are to be dried for 20-40 minutes until visibly dry. The carriers were dried for a full 40 minutes, but were still not visibly dry when used in testing.
b. Per the protocol and protocol modifications, the test substance was to be used within 40 minutes following the mixing of the test substance. The test substance was inadvertently used 13-14 minutes after the expiration time.

**Testing performed on December 9, 2015 was completed using carriers that were not visibly dry (see Protocol Deviation)**. Therefore, data from this test date is invalid and presented in Attachment I. Due to the carriers being wet, testing was repeated in its entirety on December 21, 2015. Data from this test date is valid and presented in the body of this report.

## V. RESULTS

### 1. Hard Non-Porous Surface Bactericidal Disinfectant (62.4g/1L):

| Contact Time | MRID No. | Organism | No. Carriers Exhibiting Growth/Total Carriers | | | | Carrier Population ($Log_{10}$ CFU/Carrier) |
|---|---|---|---|---|---|---|---|
| | | | Batch #4562-132 | Batch #4562-143 | Batch #4699-40 | Batch #4779-9 | |
| 9.5 minutes | 49795318 | *Escherichia coli* 0157:H7 (ATCC 43888) | 0/10 | -- | 0/10 | -- | 6.45 |
| | 49795317 | *Pseudomonas aeruginosa* (ATCC 15442) | 0/60 | 0/60 | 2/60 | -- | 6.79 |
| | | *Salmonella enterica* (ATCC 10708) | 0/60 | 0/60 | 0/60 | -- | 5.84 |
| | | *Staphylococcus aureus* (ATCC 6538) | 0/60 | **7/60** | 0/60 | 2/60 | 6.53 |

2. **Hard Non-Porous Surface Virucidal Disinfectant (62.4g/1L):**

| MRID No. | Contact Time | Organism | Results | | |
|---|---|---|---|---|---|
| | | | | Batch #4562-132 | Batch #4699-40 |
| 49795319 | 4.5 minutes | 2009-H1N1 Influenza A Virus (novel H1N1) + 1% FBS | **Description** | **Rep. 1** | **Rep. 1** |
| | | | $10^{-1}$ to $10^{-6}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |
| | | | $Log_{10}$ Reduction | ≥5.25 | ≥5.25 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.75}$** | |
| 49795320 | | Herpes simplex virus type 1 + 1% FBS | $10^{-1}$ to $10^{-4}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.00 | ≥4.00 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{4.50}$** | |
| 49795321 | | Rotavirus + 1% FBS | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity |
| | | | $10^{-2}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ |
| | | | $Log_{10}$ Reduction | ≥3.50 | ≥3.50 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.00}$** | |
| 49795322 | | Rhinovirus type 39 + 1% FBS | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity |
| | | | $10^{-2}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ |
| | | | $Log_{10}$ Reduction | ≥3.50 | ≥3.50 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.00}$** | |
| 49795323 | | Human Immunodeficiency virus type 1 + 5% FBS | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity |
| | | | $10^{-2}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/200µL | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.00 | ≥4.00 |
| | | | **Dried Virus Control ($TCID_{50}$/200µL)** | **$10^{5.50}$** | |

3. **Hard Non-Porous Non-Food Contact Surface Sanitizer (62.4g/2L):**

| Contact Time | MRID No. | Organism | Results | | | Carrier Population CFU/Carrier (Avg. $Log_{10}$) |
|---|---|---|---|---|---|---|
| | | | Batch# | CFU/Carrier (Average $log_{10}$) | Percent Reduction | |
| 4.5 minutes | 49795324 | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | 4562-132 | $6.17 \times 10^2$ (2.79) | >9.99 | $1.26 \times 10^6$ (6.10) |
| | | | 4562-143 | $6.03 \times 10^2$ (2.78) | >9.99 | |
| | | | 4699-40 | $5.89 \times 10^2$ (2.77) | >9.99 | |
| | | | 4562-132 | $<2.51 \times 10^1$ (<1.40) | >9.99 | $4.07 \times 10^6$ (6.61) |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS | 4562-143 | <2.51 x $10^1$ (<1.40) | >9.99 | |
| | | | 4699-40 | <2.51 x $10^1$ (<1.40) | >9.99 | |
| | 49795325 | *Escherichia coli* 0157:H7 (ATCC 43888) + 5% FBS | 4562-132 | <2.51 x $10^1$ (<1.40) | >9.99 | 2.04 x $10^5$ (5.31) |
| | | | 4699-40 | <2.51 x $10^1$ (<1.40) | >9.99 | |

**4. Soft, Non-Food Contact Surface Sanitizer (62.4g/L)**

| Contact Time | MRID No. | Organism | Results | | | | |
|---|---|---|---|---|---|---|---|
| | | | | 100% Plain Cotton Weave | | 100% Polyester | |
| | | | Batch# | CFU/Carrier (Average $log_{10}$) | Percent Reduction | CFU/Carrier (Average $log_{10}$) | Percent Reduction |
| 4.5 minutes | 49795326 | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | 4562-132 | 3.98 x $10^2$ (2.60) | >9.99 | <3.31 x $10^2$ (2.52) | >9.99 |
| | | | 4562-143 | 1.66 x $10^2$ (2.22) | >9.99 | <8.32 x $10^1$ (1.92) | >9.99 |
| | | | 4699-40 | <8.71 x $10^1$ (<1.94) | >9.99 | <3.80 x $10^1$ (<1.58) | >9.99 |
| | | **Carrier Population CFU/Carrier (Avg. $Log_{10}$)** | | **1.20 x $10^6$ (6.08)** | | **1.91 x $10^6$ (6.28)** | |
| | | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS | 4562-132 | <2.51 x $10^1$ (<1.40) | >9.99 | <2.51 x $10^1$ (<1.40) | >9.99 |
| | | | 4562-143 | <2.51 x $10^1$ (<1.40) | >9.99 | <2.51 x $10^1$ (<1.40) | >9.99 |
| | | | 4699-40 | <2.51 x $10^1$ (<1.40) | >9.99 | <2.51 x $10^1$ (<1.40) | >9.99 |
| | | **Carrier Population CFU/Carrier (Avg. $Log_{10}$)** | | **3.09 x $10^7$ (7.49)** | | **2.82 x $10^7$ (7.45)** | |
| | 49795327 | *Escherichia coli* 0157:H7 (ATCC 43888) + 5% FBS | 4562-132 | <2.51 x $10^1$ (<1.40) | >9.99 | <2.51 x $10^1$ (<1.40) | >9.99 |
| | | | 4779-9 | <2.51 x $10^1$ (<1.40) | >9.99 | <2.51 x $10^1$ (<1.40) | >9.99 |
| | | **Carrier Population CFU/Carrier (Avg. $Log_{10}$)** | | **1.74 x $10^5$ (5.24)** | | **1.48 x $10^7$ (7.71)** | |
| | 49795328 | *Salmonella enterica* (ATCC 10708) + 5% FBS | 4562-132 | <2.51 x $10^1$ (<1.40) | >9.99 | <2.51 x $10^1$ (<1.40) | >9.99 |
| | | | 4779-9 | <2.51 x $10^1$ (<1.40) | >9.99 | <2.51 x $10^1$ (<1.40) | >9.99 |
| | | **Carrier Population CFU/Carrier (Avg. $Log_{10}$)** | | **1.86 x $10^6$ (6.27)** | | **1.10 x $10^7$ (7.04)** | |

5. **Hard Surface Mildew-Fungistatic (62.4g/L):**

| Contact Time | MRID No. | Organism | Visual Evaluation | | Magnified Evaluation | | *Untreated Carrier Results (Pass/Fail) |
|---|---|---|---|---|---|---|---|
| | | | Batch #4562-132 | Batch #4699-40 | Batch #4562-132 | Batch #4699-40 | |
| Day 7 | 49795329 | *Aspergillus niger* (ATCC 6275) + 5% FBS | 0% coverage on 10 carriers | 0% coverage on 10 carriers | No growth on 10 carriers | No growth on 10 carriers | Pass on 10 carriers |

*To be considered passing, each control carrier must demonstrate ≥50% coverage at Day 7.

6. **Fabric Mildew-Fungistatic (62.4g/L):**

| MRID No. | Organism | Contact Time | Visual Evaluation | | Magnified Evaluation | | *Untreated Carrier Results (Pass/Fail) |
|---|---|---|---|---|---|---|---|
| | | | Batch #4562-132 | Batch #4699-40 | Batch #4562-132 | Batch #4699-40 | |
| 49795330 | *Aspergillus niger* (ATCC 6275) & *Penicillium variabile* (ATCC 32333) + 5% FBS | Day 7 | 0% coverage on 10 carriers | 0% coverage on 10 carriers | No growth on 10 carriers | No growth on 10 carriers | Pass on 10 carriers |
| | | Day 14 | 0% coverage on 10 carriers | 0% coverage on 10 carriers | No growth on 10 carriers | No growth on 10 carriers | Pass on 10 carriers |
| | | Day 21 | 0% coverage on 10 carriers | 0% coverage on 10 carriers | No growth on 10 carriers | No growth on 10 carriers | Pass on 10 carriers |
| | | Day 28 | 0% coverage on 10 carriers | 0% coverage on 10 carriers | No growth on 10 carriers | No growth on 10 carriers | Pass on 10 carriers |

*To be considered passing, each control carrier must demonstrate ≥50% coverage.

7. **Laundry Presoak Bactericide Disinfectant (62.4g/2L):**

| Contact Time | MRID No. | Organism | No. Carriers Exhibiting Growth/Total Carriers | | | Carrier Population ($Log_{10}$ CFU/Carrier) |
|---|---|---|---|---|---|---|
| | | | Batch #4562-132 | Batch #4562-143 | Batch #4699-40 | |
| 14.5 minutes | 49795331 | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | **2/60** | **3/60** | 1/60 | 6.50 |
| | | *Pseudomonas aeruginosa* (ATCC 15442) + 5% FBS | 0/60 | 0/60 | 0/60 | 7.09 |
| | | *Salmonella enterica* (ATCC 10708) + 5% FBS | 0/60 | 1/60 | 0/60 | 6.07 |
| 15 minutes | 49795332 | *Escherichia coli* 0157:H7 (ATCC 43888) + 5% FBS | 0/60 | -- | 0/60 | 6.58 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 49795333 | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS | 0/60 | -- | 0/60 | 7.07 |

## 8. Laundry Presoak Virucide Disinfectant (62.4g/2L):

| MRID No. | Contact Time | Organism | Results | | |
|---|---|---|---|---|---|
| | | | | Batch #4562-132 | Batch #4699-40 |
| 49795334 | 14.5 minutes | 2009-H1N1 Influenza A Virus (novel H1N1) + 5% FBS | **Description** | **Rep. 1** | **Rep. 1** |
| | | | $10^{-1}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.75 | ≥4.75 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.25}$** | |
| 49795335 | | Herpes simplex virus type 1 + 5% FBS | $10^{-1}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.75 | ≥4.75 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.25}$** | |
| 49795336 | | Rotavirus + 5% FBS | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity |
| | | | $10^{-2}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.25 | ≥4.25 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.75}$** | |
| 49795337 | | Rhinovirus type 39 + 5% FBS | $10^{-1}$ to $10^{-5}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/100µL | $\leq 10^{0.50}$ | $\leq 10^{0.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.75 | ≥4.75 |
| | | | **Dried Virus Control ($TCID_{50}$/100µL)** | **$10^{5.25}$** | |
| 49795338 | | Human Immunodeficiency virus type 1 + 5% FBS | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity |
| | | | $10^{-2}$ to $10^{-6}$ dilutions | Complete Inactivation | Complete Inactivation |
| | | | $TCID_{50}$/200µL | $\leq 10^{1.50}$ | $\leq 10^{1.50}$ |
| | | | $Log_{10}$ Reduction | ≥4.25 | ≥4.25 |
| | | | **Dried Virus Control ($TCID_{50}$/200µL)** | **$10^{5.75}$** | |

## 9. Laundry Presoak Sanitizer (62.4g/2L):

| Contact Time | MRID No. | Organism | Results | | | Carrier Population CFU/Carrier (Avg. $Log_{10}$) |
|---|---|---|---|---|---|---|
| | | | Batch# | CFU/Carrier (Average $log_{10}$) | Percent Reduction | |
| 9.5 minutes | 49795339 | *Staphylococcus aureus* (ATCC 6538) + 5% FBS | 4562-132 | $<3.02 \times 10^1$ (<1.48) | >9.99 | $1.15 \times 10^6$ (6.06) |
| | | | 4562-143 | $<3.02 \times 10^1$ (<1.48) | >9.99 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | 4699-40 | <3.47 x $10^1$ (<1.54) | >9.99 | |
| | | *Klebsiella pneumoniae* (ATCC 4352) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >9.99 | 1.51 x $10^6$ (6.18) |
| | | | 4699-40 | <3.02 x $10^1$ (<1.48) | >9.99 | |
| | | | 4779-9 | <3.02 x $10^1$ (<1.48) | >9.99 | |
| | 49795340 | *Escherichia coli* 0157:H7 (ATCC 43888) + 5% FBS | 4562-132 | <3.02 x $10^1$ (<1.48) | >9.99 | 7.41 x $10^5$ (5.87) |
| | | | 4699-40 | <3.02 x $10^1$ (<1.48) | >9.99 | |

## VI. CONCLUSION

1. The submitted efficacy data **support** the use of the product, Capricorn, as a disinfectant with bactericidal activity against the following microorganisms tested without a 5% organic soil load on hard, non-porous surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness for a 9.5 minute contact time.

   MRID 49795317 *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538)
   MRID 49795318 *Escherichia coli* 0157:H7 (ATCC 43888)

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of the product, Capricorn, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness for a 4.5 minute contact time.

   Cultures included 1% fetal bovine serum as organic soil load:
   MRID 49795319 2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009 CDC #2009712192
   MRID 49795320 Herpes simplex virus type 1, ATCC VR-733, Strain F(1)
   MRID 49795321 Rotavirus, ATCC VR-2018, Strain WA
   MRID 49795322 Rhinovirus type 39, ATCC VR-340, Strain 209

   Cultures included 5% fetal bovine serum as organic soil load:
   MRID 49795323 Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$

   Recoverable virus titer of at least 4 $log_{10}$ were achieved for the required product lots. Complete inactivation (no growth) was demonstrated in all dilutions tested. When cytotoxicity is evident, at least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

3. The submitted efficacy data **support** the use of the product, Capricorn, as a non-food contact sanitizer against the following microorganisms, tested with 5% fetal bovine serum

as organic soil load, on hard, non-porous surfaces when diluted using 62.4g of product in 2L of water of up to 100ppm hardness for a 4.5 minute contact time.

MRID 49795324 *Staphylococcus aureus* (ATCC 6538)
*Klebsiella pneumoniae* (ATCC 4352)
MRID 49795325 *Escherichia coli* 0157:H7 (ATCC 43888)

Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

4. The submitted efficacy data **support** the use of the product, Capricorn, as a non-food contact sanitizer against the following microorganisms, tested with 5% fetal bovine serum as organic soil load, on soft surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness for a 4.5 minute contact time (using plain cotton weave and polyester as the types of carriers).

   MRID 49795326 *Staphylococcus aureus* (ATCC 6538)
   *Klebsiella pneumoniae* (ATCC 4352)
   MRID 49795327 *Escherichia coli* 0157:H7 (ATCC 43888)
   MRID 49795328 *Salmonella enterica* (ATCC 10708)

   Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

5. The submitted efficacy data **support** the use of the product, Capricorn, as a mildew-fungistat against the following microorganisms, tested with 5% fetal bovine serum as an organic soil load, on hard, non-porous surfaces when diluted using 62.4g of product in 1L of water of up to 100ppm hardness after 7 days of incubation.

   MRID 49795329 *Aspergillus niger* (ATCC 6275)

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Purity controls were reported as pure. Sterility controls did not show growth.

6. The submitted efficacy data **support** the use of the product, Capricorn, as a mildew-fungistat against the following microorganisms, tested with 5% fetal bovine serum as an organic soil load, on fabrics when diluted using 62.4g of product in 1L of water of up to 100ppm hardness after 7, 14, 21, and 28 days of incubation.

   MRID 49795330 *Aspergillus niger* (ATCC 6275),
   *Penicillium variabile* (ATCC 32333)

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Purity controls were reported as pure. Sterility controls did not show growth.

7. The submitted efficacy data **did not support** the use of the product, Capricorn, as a laundry presoak disinfectant with bactericidal activity against the following microorganisms, tested

with 5% fetal bovine serum as an organic soil load, on stainless steel penicylinders when diluted using 62.4g of product in 2L of water of up to 100ppm hardness.

In 14.5 minute contact time:

| | |
|---|---|
| MRID 49795331 | *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538) |

In 15 minute contact time:

| | |
|---|---|
| MRID 49795332 | *Escherichia coli* 0157:H7 (ATCC 43888) |
| MRID 49795333 | *Klebsiella pneumoniae* (ATCC 4352) |

Killing was not observed in the subcultures of the required number of carriers tested against the required number of product lots. Data for *Staphylococcus aureus* (ATCC 6538) did not satisfy the performance standards, which specify that the product should kill all test microorganisms on 59 out of each set of 60 carriers in the specified contact time (Refer to OCSPP 810.2400 section (d)(1)(iii)(B)). Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

8. The submitted efficacy data below **support** the use of the product, Capricorn, as a laundry presoak disinfectant with virucidal activity against the following microorganisms, tested with 5% fetal bovine serum as an organic soil load, on glass petri dish surfaces when diluted using 62.4g of product in 2L of water of up to 100ppm hardness for a 14.5 minute contact time.

| | |
|---|---|
| MRID 49795334 | 2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009 CDC #2009712192 |
| MRID 49795335 | Herpes simplex virus type 1, ATCC VR-733, Strain F(1) |
| MRID 49795336 | Rotavirus, ATCC VR-2018, Strain WA |
| MRID 49795337 | Rhinovirus type 39, ATCC VR-340, Strain 209 |
| MRID 49795338 | Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$ |

Recoverable virus titer of at least 4 $\log_{10}$ were achieved for the required product lots. Complete inactivation (no growth) was demonstrated in all dilutions tested. When cytotoxicity is evident, at least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

9. The submitted efficacy data **support** the use of the product, Capricorn, as a presoak sanitizer against the following microorganisms, tested with 5% fetal bovine serum as organic soil load, on unglazed ceramic tiles when diluted using 62.4g of product in 2L of water of up to 100ppm hardness for a 4.5 minute contact time.

| | |
|---|---|
| MRID 49795339 | *Staphylococcus aureus* (ATCC 6538)<br>*Klebsiella pneumoniae* (ATCC 4352) |
| MRID 49795340 | *Escherichia coli* 0157:H7 (ATCC 43888) |

Product demonstrated at least 3 $\log_{10}$ reduction of the microorganisms for the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms (reported as passing). Purity controls were reported as pure. Sterility controls did not show growth.

## VII. LABEL RECOMMENDATIONS (Dilution of product must be done with deionized water or water with up to 100ppm hardness)

1. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a disinfectant with bactericidal activity against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 10-minute contact time with pre-cleaning instructions.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):
   *Pseudomonas aeruginosa* (ATCC 15442),
   *Salmonella enterica* (ATCC 10708),
   *Staphylococcus aureus* (ATCC 6538)
   *Escherichia coli* 0157:H7 (ATCC 43888)

   These claims **are supported** by the applicant's data

2. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a disinfectant with virucidal activity against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 5-minute contact time with pre-cleaning instructions.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):
   2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009
   Herpes simplex virus type 1, ATCC VR-733, Strain F(1)
   Rotavirus, ATCC VR-2018, Strain WA
   Rhinovirus type 39, ATCC VR-340, Strain 209
   Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$

   These claims are **supported** by the applicant's data.

3. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a non-food contact sanitizer against the following organisms for use on hard, non-porous surfaces using the following dilution rate in a 5-minute contact time.

   31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):
   *Staphylococcus aureus* (ATCC 6538),
   *Klebsiella pneumoniae* (ATCC 4352),
   *Escherichia coli* 0157:H7 (ATCC 43888)

   These claims **are supported** by the applicant's data.

4. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a non-food contact sanitizer against the following organisms for use on soft (fabric) surfaces using the following dilution rate in a 5-minute contact time.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):
   *Staphylococcus aureus* (ATCC 6538),
   *Klebsiella pneumoniae* (ATCC 4352),
   *Escherichia coli* 0157:H7 (ATCC 43888),
   *Salmonella enterica* (ATCC 10708)

   These claims **are supported** by the applicant's data.

5. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a mildewstat against the following organisms for use on soft (fabric) surfaces using the following dilution rate for a 28-day contact period.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):
   *Aspergillus niger* (ATCC 6275)

   These claims **are supported** by the applicant's data.

6. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a mildewstat against the following organisms for use on hard, non-porous surfaces using the following dilution rate for a 7-day contact period.

   62.4 grams of product/1 liter of water (236 grams product/1 gallon of water):
   *Aspergillus niger* (ATCC 6275),
   *Penicillium variabile* (ATCC 32333)

   These claims **are supported** by the applicant's data.

7. The proposed label claims are not acceptable regarding the use of the product, Capricorn, as a laundry presoak disinfectant against the following organisms for use in laundry using the following dilution rate by total immersion application for a 15-minute contact time.

   31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):
   *Pseudomonas aeruginosa* (ATCC 15442),
   *Salmonella enterica* (ATCC 10708),
   *Staphylococcus aureus* (ATCC 6538),
   *Escherichia coli* 0157:H7 (ATCC 43888),
   *Klebsiella pneumoniae* (ATCC 4352),
   2009-H1N1 Influenza A virus, Novel H1N1, Strain A/Mexico/4106/2009,
   Herpes simplex virus type 1, ATCC VR-733, Strain F(1),
   Rotavirus, ATCC VR-2018, Strain WA,
   Rhinovirus type 39, ATCC VR-340, Strain 209,
   Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$

   These claims **are not supported** by the applicant's data. In addition, product must be approved as a disinfectant with bactericidal activity against the base microorganisms to qualify as a disinfectant with virucidal activity.

8. The proposed label claims are acceptable regarding the use of the product, Capricorn, as a laundry presoak sanitizer against the following organisms for use in laundry using the following dilution rate by total immersion application for a 10-minute contact time.

   31.2 grams of product/1 liter of water (118 grams product/1 gallon of water):
   *Staphylococcus aureus* (ATCC 6538)
   *Klebsiella pneumoniae* (ATCC 4352)
   *Escherichia coli* 0157:H7 (ATCC 43888)

   These claims **are supported** by the applicant's data.

9. On the proposed label, registrant must remove laundry pre/post-soak disinfection use and all claims associated with pre/post-soak laundry disinfection. Data did not show the required performance level for laundry pre-soak disinfection.

10. On the proposed label, registrant must include the dilution of product in water that has up to 100 ppm Calcium carbonate, which accurately represents the hardness of the water used for testing. Regular tap water contains more than 100 ppm of hard water and cannot be used to dilute the product.

11. On the proposed label, registrant must add pre-cleaning instructions to all application uses on hard, non-porous surfaces (i.e. disinfectant, sanitizer and mildewstat). Registrant must also remove "one-step" claims from these uses. Product was not tested using at least 5% organic soil load for hard, non-porous surface disinfection.

12. On page 3 of the proposed label, under Laundry Sanitization, registrant must specifically instruct users to prepare the solution accordingly using the accurate doses of product in the required amount of water (as tested) for laundry immersion before adding the treated load to the washing machine. The contact time and amount of water to dilute the product generated from washing machines are difficult to measure and monitor if presoak sanitization were to be done inside the washing machines.

13. On the proposed label, registrant must remove all claims against cold viruses and claims concerning cold prevention. Agency's criteria for this claim requires effectiveness against 2 of the 3 cold-associated viruses, which are Rhinovirus, Coronavirus, and Respiratory Syncytial virus.

14. On page 4 under soft surface sanitization, the term "spot" should be removed from the brackets as it is not optional.

15. On the proposed label, registrant must remove all claims against "black mold". The microorganisms tested are not considered black mold-associated microorganisms.

16. On page 7 of the proposed label, under "Marketing Claims", registrant must remove the claim "ready to use".

17. On the proposed label, registrant must remove all claims concerning "antibacterial protection".

18. On page 12 of the proposed label, registrant must specify the claim concerning "cross contamination". Registrant must specify the claim to, "Can help prevent cross-contamination between treated surfaces by [household] bacteria."

19. On page 13 of the proposed label, registrant must remove the brackets from the word "surfaces" from the claim, "[This product] will help [you] keep your [surfaces] clean [and disinfected]". This term is not optional.

20. On pages 13 and 14 of the proposed label, remove the "99.99%" claims from multiple locations under the hard, non-porous disinfection section.

21. On page 14 of the proposed label, registrant must remove "more than" from the claim "Kills more than 99.9% of bacteria and viruses".

22. On page 21, Table 8: Testing and Dilution Type, Fungi must be removed from the Type of Organism column. The name, "Mold and mildew", is more appropriate according to Agency's criteria.

23. On the proposed label, registrant must qualify all of the "virus", "virucide", and "virucidal" claims with an asterisk or other symbols to refer the claims mentioned to the viruses tested.

24. On the proposed label, registrant must remove all claims against "fungi", "fungus" and "fungal spores". Product was not tested against the Agency-required microorganism to qualify for the claims.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

June 7, 2016

MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA Reg. No.: 10772-EG
Capricorn
DP Barcode: D432546

FROM: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Julie Chao PM 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Church & Dwight Company, Inc.

FORMULATION FROM LABEL:

| | |
|---|---|
| Active Ingredient(s): | |
| Sodium percarbonate | 18.50 % |
| Tetraacetylethylenediamine | 4.44 % |
| Other Ingredient(s): | 77.06 % |
| Total: | 100.00 % |

BACKGROUND: The registrant has submitted an acute toxicity package for the registration of this integrated end-use product for non-food use. The package includes a label, a Confidential Statement of Formula (CSF) for the basic formulation, an acute oral toxicity study (MRID 49795311), an acute dermal toxicity study (MRID 49795312), an acute inhalation toxicity study (MRID 49795313), an eye irritation study (MRID 49795314), an acute dermal irritation study (49795315), and a dermal sensitization study (MRID 49795316).

FINDINGS:

1. The acute toxicity studies are **acceptable**.

2. The current acute toxicity profile for EPA Registration 10772-EG is:

| Study | MRID Number | Toxicity Category | Status |
|---|---|---|---|
| Acute Oral Toxicity | 49795311 | III | Acceptable |
| Acute Dermal Toxicity | 49795312 | IV | Acceptable |
| Acute Inhalation Toxicity | 49795313 | IV | Acceptable |
| Acute Eye Irritation | 49795314 | I | Acceptable |
| Acute Dermal Irritation | 49795315 | IV | Acceptable |
| Dermal Sensitization | 49795316 | Nonsensitizer | Acceptable |

**LABELING**

1 The signal word is **DANGER**.

2. This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.

3. Based upon data placing it in toxicity category I for primary eye irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP in addition to Restricted-Use Classification. CRP requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that

the Product Manager assign this product Restricted-Use classification; if not, the registrant should place this product in CRP. The CRP statements are **acceptable**.

4. The precautionary statements must read, "Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse."

5. The first aid statements must read:

**If in eyes**:

-Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.

-Call a poison control center or doctor for treatment advice.

**If swallowed**:

-Call a poison control center or doctor immediately for treatment advice.

-Have a person sip a glass of water if able to swallow.

-Do not induce vomiting unless told to by a poison control center or doctor

-Do not give anything by mouth to an unconscious person.

6. The following first aid statements are optional:

**If inhaled**:

-Move person to fresh air.

-If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

**If on skin**:

-Take off contaminated clothing.

-Rinse skin immediately with plenty of water for 15-20 minutes.

-Call a poison control center or doctor for treatment advice.

7. The **Note to Physician** "Probable mucosal damage may contraindicate the use of gastric lavage" must be added to the label because the product is toxicity category I for eye irritation.

# PROCESSING REQUEST

**Reg #** 10772-23 **Decision #** 514854

**Description:** New Registration

| **Electronic Label & Letter** (see PPLS): | OR | **Non Electronic Label & Letter** (Scanning required): |
|---|---|---|
| ☒ Dated: 8/26/16 | | ☐ Dated: |

***Only one label type should be selected***

## Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 2/12/16 (Basic)

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

**Reviewer:** Julie Chao

**Division:** AD/RMB1

**Phone:** 308-8735 **Date:** 8/26/16

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

| EPA Reg. Number: | Date of Issuance: |
|---|---|
| 10772-23 | 8/26/16 |

**Term of Issuance:** Conditional

**Name of Pesticide Product:** Capricorn

**Name and Address of Registrant (include ZIP Code):**

Church & Dwight Co., Inc.
500 Charles Ewing Blvd.
Ewing, NJ 08628

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

**Signature of Approving Official:**

Julie Chao, Product Manager 33
Regulatory Management Branch 1, Antimicrobials Division (7510P)

**Date:** 8/26/16

EPA Form 8570-6

2. Be aware that proposed data requirements have been identified in a Final Work Plan for TAED. For more information on these proposed data requirements, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division.

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

4. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 10772-23."

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 02/12/2016

If you have any questions, please contact me by phone at (703) 308-8735, or via email at chao.julie@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1

Enclosure: Accepted Label

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Capricorn

{Alternate Brand Names}

OXICLEAN™ Antibacterial Cleaner

OXICLEAN™ Antibacterial Laundry Additive

OXICLEAN™ Antibacterial [Chlorine]Bleach Alternative

OXICLEAN™ White Revive Laundry Stain Remover [with Disinfection]

OXICLEAN™ Color Safe Disinfection

KABOOM™ Plus Disinfex [Toilet Bowl Cleanser]

OXICLEAN Antibacterial Versatile Stain Remover & Disinfectant [Kills 99.9% of Bacteria & Viruses*]

**Active Ingredient:**

| | |
|---|---|
| Sodium Percarbonate | 18.50% |
| Tetraacetylethylenediamine | 4.44% |
| Other ingredients | 77.06% |
| Total: | 100.00% |

**FRONT PANEL:**

**DANGER**
KEEP OUT OF REACH OF CHILDREN

**See back panel for First Aid and additional Precautionary Labeling.**
EPA Reg. No. #10772-XX

EPA Establishment #XXXXX-XX-XXX, #XXXXX-XX-XXX

Manufactured [by] [for]:
Church & Dwight Co., Inc.
500 Charles Ewing Blvd.
Ewing, NJ 08628

ACCEPTED
Aug 26, 2016
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 10772-23

Net contents:
1.7 LB (0.77kg)
2.0 LB (0.90kg)
2.5 LB (1.13kg)
2.6 LB (1.17kg)
3.0 LB (1.36kg)
4.0 LB (1.81kg)
4.5 LB (2.04kg)
5.0 LB (2.26kg)
6.5 LB (2.94kg)
10.0 LB (4.53kg)
10.5 LB (4.76kg)
11.0 LB (4.98kg)
13.5 LB (6.123kg)

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

*{NOTE TO REVIEWER: This product meets the EPA's criteria of Toxicity Category 1 for the eye route of exposure, Toxicity Category 3 for orol route of exposure and Toxicity Category 4 for all other routes of exposure. Therefore a Signal Word, Precoutionary Languoge and First Aid Statements are required in accordance with EPA Label Review Manual: Chapter 7. The Precautionary Stotements and First Aid Statements below are mandotory and will appear on the cantainer labeling. The skin and inhalation first aid statements below are optionol os the corresponding acute toxicity studies were Toxicity Category 4.}*

**BACK PANEL:**

**PRECAUTIONARY STATEMENTS: Hazardous to Humans and Domestic Animals**

**Danger.** Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**FIRST AID. If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. **If swallowed**: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person. [**If on skin:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.][**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.] Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, call the National Pesticides Information Center at 1-800-858-7378. For emergencies, call the poison control center 1-800-222-1222. **Note to Physician** - Probable mucosal damage may contraindicate the use of gastric lavage

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label.

[[1]] Always ensure powder is fully dissolved.

[[2] [Always test [product] [powder] on an inconspicuous area first.]

[[3] [Follow manufacturer's instructions for cleaning.]

[[4] [Do not use on] [wool] [wool blends], [silk], [silk blends], [leather], [or on] [fabrics labeled dry clean only.] [Not for use on] [jewelry], [latex paints], [woven baskets], [unpainted wicker]. [jute], [teak], [or] [unfinished wood]. [Metal must not be soaked and must be rinsed immediately and thoroughly.] [Not for use on] [rust], [dried paint], [or bleach damage].]

[[5] [Treat stains while fresh. Do not place fabric that has not been thoroughly rinsed into dryer.]]

[[6] [Some stains require repeated or longer treatments.] [Adding more [powder] [product] than directed increases the risk of color loss.] [Do not rinse or soak overnight.]]

**[Shake container before pouring.]**
**[[Before pouring,] [G][g]ently tap container on a [hard] surface.]**

## LAUNDRY [USE]

[To] Clean [and] [&] [Remove Stains]: [Soak [1- 6 hours] for best results]
TOP LOADER: Fill washer [drum] with water. Add up to [1] [2] [scoop] [scoops] [cap] [caps] [capful] [capfuls] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. [Add detergent directed.] [Add regular laundry detergent.]
HE WASHER[**]: Add up to [1] [2] [scoop] [scoops] [cap] [caps] [capful] [capfuls] [of product] [of powder] [into] [to] washer [drum] BEFORE adding laundry. [**Do not mix [powder] [product] with detergent in the dispenser.]

**[LAUNDRY] [SANITIZATION] [and] [DISINFECTION]**

[To] Sanitize [Laundry]:
[Pre-soak [Use]:] *{Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.* Immerse laundry for [at least] 10 minutes prior to starting the wash cycle. [Light soils do not require precleaning.] Effective against *{insert laundry sanitization bacteria from Table 7.}*

[To] Disinfect [Laundry]:
[To kill] bacteria and viruses†[:] *{Insert directions for 1X dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}* . Immerse laundry for [at least] 15 minutes prior to starting the wash cycle. [Light soils do not require precleaning.] Effective against *{insert laundry disinfectian bacteria and/or viruses from Table 7}.*

[Post-Wash [Sanitization/Disinfection] [Use]: For additional sanitization/disinfection, refill washing machine with [clean] water. *{insert directions for "1X" and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}* in washing machine. Immerse laundry for [at least] 10 minutes for sanitization or 15 minutes for disinfection. Rinse thoroughly.]

[Safe for colorfast fabrics][Follow manufacturer's instructions for water temperature and for cleaning garment or item.]

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

## HOUSEHOLD USE

### HARD NON-POROUS [SURFACES]

[To] Clean [and] [&] [Remove Stains]:
[1] *{Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [using a] [cloth] [sponge] [brush] [mop] [or by] [pouring] [solution] directly onto surface.
[3] Let stand 5-30 [minutes] [min]. Scrub as needed.
[4] Rinse thoroughly {with] [cool] [water] [and let air dry].

[[For use on] [Use only on] {Insert hard non-porous surfaces from Table 3 and/or 5}]

[To] Sanitize [Hard Surfaces]:
[1] *{Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 5 minutes.
[3] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop]. [Pre-clean heavily soiled surfaces.] [*Effective against {Insert non-food contact sanitization bacteria from Table 7}.]*

[To] Disinfect [Hard Surfaces]:
[1] Pre-clean surface.
[2] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[3] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 10 [minutes] [min.] for bacteria and 5 [minutes] {min.] for viruses†.
[4] Wipe clean [using a] {with a] [damp] [cloth] [sponge] [or] [mop]. [Effective against *{Insert disinfection bacteria and/or viruses from Table 7}.]*

[To] Prevent Mold [and Mildew]:
[1] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (cops)}.*
[2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet.
[3] Air dry. Repeat [application] every 7 days [to inhibit] [mold] [and mildew] [growth]. [Effective against Aspergillus [A.] niger [mildew].

### SOFT SURFACES [AND] [&] [FABRICS]

[To] Clean [and] [&] [Remove Stains]:
[1] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [only] [enough] solution to saturate [the] stain. Let stand 1-5 [minutes] [min].
[3] Blot [stained] [area] [gently] with a [white] [dye-free] cloth. Repeat [steps 2 and 3] until stain is no longer visible.
[4] Rinse [surface] with [clean] water and pat dry.

[To] Spot Sanitize [Soft Surfaces]:
[1] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Saturate [fabric] surface until it is thoroughly wet. Let stand 5 minutes.
[3] [Blot] [stained] [area] [gently] with a [white] [dye-free] [cloth] [or sponge]. [Pre-clean heavily soiled surfaces.] *{Effective against {Insert soft surface sanitization bacteria from Table 7}.*] [Blot dry with cloth.]

[To] Prevent Mold [and Mildew] [growth] [on Fabric] :
[1] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] [Saturate] [Mop, spray, wipe or sponge on] [fabric] surface until thoroughly wet.

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

[3] Air dry. [Pre-clean heavily soiled surfaces.] Repeat [application] every 28 days [to inhibit] [mold] [and mildew] [growth]. [Effective against Aspergillus [A.] niger [mildew] and Penicillium [P.] variable.

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1 AIDS Virus] ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids; and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV-1 [associated with AIDS].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface/object to remain wet for 5 minutes for HIV-1 on hard non-porous surfaces. For laundry allow object to pre-soak for 15 minutes for HIV-1.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

***{Residential Containers}***

**STORAGE AND DISPOSAL:**
Store in original container in areas inaccessible to children and pets. Keep securely closed. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.
***{Institutional Containers}***
*{Nonrefillable containers}*

**STORAGE AND DISPOSAL:**
Do not contaminate water, food or feed by storage and disposal.
**PESTICIDE STORAGE:** Store in original container in areas inaccessible to children and pets. Keep securely closed.
**PESTICIDE DISPOSAL:** To avoid waste, use all material in this container according to label directions. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.
**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Questions or Comments:
[Call]1.XXX.XXX.XXXX
Mon-Fri 9AM-5PM ET

Website:
www.oxiclean.com/XXXXXXX
www.kaboomkaboom.com/XXXXXXX

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

*NOTE: Any claim may appear on either FRONT / BACK panel in bullet / paragraph formot*

**Marketing Claims:**

1. [Clean & Simple]
2. [Complete]
3. [Complete OXICLEAN™ Clean]
4. [Easy]
5. [Easy to use]
6. [Everyday Cleaner]
7. [Everyday Use]
8. [Effective]
9. [$O_2$ Powered]
10. [Oxygen Powered]
11. [Modern]
12. [Multi-Action]
13. [Multi-Clean]
14. [Multi-Purpose]
15. [Multi-Surface]
16. [Multi-Task]
17. [Power & Clear]
18. [Simple Power]
19. [Triple Action]
20. [Streak-Free]
21. [Versatile][with Oxygen]
22. [Beautiful]
23. [Bright]
24. [Brilliant]
25. [Glistening]
26. [Shine] formula
27. [Cleaner]
28. [Cleans]
29. [Cleaning]
30. [Degreaser]
31. [Degreases]
32. [Grease releaser]
33. [with Grease Release Action]
34. [Deodorize]
35. [Deodorizer]
36. [Deodorizes]
37. [Deodorizing]
38. [Bathroom]
39. [Floor]
40. [Kitchen][Multi-Purpose] [Cleaner] [Disinfectant] [Deodorant]
41. [Cleans][Cuts][Cuts through] [Degreases] [Destroys] [Dissolves][Eliminates] [Penetrates] [[Removes][the following] {*Insert one or more items from Table 1*}] [tough] [the toughest] [even the toughest] [stubborn] [everyday] [stains] [with no] [without] [chlorine bleach] [with no] [without] [chlorine bleach]
42. [Effective]
43. [Effectively]

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

44. {Effortlessly}
45. [Fresh] [Good][Great][Maximum Cleaning Power][Smell][Smelling] [Smells]
46. [Clean] [Cleans] [Cleaner] [Cleaning]

47. New [!] *{to be used as a claim descriptor only for the first 6 manths on shelf}*

48. From OXICLEAN™, your stain removal partners

49. It's from OXICLEAN™, removing stains *{insert stain from Table 1}* for over XX years

50. From the makers of OXICLEAN™, tackles the toughest stains *{insert stain from Table 1}* all around the house [in the home]

51. From OXICLEAN™, tackling the toughest stains *{insert stain from Table 1}* all around the house [in the home] for XX years

52. Leaves surfaces sparkling

53. Clear drying formula for multiple surfaces

54. Clean the OXICLEAN™ way

55. [Clean] with the power of Oxygen

56. Bleach like whitening

57. From couch to counter

58. *{Insert number of loads according to package weight and corresponding value on Table 11}.* [Mix until powder is fully dissolved]{Laundry] [Disinfecting] [Disinfection] Loads

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

**Fragrance Claims**

1. Fresh Scent
2. Fresh Water Splash
3. Fresh Water Sparkle
4. Fresh Water Springs
5. Arctic Chill
6. Arctic Splash
7. Blue Wave
8. Cool Summer Shower
9. Classic Clean
10. Crisp Morning Air
11. Ocean Air
12. Moonlit Ocean
13. Rain Mist
14. Refreshing spring
15. Sparkling Water
16. Summer Dew
17. Waterfall
18. Water Lily

**Packaging Claims**

1. [Bonus]
2. [Bonus x%]
3. [Bonus x oz.]
4. [X% Discount]
5. [X% More Free]
6. [X oz. Free]
7. [X oz. at x oz. Price]
8. [X oz. for the x oz. Price]
9. [X oz. at the Price of x oz.]
10. [X oz. for the Price of x oz.]
11. [More than]
12. [Over]
13. [Great]
14. [Mega]
15. [Super]
16. [Trial]
17. [Value]
18. [Pack]
19. [Refill]
20. [Size]
21. [Money back guarantee]
22. [Satisfaction guaranteed]
23. [Your # 1 choice]
24. [For more stain fighting ideas visit [website]]

**Cleaning Claims**

1. [A] friendly [cleaner] [cleaning]
2. A shining [beautiful] clean you can see/trust
3. All-in-1 [complete] [cleaning] [action]

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

4. Alternative [chlorine] bleach cleaner
5. [Available in] [Economy] Economical refill
6. Bathrooms, sinks and faucets and floor areas
7. Better than ever on {stains} *{insert stain from Table 1 below}*
8. Bleach-free
9. Bleach power without the damaging effects and chlorine [fumes] [smell]
10. Boost Laundry Cleaning Power
11. Breaks down [and lifts out] tough stains with supercharged OXICLEAN™ Stain Fighters
12. Brightens
13. [Chlorine] Bleach alternative
14. Chlorine bleach alternative cleaner
15. [Chlorine] bleach free
16. Chlorine free
17. Chlorine free bleach
18. [OXICLEAN™] [a clean] you can trust
19. Cleans
20. Cleans bathroom soils
21. Cleans blood
22. Cleans everyday messes
23. Cleans fingerprints
24. Cleans food
25. Cleans mildew [stains] [odor]
26. Cleans rust stains
27. Cleans to a shine
28. Cleans [up] grease and grime
29. Cleans x [countertops] [floors] [square feet] [area]
30. Cleans and shines
31. Cleans [and smells] [great] [fantastic]
32. Cleans non-food contact surfaces
33. Cleans {tough] grease [better than] [ever] [before]
34. Cleans with a {sparkling] [fresh] [floral] [citrus] scent
35. Cleans without leaving a [dull] residue [behind]
36. Clings to surfaces for a powerful clean
37. Color safe
38. Compatible with equipment surfaces *{insert surface/site from Table 3, 5, 6}*
39. [Compatible with -or- Suitable] [for use on] equipment surfaces
40. Compatible with -or- Suitable –or compatible with equipment surfaces for computer surfaces
41. VOC Compliant
42. Confidence in cleaning
43. Contains [just enough] [cleaning] ingredients for [those] everyday touch ups
44. Contains maximum stain fighting power
45. Contains [effective] [fast-acting] [grease cutters] [cleaning agents]
46. Contains no [chlorine] bleach
47. Contains [water] and [active] [oxygen]
48. Controls [pet] [smoke] [cooking] odors [fast] [quickly]
49. Convenient [surface] cleaner *{insert surface/site from lists below}*
50. Convenient [kitchen] [and] [bathroom] surface cleaner *{insert surface/site from lists below}*
51. Customize your cleaning
52. Cuts -and/or- removes grease -and/or grime-and/or- sweat
53. Cuts Tough Grime without 5crubbing

54. Cuts cleaning time
55. Deep down clean
56. Designed -or- Ideal for daily [cleaning] [use]
57. Designed – or – Ideal for in home cleaning
58. Does not contain [chlorine] bleach
59. Does not contain [dyes]
60. Dye free
61. Easy [cleaning]
62. Easy to use [formula] [formulation]
63. [Easily] removes soap scum
64. Easily removes soap scum, hard water stains, and [dirt][grime]
65. Effective [cleaner -or- cleaning] [formula]
66. Effective cleaning [without chlorine bleach]
67. Effectively works on [many] [hard] non-porous surfaces
68. Efficacious cleaner [without compromise]
69. [OXICLEAN™] essential for oxygen clean
70. Foaming action penetrates your toughest messes
71. Foams [and] [bubbles] so you know it's working
72. For a deep down clean
73. For a deep clean
74. For easy cleaning
75. For everyday [use] [usage] [touch-ups]
76. For multiple cleaning [tasks]
77. Free from [chlorine] bleach
78. Friendly to your [floor] surfaces
79. Friendly to your clothes
80. Get a true clean [with] [this product]
81. Gives you multiple cleaning actions [-] [removes] [eliminates] [cuts through] [stains] *{insert stain from Table 1}* [and] [deodorizes]
82. Go ahead [use around the house on floors] [and counters]
83. Good for use with microfiber cloths
84. Grease cut [-ter] [-ting] formula
85. Groundbreaking formula [is a] cleaner + stain remover + antibacterial protection
86. Help[s] make your room OXICLEAN™ clean
87. Ideal for larger soft surface areas like [couches, throw rugs, curtains] [sanitize and] to remove stains
88. Ideal for larger surface areas like couches, rugs and countertops
89. Ideal for use in gyms -and/or- health clubs-and/or- wellness centers
90. Ideal for use in schools -and/or- offices -and/or- public places
91. Ideal for use on high touch surfaces
92. Just [apply] mixture[,] wipe. rinse [and you're done] [; no scrubbing required!]
93. Knocks out the toughest kid and pet messes, removing stains and odor [on carpet] [in laundry]
94. Knocks out the toughest kid and pet messes, removing stains and odor [fabrics]
95. Labor saving no-rinse formula
96. Leaves a [long-lasting] [fresh] [clean] scent
97. Leaves a [whitening] shine
98. Leaves no [dull] [filmy] [sticky] residue
99. Leaves nothing behind [except] [but] [the] [smell] [of clean] [shine]
100. Leaves [virtually] no [annoying] [chemical] [scum] [residue] [film]
101. Leaves your *{insert surface/site from Table 3, 5, 6}* [fresh] [clean] [and] [fragrant]
102. Leaves your *{insert surface/site from Table 3, 5, 6}* [fresh] [clean] [and] [sparkling] [shiny]

103. Leaves your *{insert surface/site from Table 3, 5, 6}* [with a] [fresh] [and] [clean] scent
104. Lifts out [and breaks down] tough stains with supercharged OXICLEAN™ Stain Fighters
105. Light touch-up quick cleaning
106. Makes your [floor] cleaning job easier [in the] [kitchen] [and] [bathroom]
107. Makes grout and hard surfaces look radiant
108. Makes cleaning easier
109. Money-saving formula [use everywhere] [use in laundry & to clean surfaces]
110. [Multipurpose][Versatile] Cleaner
111. No [chlorine] bleach harshness
112. No [chlorine] bleach [fumes] [smell]
113. No harsh chemical residue
114. No harsh chlorine [bleach] fumes -or- smell –or odor-and/or- build-up -and/or- residue
115. No mess [cleaner] [cleaning]
116. No mixing, measuring, or rinsing required
117. No phosphates
118. No scrubbing necessary!
119. No sorting necessary!
120. No [sticky] [tacky] [residue] [film]
121. Non-abrasive
122. Non-[chlorine] bleach
123. Now cleans [tough] grease [better than] [ever] [before]
124. Packaging made with [x%] recycled –or recyclable plastic
125. Pleasant smell
126. Powerful [cleaner] [additive]
127. Proof is in the clean
128. Quickly deodorizes
129. [Quickly] removes dirt and grime
130. Radiant shine
131. Releases powerful cleaning agents [on contact]
132. Releases powerful OXICLEAN™ Stain Fighters [on contact]
133. Removes offensive odors from *{insert surface/site from Table 3, 5, 6}*
134. Removes [oxidizable] stains
135. Removes stains
136. Shine[s] like new
137. Smell of clean
138. Sparkling shine
139. Stain remover
140. Stains disappear [before your eyes]
141. Starts cleaning on contact
142. Starts to work before you do [on]
143. Starts to work before [you do] [your eyes]
144. Strong cleaning
145. Strong [effective] cleanser
146. Strong effective cleanser [with a] [non-chemical] [fresh] [scent]
147. Strong effective cleanser [with a non-chemical scent]
148. Suitable for everyday use
149. [The] smell of clean
150. The smell of [OXICLEAN™] [clean]
151. The toughest stains [instantly] disappear
152. [This product] cleans and shines

153. This product's formula cleans and shines
154. This room is OXICLEAN™ clean
155. Tough on grime
156. Tough stains [instantly] disappear
157. Trusted heritage [of] [Oxygen Cleaning]
158. Versatile for all bathroom surfaces
159. Watch [this] [these] stains [start to] [disappear] [dissolve] [breakdown] right before your eyes
160. Watch [this] [the] [tough] [toughest] stains disappear
161. Works great [smells great]

**Stain Claims**

1. Removes -and/or- Cleans the following: *[insert stain(s)/soil(s) from Table 1]*
2. Removes dried on [blood]
3. Removes grease and grime
4. Removes *[insert stain(s)/soil(s) from Table 1]*
5. Removes [tough] *[insert stain(s)/soil(s) from Table 1]*
6. Use it [in the wash or] [as a] pre-treater [with it] to remove more stains

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

**Deodorizing Claims**

1. Deodorizer
2. Deodorizes
3. Deodorizes food odors [like garlic and onion] [left behind on kitchen surfaces] [after cooking]
4. Eliminates odors [as it cleans]
5. No harsh chlorine [fumes] [smells]
6. No harsh alcohol smell
7. Pleasant odor
8. Removes odors
9. [This product] will deodorize hard, nonporous surfaces from [where obnoxious odors may develop]
10. [This product] will deodorize surfaces in [and] [other] places bacteria growth can cause malodors

**General Antimicrobial Claims**

1. [3-in-1] [clean –s, -er, -ing][deodorize –s, -er, -ing][disinfect –s, -ant, -ing]
2. [3x Cleaning Power] [clean -s][deodorize -s][disinfect -s]
3. 3 [cleaning] actions [in one bottle] [clean –s, -er, -ing] [deodorize -s, -er, -ing] [disinfect -s, -ant, -ing]
4. 3 [cleaning] actions [in one bottle] [remove -s stains] [clean -s] [disinfect –s] [deodorize -s]
5. [4-in-1] [clean–s, -er, -ing][disinfect –s, -ant, -ing]{remove -s non-living allergens][sanitize -s hard surfaces][sanitize -s fabric -s]
6. [4x Cleaning Power] [cleans]][disinfects][removes non-living allergens][sanitizes hard surfaces][sanitizes fabrics]
7. [4-in-1] [cleans][disinfects][removes non-living allergens][sanitizes hard surfaces][sanitizes fabrics]
8. 4 [cleaning] actions [in one bottle] [disinfects] [removes non-living allergens] [sanitizes hard surfaces] [sanitizes fabrics]
9. 3-in-1 Bathroom Cleaner [Disinfectant] [Cleaner] [Deodorizer]
10. A convenient way to [clean] [disinfect] [and] [deodorize]
11. [All-in-1] [cleaner][deodorizer][disinfectant]
12. [All-in-1 Complete] [cleaner/cleans][deodorizer/deodorizes][disinfectant/disinfects]
13. For a better [4-in-1] [kind of] clean [disinfects] [removes non-living allergens] [sanitizes hard surfaces] [sanitizes fabrics]
14. For [a] complete [clean] [cleaning action]
15. [Antibacterial] [Antibacterial Action] [Bactericidal] [Bactericide] [Germicidal*] [Virucidal†]
16. [Disinfect] {Disinfects} [Disinfectant] [Disinfecting]
17. Antibacterial Cleaner cleans and kills bacteria
18. Antibacterial [surface] *{insert surface/site from Table 3, 5, 6}* cleaner
19. Antibacterial [kitchen] [and] [bathroom] surface *{insert surface/site from Table 3, 5, 6}* cleaner
20. Antibacterial 4-in-1 action [disinfects] [removes non-living allergens] [sanitizes hard surfaces] [sanitizes fabrics]
21. Can help prevent cross-contamination on treated surfaces by [household] bacteria
22. Cleans & Disinfects *{insert hord nonporous surfaces from Table 5}*
23. Cleans as it disinfects
24. Cleaner + stain fighting power + antibacterial protection for all around the house
25. Combines [streak-free] cleaning with antibacterial action
26. [Kills][Effective against] [Controls] odor-causing bacteria
27. [Kills][Effective against] [Controls] odor-causing bacteria in the [kitchen] [and] [bathroom]
28. Designed as a general [multipurpose] [multi surface] [versatile] cleaner and disinfectant
29. Disinfection for your [kitchen] [and] [bathroom] [floors]
30. Disinfects [and] [deodorizes]
31. Disinfects [and] [deodorizes] hard, non-porous surfaces
32. [Disinfectant] [Cleaner] [Deodorizer]
33. Helps prevent the spread of cold° and flu[‡] viruses†
34. Multi surface [multipurpose] [versatile] cleaner disinfectant

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

35. Oxygen-based formula cleans and sanitizes
36. Surface cleaner [with antibacterial formula]
37. [This product] deodorizes areas that are hard to keep fresh smelling [or other areas prone to odors caused by microorganisms]
38. [This product] will help [you] keep your surfaces clean [and disinfected]
39. Three steps to clean [Disinfectant] [Cleaner] [Deodorizer]
40. Use [only] one product to get a streak-free shine [plus antibacterial action]
41. Deodorizes odors caused by bacteria
42. Kills odor causing bacteria in the kitchen -or- bathroom

**Hard Non-Porous Surface Sanitizing Claims**

1. Sanitization [against bacteria]
2. Oxygen based formula cleans and sanitizes
3. Kills [and] [Sanitizes] 99.9% of bacteria [including] [*Insert 1 or more strains from Table 7 under non-food contact sanitization]*
4. Powers out the toughest stains and bacteria without stripping color
5. Sanitizer [Sanitizes]
6. [5 minute] [One Step] [1 Step] Sanitizer
7. [5 minute] [One Step] [1 Step] Non-Food Contact Sanitizer
8. Cleans and sanitizes [in One Step]
9. Cleans, deodorizes, and sanitizes in one step
10. When you need sanitization!
11. When you need to kill bacteria [in one [easy] step]!
12. Kills 99.9% bacteria [in 5 minutes]!
13. In 5 minutes, 99.9% bacteria are dead!
14. Kills 99.9% {*Insert bacteria from Table 7 list under non-food contact sanitizer}* [in 5 minutes]
15. {Non-Food Contact Sanitizer] Effective against {*Insert bacteria from Table 7 list under non-food contact sanitizer}*
16. Kill bacteria where you need it most
17. Eliminates 99.9% of [household] bacteria in 5 minutes

**Hard Non-Porous Surface Disinfecting Claims**

1. [Chlorine] Bleach-free
2. Broad spectrum [general] [hospital] disinfectant
3. Destroys bacteria on {*insert site from Table 3, 5, 6*}
4. Disinfectant [&] Cleaner
5. Disinfects bathroom bacteria
6. Kills [*insert organism(s) from Table 7*}]
7. Kills bacteria on {*{insert surface/site from Table 3, 5, 6*}
8. Oxygen-based [disinfectant] kills [99.9%] of bacteria/viruses†
9. Oxygen-based [disinfectant] [cleaner] kills [99.9%] of bacteria/viruses/germs*
10. Reduces bacteria on {*{insert surface/site from Table 3, 5, 6*}
11. Kills 99.9% of [bacteria,] [germs*] [virus†] [and], [Influenza A plus H1N1 virus†]
12. Kills [99.9%] [99.99%] of odor causing bacteria
13. Kills [99.9%] of odor causing [germs*] [With Germfighter* Technology]
14. Designed as a general [versatile] [multipurpose] [multi surface] cleaner and disinfectant [/sanitizer]
15. Cuts tough dirt [grease] and grime and kills 99.9% [99.99%] of bacteria [in the bathroom] [on] *{insert surface/site from Table 3, 5, 6}*
16. Cuts tough grease and grime [killing] 99.9% of bacteria [germs*] [in the kitchen] [on] {*insert surface/site from Table 3, 5, 6}*

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

17. Destroys germs* [bacteria] [that ordinary cleaners [can't] [don't]]
18. Disinfects *{insert surface/site from Table 3, 5, 6}*
19. Disinfects and removes offensive odors from *{insert surface/site from Table 3, 5, 6}*
20. *Disinfects bacteria and viruses† [in {insert location from Table 6}] [on {Insert items from Table 3 or 5}]*
21. Effective against *{Insert organisms from Table 7 under disinfection}*
22. Eliminates 99.9% of bacteria [germs*] [virus†]
23. Eliminates [99.9% of] [99.99% of] [household] bacteria [in] [10 minutes]
24. Eliminates 99.9% of [household] germs* [in] [10 minutes]
25. Eliminates [99.9% of] [99.99% of] bacteria from [kitchen] [and] [bathroom] *{insert surface/site from Table 3, 5, 6}*
26. Eliminates [99.9% of] [99.99% of] bacteria [in] [the] [kitchen] [and] [bathroom]
27. Eliminates [99.9% of] germs* [that ordinary cleaners [can't] [don't]]
28. Eliminates [99.9% of] [99.99% of] of hidden bacteria
29. Eliminates [99.9% of] [99.99% of] [kitchen] [and] [bathroom] bacteria
30. Kills [99.9% of] [99.99% of] bacteria
31. Kills [99.9% of] [99.99% of] bacteria and leaves surfaces sparkling
32. Kills [99.9% of] germs*
33. Kills [99.9% of] bacteria and [&] viruses†
34. Kills [99.9% of] [99.99% of] bacteria for a deep down clean
35. Kills [99.9% of] [99.99% of] bacteria on home healthcare surfaces
36. Kills [99.9% of] [99.99% of] [Escherichia coli O157:H7 (E. coli)) (and) [Salmonella enterica] [other organisms] *{insert organism from Table 7 under disinfection}*
37. Kills [99.9% of] germs* [including [the] cold° and flu[‡] viruses†]
38. Kills [99.9% of] [99.99% of] [household] bacteria [in] [10 minutes]
39. Kills [99.9% of] [99.99% of] the following [household] bacteria commonly found in kitchens on hard, non-porous surfaces in 10 minutes:{organisms} *{insert organism from Table 7 under disinfection}*
40. Kills [99.9% of] [99.99% of] the following [household] bacteria commonly found in bathrooms on hard, non-porous surfaces in 10 minutes:{organisms} *{insert organism from Table 7 under disinfection}*
41. Kills [99.9% of] viruses† and [&] bacteria
42. Kills [99.9% of] viruses† and [&] bacteria [including [the] cold° and flu[‡] viruses]
43. Kills bacteria on hard, non-porous [kitchen] [and] [bathroom] surfaces in 10 minutes
44. Kills viruses† on hard, non-porous [kitchen] [and] [bathroom] surfaces in 5 minutes
45. Kills bacteria on hard, non-porous [kitchen] surfaces in 10 minutes
46. Kills viruses† on hard, non-porous [kitchen] surfaces in 5 minutes
47. Kills bacteria commonly found in [the] [kitchen] [and] [bathroom] [in] [10 minutes)
48. Kills bacteria for a deep down clean
49. Kills germs* [that ordinary cleaners] [don't] [can't]
50. Kills germs*
51. Kills [household] bacteria [germs*]
52. Kills [household] bacteria [commonly found in] [bathrooms] [and] [kitchens] [on hard, non-porous surfaces] [in] [10 minutes]
53. Kills [household] bacteria [in] [10 minutes] [commonly found in] [bathrooms] [and] [kitchens] [and on] [floors]
54. Kills [kitchen] [and] [bathroom] germs*
55. Kills [kitchen] [household] bacteria [germs*]
56.
57. Kills Viruses†
58. Reduces the amount of bacteria [germs*] on a surface
59. Removes bacteria [germs*]
60. Designed as a general [versatile] [multi-surface] [multipurpose] cleaner and disinfectant

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

*{Qualified "germs" claim: One of the two following footnotes must appear wherever "germs*" or related words (e.g. Germicidal*) is used on label:*

***[Kills] {*insert at least one bacteria and one virus from Table 7*}**
***Insert Table 7**

**Soft Surface Sanitizer Claims**

1. [Oxygen based] Soft Surface Sanitizer [Sanitization]
2. [Oxygen based] Soft Surface Spot [Fabric] Sanitizer [Sanitization]
3. Kills 99.9% of bacteria on soft surfaces [fabric] [upholstery] [{*insert one or more items from Table 4*}]
4. Oxygen based formula cleans and spot sanitizes soft surfaces [fabric] [upholstery] [{*insert one or more items from Table 4*}]
5. Powers out the toughest stains and bacteria without stripping color in fabrics
6. [5 minutes] [bacteria] [*Insert 1 or more strains from Table 7 under soft surface sanitization]* soft surface sanitization [Sanitizer]
7. [*Insert 1 or more strains from Table 7 under soft surface sanitization]* soft surface spot sanitizer
8. Soft Surface [Fabric] Sanitizer [Sanitizes]
9. [5 minutes] [One Step] [1 Step] Soft Surface [Fabric] Sanitizer
10. [5 minutes] [One Step] [1 Step] soft surface sanitizer [for the [*Insert one or more locations from {Table 6}*]]
11. Cleans and sanitizes fabrics [soft surfaces] [soft and hard surfaces] [in One Step]
12. Cleans, deodorizes, and sanitizes fabrics [soft surfaces] and [hard surfaces] in one [easy] step
13. When you need fabric [and surface] sanitization[!]
14. When you need to kill bacteria on soft and hard surfaces[!]
15. Kills 99.9% bacteria [in] [5 minutes]
16. In 5 minutes, 99.9% bacteria are dead on soft surfaces[!]
17. Kills 99.9% {*Insert bacteria from Table 7 list under soft surface sanitizer}* [in] [5 minutes]
18. [Soft Surface Sanitizer] Effective against {*Insert bacteria from Table 7 list under soft surface sanitizer}*
19. Eliminates 99.9% of [household] bacteria on fabric [soft surfaces] in 5 minutes

**Laundry Disinfection**

1. Antibacterial [laundry] additive cleans and kills bacteria [germs*]
2. Can help prevent cross-contamination across treated laundry
3. Cleaner + stain fighting power + antibacterial protection for all your laundry needs
4. [Kills][Eliminates]Controls odor-causing bacteria
5. [Kills][Eliminates]Controls odor-causing bacteria in the [laundry]
6. Deodorizes odors causing bacteria
7. Disinfection for all your laundry needs
8. Disinfects [and] [deodorizes]
9. Disinfects your clothes
10. [Disinfecting] [Antibacterial] [laundry] presoak
11. Dissolve and eliminate tough stains
12. Eliminates 99.9% of bacteria [germs*] [virus†] in your laundry
13. Eliminates [99.9% of] [99.99% of] bacteria [in] [15 minutes] [on your clothing]
14. Eliminates 99.9% of germs* [in] [15 minutes] [on] [{*insert surface/site from Table 4}*
15. Eliminates [99.9% of] [99.99% of] bacteria from {*insert surface/site from Table 4}*
16. Eliminates [99.9% of] [99.99% of] bacteria [in] [the] [laundry] [and] [on] [soft surface]
17. Eliminates [99.9% of] germs* [that ordinary additives [can't] [don't]]
18. Eliminates [99.9% of] [99.99% of] of hidden bacteria
19. Eliminates [99.9% of] [99.99% of] bacteria

20. Freshens while killing bacteria [germs*] [virus†]
21. Helps prevent the spread of cold° and flu[i] viruses†
22. Kills odor causing bacteria in the [wash and/or laundry]
23. [Kills] [Eliminates] [Destroys] [99.9% of] [99.99% of] bacteria in your laundry
24. [Kills] [Eliminates] [Destroys] [99.9% of][germs*] in your laundry
25. [Kills] [Eliminates] [Destroys] odor causing bacteria on {*Insert soft surface from Table 4 list under soft surface sanitizer}*
26. [Kills] [Eliminates] [Destroys] [99.9% of] viruses†, bacteria, and in your laundry [or on {*Insert soft surface from Table 4 list under soft surface sanitizer}*
27. Kills [99.9%] of odor causing bacteria [germs*] [With Germfighter* Technology]
28. Kills 99.9% of [bacteria,] [germs*] [virus†] [and], [Influenza A plus H1N1 virus†] in your laundry
29. Kills [99.9% of] germs*
30. Kills [99.9% of] bacteria and [&] viruses†
31. Kills [99.9% of] [99.99% of] bacteria for a deep clean
32. Kills [99.9% of] [99.99% of] [Escherichia coli O157:H7 (E. coli)) [and) [Salmonella enterica] [other organisms] *{insert organism from Table 7 under disinfection}*
33. Kills [99.9% of] germs* [including [the] cold° and flu[i] viruses†]
34. Kills [99.9% of] [99.99% of] [odor causing] bacteria [in] [15 minutes]
35. Kills [99.9% of] viruses† and [&] bacteria
36. Kills [99.9% of] viruses† and [&] bacteria [including [the] cold° and flu[i] viruses]
37. Kills bacteria [on] [laundry] [and] [soft surfaces] in 15 minutes
38. Kills viruses† [on] [laundry] [and] [soft surfaces] in 15 minutes
39. Kills germs* [that ordinary cleaners] [don't] [can't]
40. Kills germs*
41. Kills [household] bacteria [germs*]
42. Oxygen-based formula cleans and sanitizes
43. [This product] [even] deodorizes areas that are hard to keep smelling fresh [or other areas prone to odors caused by microorganisms]
44. [This product] will help [you] remove stains from your [laundry] and [and disinfect]
45. Versatile for [all colors] [and loads] [use on {*Insert from Table 1,2,3,4,5,6,7 list under soft surface sanitizer)}*

**Hard Surface Non-Porous Mildewstat Claims**

1. Inhibits [the growth of] [mold] [and] [mildew] for [up to] [7 days]
2. Inhibits [the growth of] [mold] [and] [mildew] for [up to] [7] days on hard surfaces
3. [Controls] [Inhibits][Prevents] [the growth of] [mold] [and] [mildew] for [up to] [7] days on hard surfaces
4. [Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] days on hard surfaces]
5. [Controls][Inhibits][Prevents] [the growth of] [mold] [and] [mildew] for [up to] [7] days on {*Insert one or more of the items in Table 3*}
6. [Controls] [Inhibits] [Prevents] [the growth of] [mold] [and] [mildew] on *{Insert one or more of the items in Table 3}*
7. [Controls] [Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] days on hard surfaces] on {*Insert one or more of the items in Table 3*}
8. [Controls] [Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on {*Insert one or more of the items in Table 3*}
9. [Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] days on [hard] [surfaces] on {*Insert one or more of the locations in Table* 3}
10. [Controls][Inhibits][Prevents] [the growth of] [mold] [and] [mildew] on [hard surfaces] like *{Insert one or more of the locations in Table 3}*

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

11. [Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] days on hard surfaces] on *{Insert one or more of the locations in Table 3}*
12. [Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on [hard surfaces] [like] [including] *{Insert one or more of the locations in Table 3}*
13. [Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on hard and [soft] [fabric] surfaces] [like] [including] *{Insert one or more of the locations in Table 3}*
14. [Controls][Inhibits][Prevents] [the growth of] [mold] [and] [mildew] on hard and [soft] [fabric] surfaces]

**Fabric Mildewstat Claims**

1. Fabric Mildewstat [fungistat]
2. [Controls] [Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] [28] days on fabric
3. [Controls][Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] [28] days on fabric]
4. [Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] [28] days on {*Insert one or more of the items in Table 4*}
5. [Controls] [Inhibits] [Prevents] [the growth of mold] [and] [mildew] on *{Insert one or more of the items in Table 4}*
6. [Controls] [Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] {28} days on fabric] on {*Insert one or more of the items in Table 4*}
7. [Controls] [Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on {*Insert one or more of the items in Table 4*}
8. [Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] [28] days on [fabric] [soft surfaces] in {*Insert one or more of the locations in Table 6*}
9. [Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] on [fabric] [soft surfaces] in *{Insert one or more of the locations in Table 6}*
10. [Controls][Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] [28] days on fabric] in *{Insert one or more of the locations in Table 6}*
11. [Controls][Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on [fabric] [soft surfaces] in *{Insert one or more of the locations in Table 6}*

**Non-Pesticidal Allergen Claims**

1. Breaks Down non-living Allergens[!][including {*insert one or more items from Table 2*}][in {*insert one or more locations from Table 6}*][on *{insert one or more items from Table 3 or 5}]*
2. Controls [the most] [common] non-living allergens [including {*insert one or more items from Table 2*}] [in {*insert one or more locations from Table 6*}] [on {*insert one or more items from Table 3 or 5*}]
3. Destroys [Eliminates] non-living Allergens[!][including {*insert one or more items from Table 2*}][in{*insert one or more locations from Table 6*}][on *{insert one or more items from Table 3 or 5}]*
4. Destroys -or- deactivates dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens [found in dust] [in{*insert one or more locations from Table 6*}][on *{insert one or more items from Table 3 or 5}]*
5. [Penetrates and] breaks down dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens [found in dust] [in {*insert one ar more locations from Table 6*}] [on {*insert one or more items from Table 3 or 5*}]
6. Reduces dust mite matter -or- particles, cockroach matter –or particles, and pet dander allergens [found in dust]
7. Reduces non-living Allergens[!][in {*insert one or more locations from Table 6*}][on {*insert one or more items from Table 3 or 5}*]
8. Reduces up to XX% of [inanimate] [non-living] allergens [that become airborne from {*insert one or more items from Table 3, 4 or 5*}], [such as {*insert one ar more items from Table 2*}]
9. [This product] kills germs* and destroys non-living allergens [while cleaning hard, nonporous surfaces.]
10. [This product] kills germs* on surfaces, controls mold & mildew on fabric, and destroys non-living allergens.
11. [Deodorizes] [Disinfects][controls mold & mildew on fabric], and destroys non-living allergens

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

{Table 1:} Soils / Odors: (Graphic - depicting soil)

| | | | | |
|---|---|---|---|---|
| Baby food | Dirt (greasy dirt) | Hard water stains | Outdoor grime | Tomato / spaghetti sauce |
| Bacon fat | Dust | Heel / scuff marks | Pancake mix | Toothpaste |
| Bathtub rings | Eggs | Juice / wine stains | Pen / Ink mark | Tough soils / stains |
| BBQ Sauce | Fingerprints | Lime scale | Pet odors | |
| Beverage stains | Food odors | Makeup | Pet stains | |
| Blood stains | Food stains | Mildew stains | Smears / smudges | |
| Blueberry | Grass | Mold stains | Smoke / smoking odors | |
| Chocolate syrup | Gravy | Motor Oil | Soap scum | |
| Coffee | Grease (splatter) | Mud | Stains / soils | |
| Cooking odors | Grime | Mustard | Sweat odors | |
| Cosmetic stains | Hair dye | Musty odors | Sweat stains | |
| Crayon / pencil marks | Handprints | Organic soils / stains | Tea | |

{Table 2:} Non-living Allergens:

| | | |
|---|---|---|
| Cat dander | Dog dander | Hair |
| Cockroach debris | Dust mite debris | Pet dander |
| Cockroach matter | Dust mite matter | Pet hair |
| Cockroach particles | Dust mite particles | Pollen particles |

{Table 3:} Hard Non-Porous Surface Types:

| | | |
|---|---|---|
| Chrome | Glazed granite | Sealed Marble |
| Corian® | Glazed porcelain | Silestone® |
| Countertop [surfaces] | Glazed tile | Stainless steel |
| Crystal | Laminate | Vinyl |
| Enamel | Linoleum | |
| Formica® | Plastic laminate | |
| Glazed ceramic | Sealed Fiberglass fixtures | |

{Table 4:} Exteriors [of] Soft Surfaces :

| | | | |
|---|---|---|---|
| Baby carriages | Curtains [Draperies] | Seat cushion [kitchen] | Suitcase [luggage] |
| Baby prams | Cushion [Pillow] | Shoes [canvas] [fabric] | Throw rug |
| Backpack[/School bag] | Dog [Pet] bed | Shoe interior | [Upholstered] booster seat |
| Bathroom mat | Diaper bag | Shower curtain [fabric] | [Upholstered] chairs |
| Bedding [Bedspread] | Duvet cover | Slippers | [Upholstered] couches |
| Box spring [cover] | Gym bag [fabric] | Sneakers [canvas] [fabric] | [Upholstered] furniture |
| Car [seat] [upholstery] | [Upholstered] Highchair seat | Sponges [rags] | Upholstery |
| Clothing | Laundry bag [fabric] | Sport[s] [bag[s]] [equipment] | Window treatments [fabric] |
| Cotton [fabric] purse | Mattress [cover] | Soft [fabric] surfaces | |
| Cots | Mop [/ broom] | Stroller [seats] | |
| Couch [Sofa] | Seat cushion [household] | Stuffed [Plush] toys | |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

{Table 5:} Hard Non-porous Surfaces: {Graphic - depicting use site}

| | | | |
|---|---|---|---|
| Appliance exterior | Fixture [chrome/stainless steel] | Microwave exterior | Shower [stall] [area] |
| Bathtub [tub] | Floor [linoleum] | Non-medical [chrome/stainless steel] | Sink [basin] |
| Bed frame | Floor [glazed ceramic/porcelain tile] | Outdoor patio furniture [non-wood] | Stove [stovetop] |
| Cabinet [non-wood] | Floor [laminate] | Oven [door] | Table [tabletop] [non-wood] |
| Chair [non-wood] | Floor [sealed marble] | Patio door | Telephone |
| Changing table [non-wood] | Floor [vinyl] | Picnic table [non-wood] | Toilet bowl exterior [Urinal] |
| Counter [Countertop] | Garbage [can] [pail] [container] | Plastic laundry [basket] [hamper] | Water fountain |
| Crib [non-wood] | Glazed ceramic tile | Range hood [stove hood] | Window [windowsill] |
| Diaper pail [non-wood] | Glazed porcelain tile | Refrigerator Shelves [drawers] | Vanity top |
| Exhaust [fan] [hood] | Grill [Barbecue] exterior | Sealed granite | |
| Faucet | Highchair [non-food contact area] | Shower [door] [curtain] | |

{Table 6: Use Sites (Graphic - depicting use site)}:

| | | | |
|---|---|---|---|
| Basement | High-touch areas | Nursery | Dining room |
| Bathroom | Home [House] | Outdoor area | Game room |
| Bedroom | Household areas | Storage [area] [room] | Rec room |
| Den [/Study] | Laundry [room] | Lodging establishments | Public transportation Terminals [air/bus/train/car] |
| Family room | Education [schools, colleges, preschools] | Locker rooms etc. | Pet shops |
| Athletic/Recreational facilities [fitness facilities, gyms] | Entertainment [Theaters, Parks, Playgrounds, etc.] | Manufacturing facilities | Retail locations [Grocery stores, Shops, Malls] |
| Automotive interiors [seats, handles, etc.] | Food service establishments [Restaurants] [Commercial Kitchens] | Other commercial facilities | Shower rooms |
| Breakrooms | Government facilities | Offices | Zoos |
| Churches | Hospitality areas [hotel, motels, extended stay, time share] | Office buildings | Cruise ships |
| Commercial laundry | Living room | Tool shed | Hotel [motel] |
| Garage | Mud room | Kitchen | |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

**Table 7: List of Organisms***

**Hard Surface Non-Porous DISINFECTANT**

| Contact Time | Bacteria |
|---|---|
| 10 minutes | *Pseudomonas aeruginosa*[P.][ATCC 15442]<br>*Salmonella enterica* [S.][ATCC 10708]<br>*Staphylococcus aureus* [(*Staph*)][S][ATCC 6538]<br>*Escherichia coli O157:H7[E.][ATCC43888]* |
| 5 minutes | **Viruses†**<br>†°Rhinovirus [(type 39)][ATCC VR-340] [Strain 209]<br>†ᵗInfluenza A [Pandemic] [(H1N1)] [CDC #2009712192] [A/Mexico/4108/2009]<br>†Herpes Simplex Virus, Type 1 [ATCC VR-733]<br>† Rotavirus [ATCC VR-2018]<br>†† Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus] |

**Hard Surface Non-Food Contact Non-Porous SANITIZER**

| Contact Time | |
|---|---|
| 5 minutes | *Staphylococcus aureus* [(*Staph*)] [S.][ATCC 6538]<br>*Klebsiella pneumoniae [K.][ATCC 4352]*<br>*Escherichia coli O157:H7[E.][ATCC43888]* |

**Hard Surface Non-Porous MILDEWSTAT**

| | |
|---|---|
| 7 day | *Aspergillus niger[A.]*[ATCC 6275] |

**Soft Surface [Fabric] SANITIZER**

| Contact Time | |
|---|---|
| 5 minutes | *Salmonella enterica* [S.][ATCC 10708]<br>*Stophylococcus oureus* [(*Staph*)] [5.][ATCC 6538]<br>*Klebsiella pneumoniae[K.][ATCC 4352]*<br>*Escherichio coli O157:H7[E.][ATCC43888]* |

**FABRIC MILDEWSTAT**

| | |
|---|---|
| 28 day | *Aspergillus niger[A.]*[ATCC 6275]<br>*Penicillium variable* [P.][ATCC 32333] |

**Laundry Pre-Soak DISINFECTANT**

| Contact Time | Bacteria |
|---|---|
| 15 minutes | *Pseudomonas aeruginosa*[P.][ATCC 15442]<br>*Salmonella enterica* [5.][ATCC 10708]<br>*Stophylococcus aureus* [(*Staph*)][S][ATCC 6538]<br>*Klebsiella pneumoniae[K.][ATCC 4352]*<br>*Escherichia coli O157:H7[E.][ATCC43888]* |
| | **Viruses†**<br>†°Rhinovirus [(type 39)][ATCC VR-340] [Strain 209]<br>†ᵗInfluenza A [Pandemic] [(H1N1)] [CDC #2009712192]<br>†Herpes Simplex Virus, Type 1 [ATCC VR-733]<br>† Rotavirus [ATCC VR-2018]<br>† Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus] |

**Laundry Pre-Soak SANITIZER**

| Contact Time | |
|---|---|
| 10 minutes | *Staphylococcus aureus* [(*Staph*)] [5.][ATCC 6538]<br>*Klebsiella pneumonioe [K.][ATCC 4352]*<br>*Escherichia coli O157:H7[E.][ATCC43888]* |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

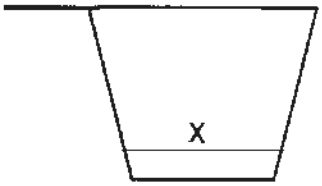
[Table 8: Testing and Dilution Type]

| Testing Type | Type of Organism | Dilution Type | Efficacy Study Dilution Rate | Gallon Conversion |
|---|---|---|---|---|
| Hard Surface Disinfection | Bacteria<br>Viruses† | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Hard Surface Mildewstat | Mold and Mildew | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Non-Food Contact Sanitization | Bacteria | 1X | 31.2 grams Product / 1 liter water | 118 grams Product / 1 gallon water |
| Soft Surface Sanitization | Bacteria | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Soft Surface Mildewstat | Mold and Mildew | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Laundry Pre-Soak Disinfection | Bacteria<br>Viruses† | 1X | 31.2 grams Product / 1 liter water | 118 grams Product / 1 gallon water |
| Laundry Pre-Soak Sanitization | Bacteria | 1X | 31.2 grams Product / 1 liter water | 118 grams Product / 1 gallon water |

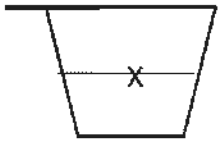
[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

| [Table 9: Scoop Directions for Use Table {[X] can equal any letter or number }]**Scoop Scenario** | **Directions for Use for insertion depending on Measuring Device and Dilution Type** | **Measuring Device** | **Dilution Type** | **grams product per measuring device** | **Total grams product per gallon of water** | **Total grams product per liter of water** |
|---|---|---|---|---|---|---|
| **Scoop X (118 grams)** | | | | | | |
| 1 | "Add 1 scoop of product to 1 gallon of water" | Scoop [X] | 1X | 118 | 118 | 31.2 |
| 2 | "Add 2 scoops of product to 1 gallon of water" | Scoop [X] | 2X | 118 | 236 | 62.4 |
| 3 | "Fill scoop to line [X] and add to 16 ounces of water." | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (59 grams)** | | | | | | |
| 4 | "Add 2 scoops of product to 1 gallon of water" | Scoop [X] | 1X | 59.0 | 118 | 31.2 |
| 5 | "Add 4 scoops of product to 1 gallon of water" | Scoop [X] | 2X | 59.0 | 236 | 62.4 |
| 6 | "Fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (118 grams @ line [X])** | | | | | | |
| 7 | "Fill scoop to line [X] and add to 1 gallon of water" | Scoop [X] Line [X] | 1X | 118 | 118 | 31.2 |
| 8 | "Fill scoop to line [X] 2 times and add to 1 gallon of water" | Scoop [X] Line [X] | 2X | 118 | 236 | 62.4 |
| 9 | "Fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (59 grams @ line [X])** | | | | | | |
| 10 | "Fill scoop to line [X] 2 times and add to 1 gallon of water" | Scoop [X] Line [X] | 1X | 59.0 | 118 | 31.2 |
| 11 | "Fill scoop to line [X] 4 times and add to 1 gallon of water" | Scoop [X] Line [X] | 2X | 59.0 | 236 | 62.4 |
| 12 | "Fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |

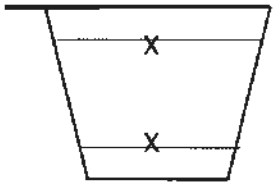
[bracketed text] is optional; *italicized* text and {bracketed text} is informational.



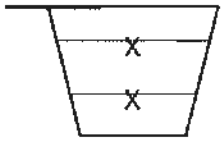

Scoop type X




Scoop type X




Scoop type X

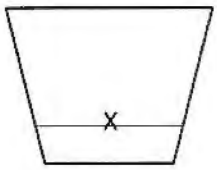



Scoop type X

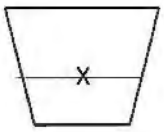
[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

[Table 10: Cap Directions for Use {[X] can equal any letter or number}]

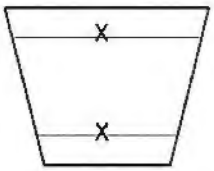
| Cap Scenario | Directions for Use for insertion depending on Measuring Device and Dilution Type | Measuring Device | Dilution Type | grams product per measuring device | Total grams product per gallon of water | Total grams product per liter of water |
|---|---|---|---|---|---|---|
| **Cap [X] (118 grams)** | | | | | | |
| 1 | "Add 1 capful of product to 1 gallon of water" | Cap [X] | 1X | 118 | 118 | 31.2 |
| 2 | "Add 2 capfuls of product to 1 gallon of water" | Cap [X] | 2X | 118 | 236 | 62.4 |
| 3 | "Fill cap to line 'X' and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 4 | "Add 2 capfuls of product to 1 gallon of water" | Cap [X] | 1X | 59.0 | 118 | 31.2 |
| 5 | "Add 4 capfuls of product to 1 gallon of water" | Cap [X] | 2X | 59.0 | 236 | 62.4 |
| 6 | "Fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 7 | "Fill cap to line [X] and add to 1 gallon of water" | Cap [X] Line [X] | 1X | 118 | 118 | 31.2 |
| 8 | "Fill cap to line [X] 2 times and add to 1 gallon of water" | Cap [X] Line [X] | 2X | 118 | 236 | 62.4 |
| 9 | "Fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 10 | "Fill cap to line [X] 2 times and add to 1 gallon of water" | Cap [X] Line [X] | 1X | 59.0 | 118 | 31.2 |
| 11 | "Fill cap to line [X] 4 times and add to 1 gallon of water" | Cap [X] Line [X] | 2X | 59.0 | 236 | 62.4 |
| 12 | "Fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |



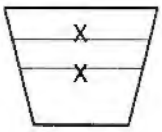

Cap type X




Cap type X




Cap type X




Cap type X

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

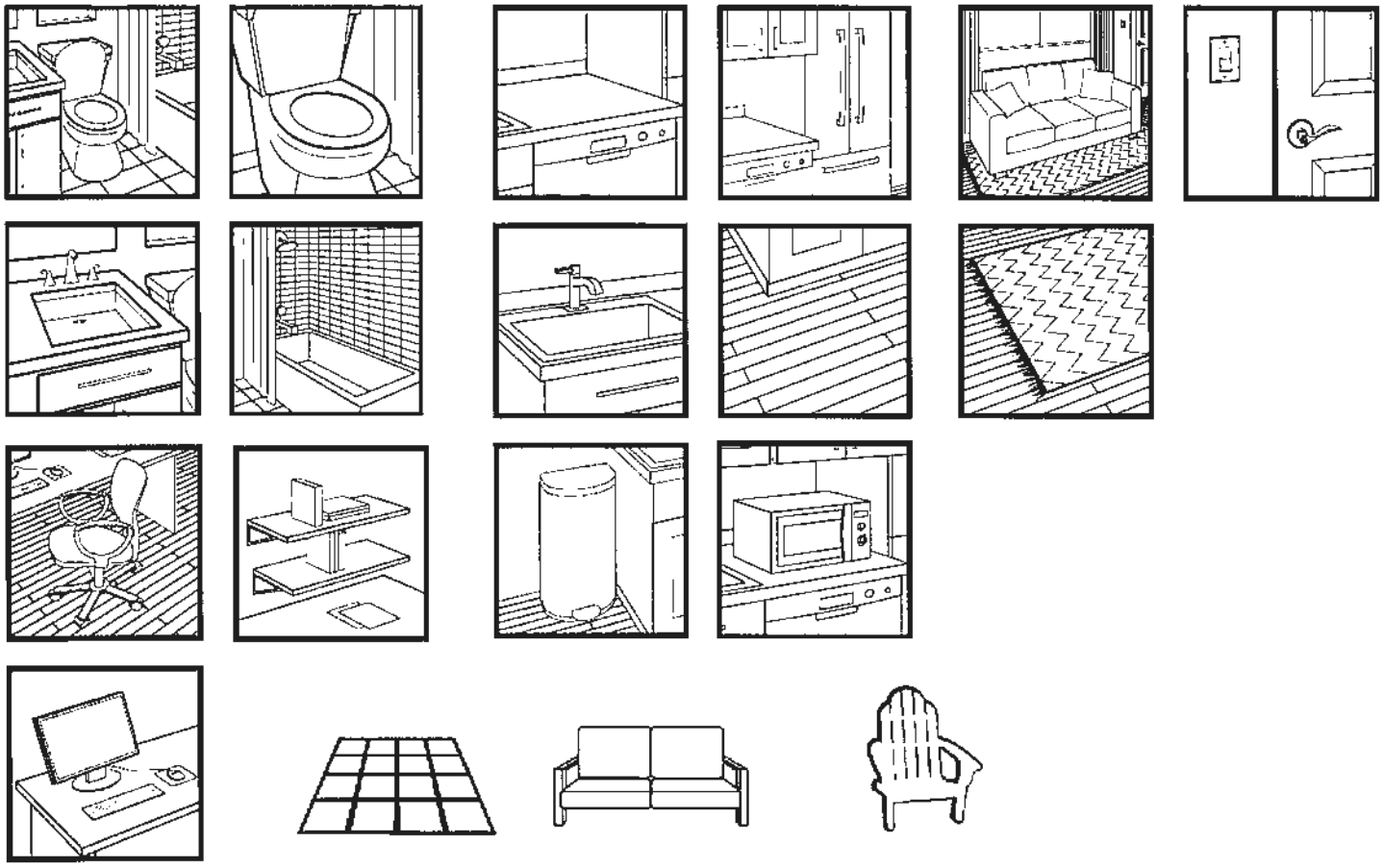
[Table 11: Package dose quantities]

| Content Wt. (lbs.) | Content Mass (kg) | Number of loads (assuming 118 grams in 1 gallon = 1 load) |
|---|---|---|
| 1.7 | 0.77 | 6 |
| 2.5 | 1.13 | 9 |
| 3.0 | 1.36 | 11 |
| 4.5 | 2.04 | 17 |
| 5.0 | 2.27 | 19 |
| 6.5 | 2.95 | 25 |
| 10.0 | 4.54 | 38 |
| 10.5 | 4.76 | 40 |
| 11.0 | 4.99 | 42 |
| 13.5 | 6.12 | 51 |

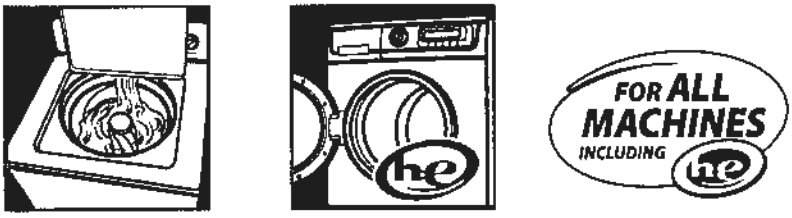
[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Optional Pictograms- Safety

Optional Pictograms- Locations usage (Bathroom, Kitchen, Living Room, Office, Grout, Soft Surface, Hard Surface)



Laundry compatible



[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Optional Pictograms- Usage

he

Per Gallon

Line A
16
oz.

Line A
16
oz.

Up to full scoop
1
GAL.

## DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (81-1, 870.1100)

**Product Manager**: Julie Chao
**MRID No.**: 49795311

**Reviewer**: Chris Jiang
**Study Completion Date**: Jan. 19, 2016
**Study No.** 19321-15

**Testing Laboratory**: Stillmeadow Incorporated
**Author**: Vincent A. Murphy

**Quality Assurance (40 CFR 160.12)**: A statement of GLP compliance was included.

**Test Material**: Capricorn, batch/lot 4562-124, granular powder
**Dosage**: 175 mg/kg, 550 mg/kg, 1750 mg/kg, 5000 mg/kg

**Species**: Female Sprague Dawley albino rats
**Age**: Eight to ten weeks
**Weight**: 169 to 221 grams on day 0
**Source**: Texas Animal Specialties, Humble, TX

**Conclusions**:

1. **$LD_{50}$ (mg/kg):** $LD_{50}$ = 1030 mg/kg
2. **The estimated $LD_{50}$ is equal to 1030 mg/kg.**
3. **Toxicity Category**: III Acceptable

**Procedure (Deviations from 81-1)**: The Up-and-Down Procedure was used. Only female rats were used because females are typically more sensitive than males. Relative humidity was at times outside of the protocol range. These deviations had no impact on the integrity of the study.

**Results**:

**Reported Mortality**

| Animal No. | Dose Level (mg/kg) | Short-Term Outcome | Long-Term Outcome |
|---|---|---|---|
| 111 | 5000 | X | X |
| 112 | 175 | S | S |
| 113 | 550 | S | S |
| 114 | 1750 | X | X |
| 115 | 550 | S | S |
| 116 | 1750 | D | D |
| 117 | 550 | O | O |
| 118 | 1750 | X | X |

S = lived, **X** = died

**Observations**:

**175 mg/kg**: Animal was active and healthy through the study.

**550 mg/kg**: Animals were active and healthy through the study.

**1750 mg/kg**: One animal experienced lethargy.

**5000 mg/kg**: Animal died on Day 1.

**Gross Necropsy Findings**:

**175 mg/kg**: Gross necropsy was unremarkable.

**550 mg/kg**: One gross necropsy had mottled lungs and lumps on the right lung.

**1750 mg/kg**: Gross necropsies revealed mottled lungs, discolored stomachs that were distended with gas, clear fluid in nostrils, lungs bright red, cecum distended with gas, yellow-orange content in cecum, brown fluid in mouth, brown content in stomach, intestines distended with gas, and white feces in colon.

**5000 mg/kg**: Gross necropsy revealed a stomach enlarged with red spot on the exterior, and intestines that were full of gas.

## DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (81-2, 870.1200)

**Product Manager**: Julie Chao
**MRID No.**: 49795312

**Reviewer**: Chris Jiang
**Study Completion Date**: Dec. 30, 2015
**Study No.** 19322-15

**Testing Laboratory**: Stillmeadow Incorporated
**Author**: Vincent A. Murphy

**Quality Assurance (40 CFR 160.12)**: A statement of GLP compliance was included.

**Test Material**: Capricorn, batch/lot 4562-124, granular powder
**Dosage**: 5050 mg/kg

**Species**: Five male and five female Sprague-Dawley albino rats
**Age**: Eight to ten weeks
**Weight**: ♂: 259 to 288 grams on day 0; ♀: 180 to 193 grams on day 0
**Source**: Texas Animal Specialties, Humble, TX

**Conclusions**:

1. **$LD_{50}$ (mg/kg):** Males: $LD_{50}$ > 5050 mg/kg
   Females: $LD_{50}$ > 5050 mg/kg
   Combined: $LD_{50}$ > 5050 mg/kg
2. **The estimated $LD_{50}$ is greater than 5050 mg/kg for males and females.**
3. **Toxicity Category**: IV **Classification**: Acceptable

**Procedure (Deviations from 81-2)**: No deviations occurred during the study.

**Results**:

**Reported Mortality**

| Dosage (mg/kg) | (Number Deaths/Number Tested) | | |
|---|---|---|---|
| | Males | Females | Combined |
| 5050 | 0/5 | 0/5 | 0/10 |

**Observations**: All animals were active and healthy through the study. Eschar, edema, blanching, and test substance staining were noted in the study.

**Gross Necropsy Findings**: Gross necropsies were unremarkable.

# DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (81-3, 870.1300)

**Product Manager**: Julie Chao
**MRID No.**: 49795313

**Reviewer**: Chris Jiang
**Study Completion Date**: Jan 11, 2016
**Study No.** 19323-15

**Testing Laboratory**: Stillmeadow Incorporated
**Author**: Andrew Doig

**Quality Assurance (40 CFR 160.12)**: A statement of GLP compliance was included.

**Test Material**: Capricorn, batch/lot 4562-124, granular powder
**Gravimetric**: 2.27 mg/L **Nominal**: 7.89 mg/L

**Species**: Five male and five female Sprague-Dawley albino rats
**Age**: Eight weeks
**Weight**: ♀: 283 to 319 on day 0; ♂: 169 to 228 grams on day 0
**Source**: Texas Animal Specialties, Humble, TX

**Summary**:

1. **$LC_{50}$ (mg/kg):** $LC_{50}$ > 2.27 mg/L
2. **The estimated $LC_{50}$ is greater than 2.27 mg/L.**
3. **MMAD**: 4.9 µm, 5.2 µm
4. **Toxicity Category**: IV **Classification**: Acceptable

**Procedure (Deviations from 81-3)**: One female was under protocol range. Relative humidity was at times outside the protocol range. These deviations had no impact on the integrity of the study.

**Results**:

**Reported Mortality**

| Exposure Concentration | (NUMBER DEATHS/NUMBER TESTED) | | |
|---|---|---|---|
| | Males | Females | Combined |
| 2.27 mg/L | 0/5 | 0/5 | 0/10 |

| Chamber Atmosphere | | | |
|---|---|---|---|
| Dose Level | MMAD (µm) | GSD (µm) | % particles < 3.4 µm, 2.4 µm |
| 2.27 mg/L | 4.9 | 2.4 | 31.04 |
| 2.27 mg/L | 5.2 | 2.6 | 23.94 |

| Chamber Environment | |
|---|---|
| Chamber Volume (L) | 500 |
| Airflow (LPM) | 292 to 446 |
| Temperature (°C) | 23.5 to 23.9 |
| Relative Humidity (%) | 40 to 43 |

**Clinical Observations**: All animals appeared normal for the duration of the study.

**Gross Necropsy Findings**: The gross necropsies of one male and four females were unremarkable. The other animals had pale lungs.

## DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (81-4, 870.2400)

**Product Manager**: Julie Chao
**MRID No.**: 49795314

**Reviewer**: Chris Jiang
**Study Completion Date**: Dec. 30, 2015
**Study No.** 19099-15

**Testing Laboratory**: Stillmeadow Incorporated
**Author**: Vincent A. Murphy

**Quality Assurance (40 CFR 160.12)**: A statement of GLP compliance was included.

**Test Material**: Capricorn, batch/lot 4562-124, granular powder
**Dosage**: 0.1 mg

**Species**: Female New Zealand White albino rabbit
**Age**: Fourteen weeks
**Weight**: 2.6 kilograms at study start
**Source**: Veterinary Clinical Resources, Hutto, TX

**Summary**:

1. **Toxicity Category**: I
2. **Classification**: Acceptable

Eye irritation was observed through day 7 and would probably continue to day 21. This was the reason that the study was stopped and the test material was called toxicity category I.

**Procedure (Deviations from 81-4)**: Relative humidity was at times outside the protocol range. This deviation had no impact on the integrity of the study.

**Individual Scores for Ocular Irritation**

| Observations | Rabbit No. 0003 (Female) | | | | | |
|---|---|---|---|---|---|---|
| | Time After Treatment | | | | | |
| | 1 hr | 24 hrs | 48 hrs | 72 hrs | Day 4 | Day 7 |
| I. Corneal Opacity | | 2 | 2 | 2 | 2 | 2 |
| II. Iritis | * | PD | PD | PC | PC | PC |
| III. Conjunctivae | | | | | | |
| A. Redness | 3b | 3b | 3b | 3b | 3b | 3b |
| B. Chemosis | 2 | 3 | 3 | 3 | 3 | 3 |
| C. Discharge | 3 | 2 | 2 | 2 | 2 | 2 |

PD – greater than three quarters up to whole area
PC – greater than half, but less than three quarters
b - blanching

## DATA REVIEW FOR PRIMARY SKIN IRRITATION TESTING (81-5, 870.2500)

**Product Manager**: Julie Chao
**MRID No.**: 49795315

**Reviewer**: Chris Jiang
**Study Completion Date**: Dec. 30, 2015
**Study No.** 19324-15

**Testing Laboratory**: Stillmeadow Incorporated
**Author**: Vincent A. Murphy

**Quality Assurance (40 CFR 160.12)**: A statement of GLP compliance was included.

**Test Material**: Capricorn, batch/lot 4562-124, granular powder
**Dosage**: 0.5 mg

**Species**: One male and two female New Zealand White albino rabbit
**Age**: Eighteen weeks
**Weight**: 2.6 to 3.0 kilograms at study start
**Source**: Veterinary Clinical Resources, Hutto, TX

**Summary**:

1. **Toxicity Category**: IV
2. **Classification**: Acceptable

**Procedure (Deviations from 81-5)**: Temperature and relative humidity were at times outside protocol range. These deviations had no impact on the integrity of the study.

**Results**:

| Animal number | Erythema/edema after unwrap | | | |
|---|---|---|---|---|
| | 30-60 min | 24 hrs | 48 hrs | 72 hrs |
| 520-M | 1/0 | 0/0 | 0/0 | 0/0 |
| 441-F | 1/0 | 1/0 | 0/0 | 0/0 |
| 443-F | 1/0 | 0/0 | 0/0 | 0/0 |

## DATA REVIEW FOR DERMAL SENSITIZATION TESTING (81-6, 870.2600)

**Product Manager**: Julie Chao
**MRID No.**: 49795315

**Reviewer**: Chris Jiang
**Study Completion Date**: Jan. 19, 2016
**Study No.** 19324-15

**Testing Laboratory**: Stillmeadow Incorporated
**Author**: Vincent A. Murphy

**Quality Assurance (40 CFR 160.12)**: A statement of GLP compliance was included.
D water
**Test Material**: Capricorn, batch/lot 4562-124, granular powder
**Positive Control**: α-Hexylcinnamaldehyde

**Species:** Hartley albino guinea pig
**Weight**: 335 to 419 grams
**Age**: Young adult
**Source**: Charles River Headquarters, Wilmington, MA

**Summary**:

1. **This Product is not a dermal sensitizer.**
2. **Classification**: Acceptable

**Procedure (Deviation From §81-6)**: No deviations occurred during the study

**Procedure**: After preliminary tests, the definitive study was undertaken. The Buehler method was tested for skin sensitization. Once each week for three weeks, either 400 mg of the undiluted test material moistened with 0.2 mL of deionized water or nothing was applied to the clipped left side of each animal using gauze patches held in place by a strip of polyethylene film that was secured in place with non-irritating tape. After the exposure period, the bindings were removed. The guinea pigs were scored at 24 and at 48 hours after each induction.
Two weeks after the final application, all animals were challenged with 400 mg of the test substance moistened with 0.2 mL of deionized water on the right side. The guinea pigs were scored at 24 and at 48 hours after challenge.

**Results**: No irritation was observed at 24 hours after the first induction, at 48 hours after the first induction, at 24 hours after the second induction, at 48 hours after the second induction, at 24 hours after the third induction, and at 48 hours after the third induction.

At 24 hours and at 48 hours after challenge, no reaction was observed in any of the animals.

The historical positive control showed appropriate results.

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**

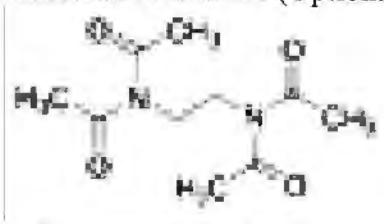
EPA United States Environmental Protection Agency **Office of Pesticide Programs**

**Antimicrobials Division (AD)**
4/27/2016

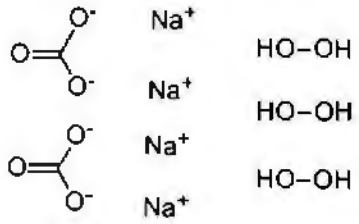
| | | | |
|---|---|---|---|
| EPA Reg. #: **10772-EG** | | DP Barcode:**432545**<br>Submission #: **982572** E-Sub: | |
| Product Name: **CAPRICORN** | | Registrant: **Church & Dwight Co Inc** | |
| Reviewer's Name: Narayanan Parthasarathy | | AD/PSB/CTT- Product Chemistry | |
| Agency due date:8/30/2016 | | PSB received date: 3/29/2016 | |
| CTT received date: 3/30/2016 | | Science received date: 3/31/2016 | |
| Formulation type: EP | | | |
| Integrated system: [X ] | Non-integrated system:[ ] | Food use: [] | Non- food use: [X] |
| Action Code: 540 | Date Completed: 4/27/2016 | | |

| PC Code(s) | CAS #(s) | Active Ingredient Names | % wt (label) |
|---|---|---|---|
| 004115 | 10543-57-4 | Tetraacetylethylenediamine | 4.44% |
| 128860 | 15630-89-4 | Sodium Percarbonate | 18.50% |

Molecular Structure (Optional)



Tetraacetylethylenediamine




Sodium Percarbonate

| | |
|---|---|
| Test Lab: | |
| MRID(s): 49795301-49795309 | |
| Approver: Karen P. Hicks | Approved date: 5/17/2016 |
| Guideline: OPPTS Guideline Series 830 Groups "A& B". Acceptable | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

**Antimicrobials Division (AD)**

4/27/2016

**MEMORANDUM**

**Subject:** Product Chemistry Review for EPA Reg# **10772-EG**
Product Name: **CAPRICORN**
DP#: **432545**

**From:** Narayanan Parthasarathy, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

**Thru:** Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

**To:** Julie Chao RM 33/Julie Chao
Regulatory Management Branch I
Antimicrobials Division (7510P)

**Applicant: Church & Dwight Co Inc**

**Action Code: 540**
**Agency Due Date:8/30/2016**

**Formulation from Label**

| **Active Ingredient(s)** | **% by wt.** |
|---|---|
| Tetraacetylethylenediamine | 4.44% |
| Sodium Percarbonate | 18.50% |

**BACKGROUND:** On behalf of **the registrant, Church & Dwight, Co Inc, Scientific & Regulatory Consultants Inc** is submitting an application for the registration of a new product, **CAPRICORN, EPA Reg # 10772-EG.** This antimicrobial, end use, integrated, non-food use product is formulated as a cleaner.

**Supporting Documents:**

1) Application form (EPA form 8570-1).
2) Cover Letter (3/8/2016).
3) Certification with respect to Citation of Data (EPA Form 8570-34).
4) Proposed Basic CSF (2/12/2016).
5) Fragrance Pilot Certification Statements form the Registrant (3/25/2015) and Supplier (12/9/2015).
6) Proposed Label
7) Data Matrix
8) MRIDS:

| | |
|---|---|
| 49795301 | Swain, D. (2016) Capricorn: Product Chemistry Identity and Composition. Unpublished study prepared by Church & Dwight Co., Inc. 92p. |
| 49795302 | Swain, D. (2016) Capricorn: Product Chemistry Data Waivers. Unpublished study prepared by Church & Dwight Co., Inc. 4p. |
| 49795303 | Sanow, W. (2015) Capricorn: Enforcement Analytical Titration Validation for Chemical Characterization: Final Report. Project Number: A18858, SRC85070215/VTT. Unpublished study prepared by Accuratus Lab Services. 28p. |
| 49795304 | Sanow, W. (2015) Capricorn: Enforcement GC Method Validation for Chemical Characterization; Final Report. Project Number: A18859, SRC85070215/VGC. Unpublished study prepared by Accuratus Lab Services. 34p. |
| 49795305 | Sanow, W. (2016) Capricorn: Product Chemistry Testing: Final Report. Project Number: A19924, SRC85070215/PCT. Unpublished study prepared by Accuratus Lab Services. 23p. |
| 49795306 | Sanow, W. (2015) Capricorn: Active Ingredient Chemical Characterization: Final Report. Project Number: A18996. Unpublished study prepared by Accuratus Lab Services. 26p. |
| 49795307 | Sanow, W. (2015) Capricorn-9: Active Ingredient Chemical Characterization; Final Report. Project Number: A19265, SRC85090215/CHR. Unpublished study prepared by Accuratus Lab Services. 25p. |
| 49795308 | Sanow, W. (2016) Capricorn: Long Term Storage Stability of Test Substances; Interim Report. Project Number: A19554, SRC85102015/LTS/1. Unpublished study prepared by Accuratus Lab Services. 29p. |
| 49795309 | Sanow, W. (2016) Capricorn: Long Term Storage Stability of Test Substances; Interim Report. Project Number: A19553, SRC85102015/LTS/2. Unpublished study prepared by Accuratus Lab Services. 29p. |

**FINDINGS:**

1) The proposed Basic CSF (2/12/2016) contains an unregistered source for one of the Active Ingredients (AI) namely, Sodium Percarbonate and therefore is integrated.
2) The concentrations of the AIs are in agreement with the proposed label.
3) All certified limits meet the EPA 40CFR standard certified limits.
4) All ingredients had been approved for pesticide formulation.
5) The registrant provided Preliminary Analysis of Product Samples (5 Lot Analysis) (MRID #49795301)

| Lot | Tetraacetylethylenediamine % | Sodium Percarbonate % |
|---|---|---|
| 1 | 4.74 | 18.37 |
| 2 | 4.68 | 18.91 |
| 3 | 4.56 | 19.15 |
| 4 | 4.51 | 19.25 |
| 5 | 4.55 | 19.24 |
| **Average** | **4.61** | **18.98** |

6) The registrant provided Enforcement of Analytical Method for the AI, Tetraacetylethylenediamine (TAED) using Gas Chromatography (MRID # 49795304). The registrant provided Enforcement of Analytical Method for the AI, Sodium Percarbonate through the quantitative analysis of Available Oxygen using Titration Method (MRID # 49795303). The results are provided below:

| Replicate | % TAED | % Available Oxygen | % Sodium Percarbonate* |
|---|---|---|---|
| 1 | 4.61 | 2.48 | 18.37 |
| 2 | 4.67 | 2.47 | 18.30 |
| 3 | 4.75 | 2.47 | 18.30 |
| 4 | 4.97 | 2.47 | 18.30 |
| 5 | 4.73 | 2.48 | 18.37 |
| 6 | 4.73 | 2.48 | 18.37 |
| **Average** | **4.74** | **2.48** | **18.34** |
| Standard Deviation | 0.12 | 0.01 | |

*- Based on the content of 13.5% Available Oxygen

7) The registrant has carried out Storage Stability (830.6317 guideline) and Corrosion Characteristics (830.6320 guideline) of the product (MRIDs#49795308-49795309). The tests were conducted with the test substance in commercial packaging material (High Density Polyethylene). The registrant has provided data for storage stability and corrosion characteristics for the duration of 3 months. The registrant had indicated that data will be provided for 6, 9 and 12 months after completion.

8) The OPPTS Guidelines Group "A & B" product chemistry data requirements applicable to integrated, non-food use, end-use product have been met except for the completed Storage Stability and Corrosion Characteristics.- MRID #s: 49795301 – 49819809.

**CONCLUSIONS:**

The proposed Basic CSF (2/12/2016) is acceptable. OPPTS Guideline, 830 Guidelines group "A" and "B" product chemistry requirements for antimicrobial, integrated, non-food use, end-use product have been met, ***with the exception of the storage stability and corrosion characteristics studies (830.6317 and 830.6320 guidelines). The unmet data requirements must be reported to the Agency upon completion.***

## PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system Yes [ ] No [ X ]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system Yes [X No [ ]
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §180.940 and §180.950.
Yes [ ] No [X]

*Note: The product consists of the active ingredient and impurities.*

*Note: All impurities are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," last updated in April 2011 and available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.*

c. Physical state of product: *Powder*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH and flammability are consistent with that given in 830 Series, Group B. Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

| f. Active ingredient | NC (%) | LCL (%) | UCL (%) |
|---|---|---|---|
| Tetraacetylethylenediamine | 4.44 | 4.00 | 4.88 |
| Sodium Percarbonate | 18.50 | 17.58 | 19.43 |

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [x]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [x]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

**Table A:**
**Product Chemistry (Series 830, Group A)**

| Data Requirements | Acceptance of Information | MRID No. |
|---|---|---|
| 830.1550 Product Identity[1] | A | 49795301 |
| 830.1600 Description of Materials | A | 49795301 And CSF |
| 830.1620 Production Process[2] | A | 49795301 |
| 830.1650 Formulation Process[3] | A | 49795301 |
| 830.1670 Formation of Impurities[4] | A | 49795301 |
| 830.1700 Preliminary Analysis[5] | A | 49795301 |
| 830.1750 Certified Limits[6] | A | 49795301 and CSF |
| 830.1800 Enforcement Analytical Method[7] | A | 49795303 & 49795304 |
| 830.1900 Submittal of Samples | A Samples of product will be submitted upon request. | 49795302 |

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

---

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

**Table B:**
**Physical and Chemical Characteristics (Series 830, Group B)**

| Physical/Chemical Properties* | Acceptance of Data | Value or Qualitative Description | MRID No. |
|---|---|---|---|
| 830.6302 Color | A | White | 49795305 |
| 830.6303 Physical State | A | Powder | 49795305 |
| 830.6304 Odor | A | Slight Fragrance | 49795305 |
| 830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions | W | Not required for end-use products. | 49795302 |
| 830.6314 Oxidation/ Reduction; Chemical Incompatibility | A | No reaction with monoammonium phosphate, turpentine. Addition of water caused partial dissolution of the solid and a temperature increase. Reacted with potassium permanganate resulting in brownish yellow reaction causing brownish colored powder. | 49795305 |
| 830.6315 Flammability/ Flame Extension | W | Not required for solid end-use products... | 49795302 |
| 830.6316 Explodability | W | The product does not contain any explosive ingredients. | 49795302 |
| 830.6317 Storage Stability | G | Discussion of Storage Stability. Will be submitted to the Agency upon completion. | 49795309 |
| 830.6319 Miscibility[1] | A | The product is not an emulsifiable liquid and the product will not be diluted with petroleum solvents. | 49795302 |
| 830.6320 Corrosion Characteristics | G | Discussion of Corrosion Characteristics. Discussion of Storage Stability. Will be submitted to the Agency upon completion. | 49795309 |
| 830.6321 Dielectric Breakdown Voltage | A | The product is not for use around electrical equipments. | 49795302 |
| 830.7000 pH[2] | A | 10.90 (1% Solution) | 49795305 |

| Physical/Chemical Properties* | Acceptance of Data | Value or Qualitative Description | MRID No. |
|---|---|---|---|
| 830.7050 UV/Visible Absorption | W | *[Not required for end-use products.]* | 49795302 |
| 830.7100 Viscosity | W | The Product is a powder end-use-product. | 49795302 |
| 830.7200 Melting Point/Melting Range | W | Not required for end-use products | 49795302 |
| 830.7220 Boiling Point/Boiling Range | W | Not required for end-use products | 49795302 |
| 830.7300 Density/Relative Density/Bulk Density | A | 0.9642 g/ml | 49795305 |
| 830.7370 Dissociation Constants | A | N/A | 49795302 |
| 830.7550/830.7560/830.7570 Partition Coefficient | A | N/A | 49795302 |
| 830.7840/830.7860 Water Solubility | A | N/A | 49795302 |
| 830.7950 Vapor Pressure | A | N/A | 49795302 |

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

---

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

10772-EG

# Memorandum

Date: 3/15/16

To: PM 33, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 14, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SCIENTIFIC & REGULATORY CONSULTANTS, INC.
CHURCH & DWIGHT CO., INC.
201 WEST VAN BUREN STREET
COLUMBIA CITY, IN 46725

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 09-MAR-16. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 982572 Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company: 10772 CHURCH & DWIGHT CO., INC.

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 10772-EG Product Name: CAPRICORN

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 08-Mar-2016 OPP Rec'vd Date: 09-Mar-2016

Front End Date: 09-Mar-2016 Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

CSF

View/Edit

Fast Track: New Ingredient:

Receipt Description:

NEW REGISTRATION WITH STUDIES

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

Root MRID 497953-XX

**Capricorn**
**EPA File Symbol 10772-X**

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

   Scientific & Regulatory Consultants, Inc.
   201 West Van Buren Street
   Columbia City, IN 46725

   AGENT FOR:
   Church & Dwight Co., Inc.
   500 Charles Ewing Blvd.
   Ewing, NJ 08628

2. Regulatory action in support of which this package is submitted:
   REGISTRATION: PRIA Code A540, PRIA Fee $5,107

3. Transmittal date:

   March 8, 2016

4. Administrative materials:

   A) Cover letter
   B) Proof of PRIA payment via pay.gov Agency tracker #74937728701
   C) Application (8570-1)
   D) Certification with Respect to Citation of Data (8570-34) (End use and Active)
   E) Data matrix (8570-35) End Use Product (EPA and Public)
   F) Data matrix (8570-35) Sodium Percarbonate Active Ingredient (EPA and Public)
   G) Formulator's Exemption Statement – TAED (8570-27)
   H) Fragrance Pilot Certification Statements
   I) Confidential statement of formula (8570-4) (Basic)
   J) Proposed product label (5 copies)

5. Vol. 1 Product Chemistry (MRID 49795301)
   OCSPP 830.1550-1800- Product Identity, Composition, and Analysis **49795301**

6. Vol. 2 Product Chemistry (MRID 49795302)
   OCSPP 830 Series- Waiver Requests **49795302**

7. Vol. 3 Product Chemistry (MRID 49795303)
   OCSPP 830.1800- Enforcement Analytical Titration Validation for Chemical Characterization (A18858) – Sodium Percarbonate **49795303**

8. Vol. 4 Product Chemistry (MRID 49795304)
OCSPP 830.1800- Enforcement GC Method Validation for Chemical Characterization (A18859) – TAED **49795304**

9. Vol. 5 Product Chemistry (MRID 49737305)
OCSPP 830.6302-7300- Product Chemistry Testing (A19924) **49795305**

10. Vol. 6 Product Chemistry (MRID 49795306)
40 CFR Part 160.105 – Active Ingredient Chemical Characterization – Capricorn-9 Lot # 4562-113 and Lot # 4562-114 (A18996) **49795306**

11. Vol. 7 Product Chemistry (MRID 49795307)
40 CFR Part 160.105 – Active Ingredient Chemical Characterization – Capricorn-9 Lot # 4562-124 (A19265) **49795307**

12. Vol. 8 Storage Stability and Corrosion Characteristics (MRID 49795308)
OCSPP 830.6317 and 6320- Long Term Storage Stability of Test Substances Interim Report (A19554) **49795308**

13. Vol. 9 Storage Stability and Corrosion Characteristics (MRID 49795309)
OCSPP 830.6317 and 6320- Long Term Storage Stability of Test Substances Interim Report (A19553) **49795309**

14. Vol. 10 Toxicity (MRID 49795310)
Acute Toxicity Discussion Volume **49795310**

15. Vol. 11 Toxicity (MRID 49795311)
OCSPP 870.1100- Acute Oral Toxicity (UDP) in Rats (19321-15) **49795311**

16. Vol. 12 Toxicity (MRID 49795312)
OCSPP 870.1200- Acute Dermal Toxicity in Rats (19322-15) **49795312**

17. Vol. 13 Toxicity (MRID 49795313)
OCSPP 870.1300- Acute Inhalation Toxicity in Rats (19323-15) **49795313**

18. Vol. 14 Toxicity (MRID 49795314)
OCSPP 870.2400- Acute Eye Irritation in Rabbits (19099-15) **49795314**

19. Vol. 15 Toxicity (MRID 49795315)
OCSPP 870.2500- Acute Dermal Irritation in Rabbits (19324-15) **49795315**

20. Vol. 16 Toxicity (MRID 49795316)
OCSPP 870.2600- Skin Sensitization in Guinea Pigs (19325-15) **49795316**

21. Vol. 17 Efficacy (MRID 49795317)
OCSPP 810.2200- AOAC Use-Dilution Method – *Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus* (A19644) **49795317**

22. Vol. 18 Efficacy (MRID 49795318)
OCSPP 810.2200- AOAC Use-Dilution Method – *Escherichia coli* O157:H7 (A19755) **49795318**

23. Vol. 19 Efficacy (MRID 49795319)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – 2009-H1N1 Influenza A virus (Novel H1N1) (A19752) **49795319**

24. Vol. 20 Efficacy (MRID 49795320)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Herpes simplex virus type 1 (A19753) **49795320**

25. Vol. 21 Efficacy (MRID 49795321)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rotavirus (A19771) **49795321**

26. Vol. 22 Efficacy (MRID 49795322)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rhinovirus type 39 (A19772) **49795322**

27. Vol. 23 Efficacy (MRID 49795323)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Immunodeficiency Virus type 1 (A19736) **49795323**

28. Vol. 24 Efficacy (MRID 49795324)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Klebsiella pneumoniae, Staphylococcus aureus* (A19683) **49795324**

29. Vol. 25 Efficacy (MRID 49795325)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Escherichia coli* O157:H7 (A19767) **49795325**

30. Vol. 26 Efficacy (MRID 49795326)
OCSPP 810.2400- Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Dilutable) – *Klebsiella pneumoniae, Staphylococcus aureus* (A19691) **49795326**

31. Vol. 27 Efficacy (MRID 49795327)
OCSPP 810.2400- Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Dilutable) – *Escherichia coli* O157:H7 (A19902) **49795327**

32. Vol. 28 Efficacy (MRID 49795328)
OCSPP 810.2400- Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces – *Salmonella enterica* (A19900) **49795328**

33. Vol. 29 Efficacy (MRID 49795329)
Subdivision G 93-30 – EPA Hard Surface Mildew-Fungistatic Test – *Aspergillus niger* (A19759) **49795329**

34. Vol. 30 Efficacy (MRID 49795330)
Subdivision G 93-30 – Fabric Mildew Fungistatic Test – *Aspergillus niger, Penicillium variabile* (A19758) **49795330**

35. Vol. 31 Efficacy (MRID 49795331)
OCSPP 810.2200- AOAC Use-Dilution Method – *Pseudomonas aeruginosa, Salmonella enterico, Staphylococcus aureus* (A19659) **49795331**

36. Vol. 32 Efficacy (MRID 49795332)
OCSPP 810.2200- AOAC Use-Dilution Method – *Escherichia coli* O157:H7 (A19757) **49795332**

37. Vol. 33 Efficacy (MRID 49795333)
OCSPP 810.2200- AOAC Use-Dilution Method – *Klebsiella pneumoniae* (A19756) **49795333**

38. Vol. 34 Efficacy (MRID 49795334)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – 2009-H1N1 Influenza A virus (Novel H1N1) (A19760) **49795334**

39. Vol. 35 Efficacy (MRID 49795335)
OC5PP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Herpes simplex virus type 1 (A19761) **49795335**

40. Vol. 36 Efficacy (MRID 49795336)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rotavirus (A19770) **49795336**

41. Vol. 37 Efficacy (MRID 49795337)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rhinovirus type 39 (A19769) **49795337**

42. Vol. 38 Efficacy (MRID 49795338)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Immunodeficiency Virus type 1 (A19728) **49795338**

43. Vol. 39 Efficacy (MRID 49795339)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Klebsiella pneumonioe, Staphylococcus aureus* (A19679) **49795339**

44. Vol. 40 Efficacy (MRID 49795340)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Escherichia coli* O157:H7 (A19749) **49795340**

45. Vol. 41 Active Ingredient Product Chemistry (MRID 49795341)
OCSPP 830.1700- Provox Preliminary Analysis of Test Substance (5 Batch Analysis) (19490-15) **49795341**

46. Vol. 42 Active Ingredient Toxicity (MRID 49795342)
OCSPP 870.1100- Provox Acute Oral Toxicity (UDP) in Rats (19318-15) **49795342**

47. Vol. 43 Active Ingredient Toxicity (MRID 49795343)
OCSPP 870.1200- Provox Acute Dermal Toxicity in Rats (19319-15) **49795343**

48. Vol. 44 Active Ingredient Toxicity (MRID 49795344)
OCSPP 870.2600- Provox Skin Sensitization: Local Lymph Node Assay in Mice (19320-15) **49795344**

49. Vol. 45 Active Ingredient Waivers (MRID 49795345)
OCSPP Guidelines Provox (Sodium Percarbonate Active Ingredient Source) Waiver Requests **49795345**

| | |
|---|---|
| Company Official: | David Swain |
| Company Name: | Agent for Church & Dwight Co., Inc. |
| Company Contact: | David Swain<br>Phone: (260) 244-6270<br>Email: dswain@srcconsultants.com |

*Product ingredient source information may be entitled to confidential treatment*

Scientific & Regulatory Consultants, Inc.

March 8, 2016

Ms. Julie Chao, PM-33
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard, 2777 5 Crystal Drive
Arlington, VA 22202

**SUBJECT: Capricorn**
**EPA Reg. No. 10772-x**

Dear Ms. Chao:

On behalf of Church & Dwight Co., Inc. (Church & Dwight), we enclose a submission for the above referenced product. Scientific & Regulatory Consultants, Inc. is the agent of record for Church & Dwight. Capricorn is a concentrated solid product to be used when diluted as instructed as a laundry pre-soak or post-soak disinfectant and sanitizer and hard surface disinfectant and sanitizer for use in homes, schools, hospitals, office buildings, etc. This submission is for a new end use product; FIFRA §2(mm) uses, and thus qualifies for PRIA code A540 with a 5 month review period and PRIA fee of $5,107. Proof of payment via www.pay.gov is attached to the application.

Capricorn will be made with a registered source of one active ingredient (tetraacetylethylenediamine (TAED)) and an unregistered source of a second active ingredient (sodium percarbonate), as indicated on the enclosed Confidential Statements of Formula (CSFs) and Formulator's Exemption Statement.

[redacted]

Relevant efficacy, acute toxicity, and product chemistry data, as well as a label, are enclosed in this submission for the end use product. The root MRID number has already been assigned to this submission by EPA Front End as MRID **497953-XX** and this is reflected in the submission.

The proposed uses for this product have already been approved for these active ingredients on other EPA registered end-use products. The laundry disinfectant use is currently approved for the EPA registered product Wash 'N Bleach Extras (EPA Reg. No. 16930-5) which contains the same active ingredients as Capricorn in similar, slightly more concentrated levels. The hard surface disinfectant use has previously been approved for the active ingredient TAED with HASTE-SSD – COMPONENT A (EPA Reg. No. 1043-1258). Finally, the hard surface disinfectant use with sodium percarbonate has been approved for Sterilex Ultra Powder (EPA Reg. No. 63761-5). The soft surface sanitization use included with Capricorn is similar to the approved uses of laundry and hard surface disinfectant. Therefore, the

201 W. Van Buren St.
Columbia City, IN 46725
www.srcconsultants.com
P: 260.244.6270
F: 260.244.6273

uses appearing on the submitted Capricorn label are already approved and the initial submission qualifies for the PRIA Code A540 and does not require a new use review.

Relevant efficacy studies are submitted to allow the product label to exhibit non-food contact surface disinfection and sanitization (including supplemental bacterial and viral claims), soft surface sanitization and laundry pre-soak or post-soak disinfection and sanitization (including supplemental bacterial and viral claims). The Agency has confirmed via email the contact times for laundry sanitization at 10 minutes and laundry disinfection at 15 minutes are acceptable claims. The correspondence with Mark Perry is attached to this cover letter in Cover Letter Addendum 2. The chemical characterization for the lot(s) used in each test is included in each efficacy report. The calculations on diluting to achieve use dilution at the LCL and how these dilutions are translated into the label Directions for Use can be found in Cover Letter Addendum 1.

MRID 49795317 is an AOAC Use-Dilution study on three organisms (Volume 17). The testing on *S. enterica* and *P. aeruginosa* met EPA requirements on three lots. All test lots were made to target the Lower Certified Limit (LCL). For *Staphylococcus aureus*, four test lots at varying levels for the two active ingredients were evaluated (See Table below). Lot 4562-143 contained the lowest level of both active ingredients well below the LCL did not meet the EPA disinfection performance criteria (7 positive tubes/60). A new lot, Lot 4779-9, was prepared with higher active ingredient levels though still below the LCL. This lot met EPA performance criteria and was used to replace Lot 4562-143 as it fell too far below the LCL. All test results are presented in the final report which demonstrates three lots met EPA performance criteria when properly formulated close to the certified limits to support the hard surface disinfection claim.

**TABLE: Comparison of Active Levels in MRID 49795317 Test Lots**

| Lot | Sodium Percarbonate | TAED | *S. aureus* Performance |
|---|---|---|---|
| LCL | 17.58% | 4.00% | - |
| 4562-132 | 17.69% | 3.99% | PASS (0/60) |
| 4779-9 | 17.48% | 4.00% | PASS (2/60) |
| 4669-40 | 17.41% | 3.97% | PASS (0/60) |
| 4562-143 | 17.29% | 3.91% | Fail (7/60) |

We look forward to a timely review of this submission. If you need any clarification or issues arise during the review of this information, please contact me immediately via phone (260-244-6270) or email (dswain@srcconsultants.com) for resolution.

Sincerely,

David Swain
Agent for Church & Dwight Co., Inc.

## Cover Letter Addendum 1

Efficacy Dilution Calculations

The following test substance lots were used to conduct the GLP efficacy testing.

| Lot | Sodium Percarbonate (LCL – 17.58%) | TAED – (LCL - 4.00%) |
|---|---|---|
| 4562-132 | *17.69% | 3.99% |
| 4562-143 | 17.29% | 3.91% |
| 4699-40 | 17.41% | 3.97% |
| 4779-9 | 17.48% | 4.00% |

*The highest concentration of sodium percarbonate allowed is 17.76% per the Lower Certified Limit Testing Guidance given by the Agency, dated December 6, 2013. For product formulations in which the active level is above 1% and ≤ 20%, the tested value may be up to 1.0% above the LCL.

- 17.58 * .01 = 0.1758
- 17.58 + 0.17 = 17.76%

The Capricorn test samples were diluted at the following rates during the efficacy testing. The two following tables below outline the way theses dilutions are represented in the Directions for Use on the label submitted with this registration action. These tables also appear on the Master Label submitted for review.

| Testing Type | Type of Organism | Dilution Type | Efficacy Study Dilution Rate | Gallon Conversion |
|---|---|---|---|---|
| Hard Surface Disinfection | Bacteria<br>Viruses | 2X | 62.4 gram Capricorn / 1 liter water | 236 gram Capricorn / 1 gallon water |
| Hard Surface Mildewstat | Fungi | 2X | 62.4 gram Capricorn / 1 liter water | 236 gram Capricorn / 1 gallon water |
| Non-Food Contact Sanitization | Bacteria | 1X | 31.2 grams Capricorn / 1 liter water | 118 gram Capricorn / 1 gallon water |
| Soft Surface Sanitization | Bacteria | 2X | 62.4 gram Capricorn / 1 liter water | 236 gram Capricorn / 1 gallon water |
| Soft Surface Mildewstat | Fungi | 2X | 62.4 gram Capricorn / 1 liter water | 236 gram Capricorn / 1 gallon water |
| Laundry Pre-Soak Disinfection | Bacteria<br>Viruses | 1X | 31.2 grams Capricorn / 1 liter water | 118 gram Capricorn / 1 gallon water |
| Laundry Pre-Soak Sanitization | Bacteria | 1X | 31.2 grams Capricorn / 1 liter water | 118 gram Capricorn / 1 gallon water |

201 W. Van Buren St.
Columbia City, IN 46725
www.srcconsultants.com
P: 260.244.6270
F: 260.244.6273

| **Scoop Scenario** Scoop Directions for Use Table {[X] can equal any letter or number} | **Directions for Use for insertion depending on Measuring Device and Dilution Type** | **Measuring Device** | **Dilution Type** | **grams product per measuring device** | **Total grams product per gallon of water** | **Total grams product per liter of water** |
|---|---|---|---|---|---|---|
| **Scoop X (118 grams)** | | | | | | |
| 1 | "add 1 scoop of product to 1 gallon of water" | Scoop [X] | 1X | 118 | 118 | 31.2 |
| 2 | "add 2 scoops of product to 1 gallon of water" | Scoop [X] | 2X | 118 | 236 | 62.4 |
| 3 | "fill scoop to line [X] and add to 16 ounces of water." | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (59 grams)** | | | | | | |
| 4 | "add 2 scoops of product to 1 gallon of water" | Scoop [X] | 1X | 59.0 | 118 | 31.2 |
| 5 | "add 4 scoops of product to 1 gallon of water" | Scoop [X] | 2X | 59.0 | 236 | 62.4 |
| 6 | "fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (118 grams @ line [X])** | | | | | | |
| 7 | "fill scoop to line [X] and add to 1 gallon of water" | Scoop [X] Line [X] | 1X | 118 | 118 | 31.2 |
| 8 | "fill scoop to line [X] 2 times and add to 1 gallon of water" | Scoop [X] Line [X] | 2X | 118 | 236 | 62.4 |
| 9 | "fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (59 grams @ line [X])** | | | | | | |
| 10 | "fill scoop to line [X] 2 times and add to 1 gallon of water" | Scoop [X] Line [X] | 1X | 59.0 | 118 | 31.2 |
| 11 | "fill scoop to line [X] 4 times and add to 1 gallon of water" | Scoop [X] Line [X] | 2X | 59.0 | 236 | 62.4 |
| 12 | "fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |

| Cap Scenario | Directions for Use for insertion depending on Measuring Device and Dilution Type | Measuring Device | Dilution Type | grams product per measuring device | Total grams product per gallon of water | Total grams product per liter of water |
|---|---|---|---|---|---|---|
| **Cap [X] (118 grams)** | | | | | | |
| 1 | "add 1 capful of product to 1 gallon of water" | Cap [X] | 1X | 118 | 118 | 31.2 |
| 2 | "add 2 capfuls of product to 1 gallon of water" | Cap [X] | 2X | 118 | 236 | 62.4 |
| 3 | "fill cap to line 'X' and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 4 | "add 2 capfuls of product to 1 gallon of water" | Cap [X] | 1X | 59.0 | 118 | 31.2 |
| 5 | "add 4 capfuls of product to 1 gallon of water" | Cap [X] | 2X | 59.0 | 236 | 62.4 |
| 6 | "fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 7 | "fill cap to line [X] and add to 1 gallon of water" | Cap [X] Line [X] | 1X | 118 | 118 | 31.2 |
| 8 | "fill cap to line [X] 2 times and add to 1 gallon of water" | Cap [X] Line [X] | 2X | 118 | 236 | 62.4 |
| 9 | "fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 10 | "fill cap to line [X] 2 times and add to 1 gallon of water" | Cap [X] Line [X] | 1X | 59.0 | 118 | 31.2 |
| 11 | "fill cap to line [X] 4 times and add to 1 gallon of water" | Cap [X] Line [X] | 2X | 59.0 | 236 | 62.4 |
| 12 | "fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |

201 W. Van Buren St.
Columbia City, IN 46725

www.srcconsultants.com

P: 260.244.6270
F: 260.244.6273

## Cover Letter Addendum 2

EPA email correspondence dated November 10, 2015

201 W. Van Buren St.
Columbia City, IN 46725

www.srcconsultants.com

P: 260.244.6270
F: 260.244.6273

**From:** Perry, Mark
**To:** rjones@srcconsultants.com
**Cc:** Mitchell, Emily
**Subject:** RE: Laundry Pre-Soak Sanitizers/Disinfectants
**Date:** Tuesday, November 10, 2015 1:16:22 PM

---

Rhonda,

We are fine with laundry presoak sanitization at 10 minutes and presoak disinfection at 15 minutes. We'll note this as a needed revision for the 2400 guideline.

Mark

**From:** rjones@srcconsultants.com [mailto:rjones@srcconsultants.com]
**Sent:** Tuesday, November 10, 2015 6:32 AM
**To:** Perry, Mark <Perry.Mark@epa.gov>
**Cc:** Mitchell, Emily <Mitchell.Emily@epa.gov>
**Subject:** Re: Laundry Pre-Soak Sanitizers/Disinfectants

Mark

I am hopeful that you were able to meet yesterday to discuss our request for longer laundry presoak claims. Is there any additional information that we can provide? Did the group come to a decision?

Rhonda Jones
SRC, Inc.

On Nov 5, 2015, at 5:36 PM, "rjones@srcconsultants.com" <rjones@srcconsultants.com> wrote:

Mark

Thank you for your guidance on the laundry pre-soak sanitization and disinfection time limits inserted into 810.2400 guidelines in 2012. The 5 and 10min exposure periods for the pre-soak categories were new additions in 2012. The previous EPA Subdivision G Product Performance Guidelines and DIS/TSS 13 "Efficacy Data and Labeling Requirements for Laundry Additives" did not include time limits. DIS/TSS13 is posted on webpage currently with no accompanying citation to 810.2400. Based on current testing, our client would like to register use directions for soaking laundry for 10 minutes for sanitization and 15 minutes for disinfection.

SRC has compiled a listing of registered laundry products (attached). We have noted the contact times for the various types of laundry products: Pre-soak Laundry Sanitization, Pre-soak Laundry Disinfection, Laundry Sanitization (In Cycle), and Laundry Disinfection (In Cycle). This review shows EPA has allowed registrants to omit contact times and use longer soak times than currently shown in 810.2400:

- For laundry pre-soak sanitization – residential use, we found 33 products with contact times ranging from 5-11minutes – 85%(28/33)% of registered times in this category exceeding the 2012 guidelines. An additional 2 products had viral claims exceeding this limit.
- For laundry pre-soak sanitization – commercial/I&I use, we found 82% (27/33) products did not list a contact time and 43% (3/7) of those with times listed had contact times exceeding the 2012 guidelines. An additional 2 products had viral claims exceeding this limit.
- For laundry pre-soak disinfection, we found 6 products with one having a 15min contact time exceeding the 2012 level.

As these markets are small and competitive, especially laundry pre-soak disinfection, we are requesting your continued flexibility with these exposure times. Requiring new registrations to comply with a guideline that has not been equally required of currently marketed products is unfair and creates a barrier to market entry. EPA's registration history (attached) shows before and after the publication of 810.2400 that EPA has continued a practice of allowing submerged laundry to have longer contact times than suggested by the 2012 Guide or no contact times. The most recent example of EPA flexibility is the registration of EPA Reg. No. 1677-243 in 2014 with an 8 minute sanitization pre-soak claim though 810.2400 limits this to a 5 minute time. While DCI's are underway on a few of these chemistries, most will not be called in and thus the majority of these registrations will still not be in compliance with the exposure periods noted in 810.2400.

The FIFRA and 810 definitions of "sanitizer" and "disinfectant" do not require EPA to enforce a contact time limit associated with these claims. While the use of liquid products on hard surfaces may require a contact time limit due to evaporation concerns, these same concerns do not exist for laundry submerged in a solution. In addition, EPA has a history of allowing longer contact times for hard surfaces when they are submerged. We are asking for the same consideration afforded to hard surfaces to be allowed for laundry. In addition, EPA has no contact time requirement for laundry sanitizers and disinfectants used in the wash cycle.

Please confirm that EPA will continue the flexible practice of allowing longer contact times in the area of laundry pre-soak sanitization and disinfection where supported by the testing outlined in 810.2400 and appropriate labeling (e.g. 10min Laundry Pre-Soak Sanitization, 15min Laundry Pre-soak Disinfection). I would like to schedule a call to discuss this at your earliest availability.

Rhonda

**Rhonda Jones, RM (NRM)**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725

www.srcconsultants.com | 260.244.6270

**Please note our NEW mailing and delivery address above.**

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

<EPA Registered Laundry Products 110515.xlsx>

# 21-Day Screen Completed by Contractor

## 21-Day Expires on 3/30/16

**Jacket #** 10772-EG
**MRID#** 497953

**Content Screen:** Recommend to Pass/Fail

**11-3 Review:** Pass/Fail/NA

**Overall Status:** Recommend to Pass/Fail

# Transfer This Jacket to:

Julie Chao

33

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 3/9/16

Experts In-Processing Signature: MP Date 3/11/16 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes _____ Date _____

| EPA Reg. Number: 10772-EG | EPA Receipt Date: 3/9/16 |
|---|---|

| | Items for Review | | | Yes | No | N/A* |
|---|---|---|---|---|---|---|
| 1 | **Application Form** (EPA Form 8570-1) signed & complete including package type | | | X | | |
| 2 | **Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) | | | X | | |
| | a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) | yes: X | no: | | | |
| 3 | **Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack) | | | X | | |
| | Certificate and data matrix consistent | | | X | | |
| | If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) | yes: | no: | | | |
| | If applicable, is there a letter of Authorization for exclusive use only. | | | | | |
| 4 | **Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical) | | | X | | |
| 5 | **Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack) | | | X | | |
| | a) Selective Method (Fee category experts use) | yes: X | no: | | | |
| | b) Cite-All (Fee category experts use) | | | | | |
| | c) Applicant owns all data (Fee category experts use) | | | | | |
| 6 | **5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)** | | | X | | |
| 7 | **Is the data package consistent with PR Notice 86-5** | | | X | | |
| 8 | **Notice of Filing included with petitions** | | | | | X |

| | | | | |
|---|---|---|---|---|
| 9 | **If applicable for conventional applications, reduced risk rationale** | | | X |
| 10 | **Required Data and/or data waivers. See Footnote C.** | | | |
| | a) List study (or studies) not included with application | | | |

**Comments:**

Documentation: PASS

-All required forms are complete.

Inerts: PASS

- Inerts approved for non-food use.
- Fragrance clarification letter included.

II-3: PASS

-MRID 497953

Status: PASS

-MS 03-16-16

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**

March 11, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-514854
EPA File Symbol or Registration Number: 10772-EG
Product Name: CAPRICORN
EPA Receipt Date: 09-Mar-2016
EPA Company Number: 10772
Company Name: CHURCH & DWIGHT CO., INC.

DAVID SWAIN
AGENT FOR: CHURCH & DWIGHT CO., INC.
SCIENTIFIC & REGULATORY CONSULTANTS, INC.
201 WEST VAN BUREN STREET
COLUMBIA CITY, IN 46725

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,
Teresa Brown
Front End Processing Staff
Information Technology & Resources Management Division

# Fee for Service

{9825726~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 33

| | |
|---|---|
| Receipt No. | S- 982572 |
| EPA File Symbol/Reg. No. | 10772-EG |
| Pin-Punch Date: | 3/9/2016 |

☐ This item is NOT subject to FFS action.

**Action Code:**

Requested: A540

Granted: A540

Amount Due: $ 5,107

**Parent/Child Decisions:**

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: E. Niederhuber Date: 3/10/16

Remarks:

Receipt for Section 3

S: 982572 Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

Print Letter

Enter More Information

Tracking

Company: 10772 CHURCH & DWIGHT CO., INC.

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 10772-EG Product Name: CAPRICORN

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 08-Mar-2016 OPP Rec'vd Date: 09-Mar-2016

Front End Date: 09-Mar-2016 Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

| Receipt Content | |
|---|---|
| Study | |
| CSF | |

View/Edit

Fast Track: New Ingredient:

Receipt Description:

NEW REGISTRATION WITH STUDIES

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

Pay.gov

# Receipt

## Your payment is complete

Pay.gov Tracking ID: 25PA274R
Agency Tracking ID: 74937728701
Form Name: Pesticide Registration Improvement Act - Prepayment
Application Name: PRIA Service Fees

## Payment Information

Payment Type: Debit or credit card
Payment Amount: $5,107.00
Transaction Date: 01/08/2016 03:50:31 PM EST
Payment Date: 01/08/2016
Registration Number: 10772-x
Company Name: Church Dwight Co., Inc.
Company Number: 10772
Action Code: A540

## Account Information

Card Holder Name: Steven T Adamy
Card Type: American Express
Card Number: **********1001

## Email Confirmation Receipt

Confirmation Receipts have been emailed to:
steve.adamy@churchdwight.com

Print Form

*Please read instructions on reverse before completing form.*

Form Approved. OMB No. 2070-0060. Approval expires 2-28

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

☑ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

## Application for Pesticide - Section I

| | | |
|---|---|---|
| 1. Company/Product Number<br>10772-XX | 2. EPA Product Manager<br>Julie Chao | 3. Proposed Classification<br>☑ None ☐ Restricte |
| 4. Company/Product (Name)<br>Capricorn | PM#<br>33 | |
| 5. Name and Address of Applicant *(Include ZIP Code)*<br>Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd. Ewing, NJ 08628<br>☐ *Check if this is a new address* | 6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:<br>EPA Reg. No. _____<br>Product Name _____ | |

## Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☑ Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Capricorn is a concentrated solid product to be used when diluted as instructed as a laundry pre-soak or post-soak disinfectant and sanitizer and hard surface disinfectant and sanitizer for use in homes, schools, hospitals, office buildings, etc. This submission is for a new end use product; FIFRA §2(mm) uses, and thus qualifies for PRIA code A540 with a 5 month review period and PRIA fee of $5,107. New efficacy, chemistry, and toxicity data is submitted. This is a PRIA action A540.
Payment has bean made on-line and proof is attached with Agency tracker 74937728701

## Section - III

**1. Material This Product Will Be Packaged In:**

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes<br>☑ No | ☐ Yes<br>☑ No | ☐ Yes<br>☑ No | ☐ Metal<br>☑ Plastic<br>☐ Glass<br>☐ Paper<br>☐ Other (Specify) _____ |
| ***Certification must be submitted** | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☑ Label ☐ Container | Various. | ☑ On Label<br>☐ On Labeling accompanying product |

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☑ Paper glued ☐ Stenciled ☐ Other _____

## Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

| Name | Title | Telephone No. (Include Area Cod |
|---|---|---|
| David Swain | Agent for Church & Dwight Co., Inc. | (260) 244-6270 |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleeding statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

| | |
|---|---|
| 2. Signature *David Swain* | 3. Title Agent for Church & Dwight Co., Inc. |
| 4. Typed Name David Swain | 5. Date 03/08/2016 |

304

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
**Environmental Protection Agency**
Washington, DC 20460

# Formulator's Exemption Statement

*(40 CFR 152.85)*

| Applicant's Name and Address | EPA File Symbol/Registration Number |
|---|---|
| Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | 10772-X |
| | Product Name<br>Capricorn |
| | Date of Confidential Statement of Formula *(EPA Form 8570-4)*<br>02/12/2016 |

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Tetraacetylethylenediamine

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

**OR**

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

**Source**

| Active Ingredient | Product Name | Registration Number |
|---|---|---|
| Tetraacetylethylenediamine | [redacted] | |

| Signature | Name and Title | Date |
|---|---|---|
| David Swain | David Swain, Agent for Church & | 03/08/2016 |

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

*Product ingredient source information may be entitled to confidential treatment*

*Product ingredient source information may be entitled to confidential treatment*

March 8, 2016

Ms. Julie Chao, PM-33
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard, 2777 S Crystal Drive
Arlington, VA 22202

**SUBJECT:** **Capricorn**
**EPA Reg. No. 10772-x**

Dear Ms. Chao:

On behalf of Church & Dwight Co., Inc. (Church & Dwight), we enclose a submission for the above referenced product. Scientific & Regulatory Consultants, Inc. is the agent of record for Church & Dwight. Capricorn is a concentrated solid product to be used when diluted as instructed as a laundry pre-soak or post-soak disinfectant and sanitizer and hard surface disinfectant and sanitizer for use in homes, schools, hospitals, office buildings, etc. This submission is for a new end use product; FIFRA §2(mm) uses, and thus qualifies for PRIA code A540 with a 5 month review period and PRIA fee of $5,107. Proof of payment via www.pay.gov is attached to the application.

Capricorn will be made with a registered source of one active ingredient (tetraacetylethylenediamine (TAED)) and an unregistered source of a second active ingredient (sodium percarbonate), as indicated on the enclosed Confidential Statements of Formula (CSFs) and Formulator's Exemption Statement.

[redacted]

Relevant efficacy, acute toxicity, and product chemistry data, as well as a label, are enclosed in this submission for the end use product. The root MRID number has already been assigned to this submission by EPA Front End as MRID **497953-XX** and this is reflected in the submission.

The proposed uses for this product have already been approved for these active ingredients on other EPA registered end-use products. The laundry disinfectant use is currently approved for the EPA registered product Wash 'N Bleach Extras (EPA Reg. No. 16930-5) which contains the same active ingredients as Capricorn in similar, slightly more concentrated levels. The hard surface disinfectant use has previously been approved for the active ingredient TAED with HASTE-SSD – COMPONENT A (EPA Reg. No. 1043-1258). Finally, the hard surface disinfectant use with sodium percarbonate has been approved for Sterilex Ultra Powder (EPA Reg. No. 63761-5). The soft surface sanitization use included with Capricorn is similar to the approved uses of laundry and hard surface disinfectant. Therefore, the

201 W. Van Buren St.
Columbia City, IN 46725
www.srcconsultants.com
P: 260.244.6270
F: 260.244.6273

uses appearing on the submitted Capricorn label are already approved and the initial submission qualifies for the PRIA Code A540 and does not require a new use review.

Relevant efficacy studies are submitted to allow the product label to exhibit non-food contact surface disinfection and sanitization (including supplemental bacterial and viral claims), soft surface sanitization and laundry pre-soak or post-soak disinfection and sanitization (including supplemental bacterial and viral claims). The Agency has confirmed via email the contact times for laundry sanitization at 10 minutes and laundry disinfection at 15 minutes are acceptable claims. The correspondence with Mark Perry is attached to this cover letter in Cover Letter Addendum 2. The chemical characterization for the lot(s) used in each test is included in each efficacy report. The calculations on diluting to achieve use dilution at the LCL and how these dilutions are translated into the label Directions for Use can be found in Cover Letter Addendum 1.

MRID 49795317 is an AOAC Use-Dilution study on three organisms (Volume 17). The testing on *S. enterica* and *P. aeruginosa* met EPA requirements on three lots. All test lots were made to target the Lower Certified Limit (LCL). For *Stophylococcus aureus*, four test lots at varying levels for the two active ingredients were evaluated (See Table below). Lot 4562-143 contained the lowest level of both active ingredients well below the LCL did not meet the EPA disinfection performance criteria (7 positive tubes/60). A new lot, Lot 4779-9, was prepared with higher active ingredient levels though still below the LCL. This lot met EPA performance criteria and was used to replace Lot 4562-143 as it fell too far below the LCL. All test results are presented in the final report which demonstrates three lots met EPA performance criteria when properly formulated close to the certified limits to support the hard surface disinfection claim.

**TABLE: Comparison of Active Levels in MRID 49795317 Test Lots**

| Lot | Sodium Percarbonate | TAED | *S. aureus* Performance |
|---|---|---|---|
| LCL | 17.58% | 4.00% | - |
| 4562-132 | 17.69% | 3.99% | PASS (0/60) |
| 4779-9 | 17.48% | 4.00% | PASS (2/60) |
| 4669-40 | 17.41% | 3.97% | PASS (0/60) |
| 4562-143 | 17.29% | 3.91% | Fail (7/60) |

We look forward to a timely review of this submission. If you need any clarification or issues arise during the review of this information, please contact me immediately via phone (260-244-6270) or email (dswain@srcconsultants.com) for resolution.

Sincerely,

David Swain

David Swain
Agent for Church & Dwight Co., Inc.

201 W. Van Buren St.
Columbia City, IN 46725

www.srcconsultants.com

P: 260.244.6270
F: 260.244.6273

## Cover Letter Addendum 1

Efficacy Dilution Calculations

The following test substance lots were used to conduct the GLP efficacy testing.

| Lot | Sodium Percarbonate (LCL – 17.58%) | TAED – (LCL - 4.00%) |
|---|---|---|
| 4562-132 | *17.69% | 3.99% |
| 4562-143 | 17.29% | 3.91% |
| 4699-40 | 17.41% | 3.97% |
| 4779-9 | 17.48% | 4.00% |

*The highest concentration of sodium percarbonate allowed is 17.76% per the Lower Certified Limit Testing Guidance given by the Agency dated December 6, 2013. For product formulations in which the active level is above 1% and ≤ 20%, the tested value may be up to 1.0% above the LCL.

- 17.58 * .01 = 0.1758
- 17.58 + 0.17 = 17.76%

The Capricorn test samples were diluted at the following rates during the efficacy testing. The two following tables below outline the way theses dilutions are represented in the Directions for Use on the label submitted with this registration action. These tables also appear on the Master Label submitted for review.

| Testing Type | Type of Organism | Dilution Type | Efficacy Study Dilution Rate | Gallon Conversion |
|---|---|---|---|---|
| Hard Surface Disinfection | Bacteria<br>Viruses | 2X | 62.4 gram Capricorn / 1 liter water | 236 gram Capricorn / 1 gallon water |
| Hard Surface Mildewstat | Fungi | 2X | 62.4 gram Capricorn / 1 liter water | 236 gram Capricorn / 1 gallon water |
| Non-Food Contact Sanitization | Bacteria | 1X | 31.2 grams Capricorn / 1 liter water | 118 gram Capricorn / 1 gallon water |
| Soft Surface Sanitization | Bacteria | 2X | 62.4 gram Capricorn / 1 liter water | 236 gram Capricorn / 1 gallon water |
| Soft Surface Mildewstat | Fungi | 2X | 62.4 gram Capricorn / 1 liter water | 236 gram Capricorn / 1 gallon water |
| Laundry Pre-Soak Disinfection | Bacteria<br>Viruses | 1X | 31.2 grams Capricorn / 1 liter water | 118 gram Capricorn / 1 gallon water |
| Laundry Pre-Soak Sanitization | Bacteria | 1X | 31.2 grams Capricorn / 1 liter water | 118 gram Capricorn / 1 gallon water |

201 W. Van Buren St.
Columbia City, IN 46725
www.srcconsultants.com
P: 260.244.6270
F: 260.244.6273

| **Scoop Scenario** Scoop Directions for Use Table {[X] can equal any letter or number} | **Directions for Use for insertion depending on Measuring Device and Dilution Type** | **Measuring Device** | **Dilution Type** | **grams product per measuring device** | **Total grams product per gallon of water** | **Total grams product per liter of water** |
|---|---|---|---|---|---|---|
| **Scoop X (118 grams)** | | | | | | |
| 1 | "add 1 scoop of product to 1 gallon of water" | Scoop [X] | 1X | 118 | 118 | 31.2 |
| 2 | "add 2 scoops of product to 1 gallon of water" | Scoop [X] | 2X | 118 | 236 | 62.4 |
| 3 | "fill scoop to line [X] and add to 16 ounces of water." | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (59 grams)** | | | | | | |
| 4 | "add 2 scoops of product to 1 gallon of water" | Scoop [X] | 1X | 59.0 | 118 | 31.2 |
| 5 | "add 4 scoops of product to 1 gallon of water" | Scoop [X] | 2X | 59.0 | 236 | 62.4 |
| 6 | "fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (118 grams @ line [X])** | | | | | | |
| 7 | "fill scoop to line [X] and add to 1 gallon of water" | Scoop [X] Line [X] | 1X | 118 | 118 | 31.2 |
| 8 | "fill scoop to line [X] 2 times and add to 1 gallon of water" | Scoop [X] Line [X] | 2X | 118 | 236 | 62.4 |
| 9 | "fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (59 grams @ line [X])** | | | | | | |
| 10 | "fill scoop to line [X] 2 times and add to 1 gallon of water" | Scoop [X] Line [X] | 1X | 59.0 | 118 | 31.2 |
| 11 | "fill scoop to line [X] 4 times and add to 1 gallon of water" | Scoop [X] Line [X] | 2X | 59.0 | 236 | 62.4 |
| 12 | "fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |

| Cap Scenario | Directions for Use for insertion depending on Measuring Device and Dilution Type | Measuring Device | Dilution Type | grams product per measuring device | Total grams product per gallon of water | Total grams product per liter of water |
|---|---|---|---|---|---|---|
| **Cap [X] (118 grams)** | | | | | | |
| 1 | "add 1 capful of product to 1 gallon of water" | Cap [X] | 1X | 118 | 118 | 31.2 |
| 2 | "add 2 capfuls of product to 1 gallon of water" | Cap [X] | 2X | 118 | 236 | 62.4 |
| 3 | "fill cap to line 'X' and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 4 | "add 2 capfuls of product to 1 gallon of water" | Cap [X] | 1X | 59.0 | 118 | 31.2 |
| 5 | "add 4 capfuls of product to 1 gallon of water" | Cap [X] | 2X | 59.0 | 236 | 62.4 |
| 6 | "fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 7 | "fill cap to line [X] and add to 1 gallon of water" | Cap [X] Line [X] | 1X | 118 | 118 | 31.2 |
| 8 | "fill cap to line [X] 2 times and add to 1 gallon of water" | Cap [X] Line [X] | 2X | 118 | 236 | 62.4 |
| 9 | "fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 10 | "fill cap to line [X] 2 times and add to 1 gallon of water" | Cap [X] Line [X] | 1X | 59.0 | 118 | 31.2 |
| 11 | "fill cap to line [X] 4 times and add to 1 gallon of water" | Cap [X] Line [X] | 2X | 59.0 | 236 | 62.4 |
| 12 | "fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |

## Cover Letter Addendum 2

EPA email correspondence dated November 10, 2015

201 W. Van Buren St.
Columbia City, IN 46725

www.srcconsultants.com

P: 260.244.6270
F: 260.244.6273

**From:** Perry, Mark
**To:** rjones@srcconsultants.com
**Cc:** Mitchell, Emily
**Subject:** RE: Laundry Pre-Soak Sanitizers/Disinfectants
**Date:** Tuesday, November 10, 2015 1:16:22 PM

---

Rhonda,

We are fine with laundry presoak sanitization at 10 minutes and presoak disinfection at 15 minutes. We'll note this as a needed revision for the 2400 guideline.

Mark

**From:** rjones@srcconsultants.com [mailto:rjones@srcconsultants.com]
**Sent:** Tuesday, November 10, 2015 6:32 AM
**To:** Perry, Mark <Perry.Mark@epa.gov>
**Cc:** Mitchell, Emily <Mitchell.Emily@epa.gov>
**Subject:** Re: Laundry Pre-Soak Sanitizers/Disinfectants

Mark

I am hopeful that you were able to meet yesterday to discuss our request for longer laundry presoak claims. Is there any additional information that we can provide? Did the group come to a decision?

Rhonda Jones
SRC, Inc.

On Nov 5, 2015, at 5:36 PM, "rjones@srcconsultants.com" <rjones@srcconsultants.com> wrote:

Mark

Thank you for your guidance on the laundry pre-soak sanitization and disinfection time limits inserted into 810.2400 guidelines in 2012. The 5 and 10min exposure periods for the pre-soak categories were new additions in 2012. The previous EPA Subdivision G Product Performance Guidelines and DIS/TSS 13 "Efficacy Data and Labeling Requirements for Laundry Additives" did not include time limits. DIS/TSS13 is posted on webpage currently with no accompanying citation to 810.2400. Based on current testing, our client would like to register use directions for soaking laundry for 10 minutes for sanitization and 15 minutes for disinfection.

SRC has compiled a listing of registered laundry products (attached). We have noted the contact times for the various types of laundry products: Pre-soak Laundry Sanitization, Pre-soak Laundry Disinfection, Laundry Sanitization (In Cycle), and Laundry Disinfection (In Cycle). This review shows EPA has allowed registrants to omit contact times and use longer soak times than currently shown in 810.2400:

- For laundry pre-soak sanitization – residential use, we found 33 products with contact times ranging from 5-11minutes – 85%(28/33)% of registered times in this category exceeding the 2012 guidelines. An additional 2 products had viral claims exceeding this limit.
- For laundry pre-soak sanitization – commercial/I&I use, we found 82% (27/33) products did not list a contact time and 43% (3/7) of those with times listed had contact times exceeding the 2012 guidelines. An additional 2 products had viral claims exceeding this limit.
- For laundry pre-soak disinfection, we found 6 products with one having a 15min contact time exceeding the 2012 level.

As these markets are small and competitive, especially laundry pre-soak disinfection, we are requesting your continued flexibility with these exposure times. Requiring new registrations to comply with a guideline that has not been equally required of currently marketed products is unfair and creates a barrier to market entry. EPA's registration history (attached) shows before and after the publication of 810.2400 that EPA has continued a practice of allowing submerged laundry to have longer contact times than suggested by the 2012 Guide or no contact times. The most recent example of EPA flexibility is the registration of EPA Reg. No. 1677-243 in 2014 with an 8 minute sanitization pre-soak claim though 810.2400 limits this to a 5 minute time. While DCI's are underway on a few of these chemistries, most will not be called in and thus the majority of these registrations will still not be in compliance with the exposure periods noted in 810.2400.

The FIFRA and 810 definitions of "sanitizer" and "disinfectant" do not require EPA to enforce a contact time limit associated with these claims. While the use of liquid products on hard surfaces may require a contact time limit due to evaporation concerns, these same concerns do not exist for laundry submerged in a solution. In addition, EPA has a history of allowing longer contact times for hard surfaces when they are submerged. We are asking for the same consideration afforded to hard surfaces to be allowed for laundry. In addition, EPA has no contact time requirement for laundry sanitizers and disinfectants used in the wash cycle.

Please confirm that EPA will continue the flexible practice of allowing longer contact times in the area of laundry pre-soak sanitization and disinfection where supported by the testing outlined in 810.2400 and appropriate labeling (e.g. 10min Laundry Pre-Soak Sanitization, 15min Laundry Pre-soak Disinfection). I would like to schedule a call to discuss this at your earliest availability.

Rhonda

**Rhonda Jones, RM (NRM)**
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725

www.srcconsultants.com | 260.244.6270

**Please note our NEW mailing and delivery address above.**

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information exempt from disclosure under law. If you have received this message in error, please inform us promptly by reply e-mail, then delete the e-mail and destroy any printed copy.

<EPA Registered Laundry Products 110515.xlsx>

Root MRID 497953-XX

**Capricorn**
**EPA File Symbol 10772-X**

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

   Scientific & Regulatory Consultants, Inc.
   201 West Van Buren Street
   Columbia City, IN 46725

   AGENT FOR:
   Church & Dwight Co., Inc.
   500 Charles Ewing Blvd.
   Ewing, NJ 08628

2. Regulatory action in support of which this package is submitted:
   REGISTRATION: PRIA Code A540, PRIA Fee $5,107

3. Transmittal date:

   March 8, 2016

4. Administrative materials:

   A) Cover letter
   B) Proof of PRIA payment via pay.gov Agency tracker #74937728701
   C) Application (8570-1)
   D) Certification with Respect to Citation of Data (8570-34) (End use and Active)
   E) Data matrix (8570-35) End Use Product (EPA and Public)
   F) Data matrix (8570-35) Sodium Percarbonate Active Ingredient (EPA and Public)
   G) Formulator's Exemption Statement – TAED (8570-27)
   H) Fragrance Pilot Certification Statements
   I) Confidential statement of formula (8570-4) (Basic)
   J) Proposed product label (5 copies)

5. Vol. 1 Product Chemistry (MRID 49795301)
   OCSPP 830.1550-1800- Product Identity, Composition, and Analysis

6. Vol. 2 Product Chemistry (MRID 49795302)
   OCSPP 830 Series- Waiver Requests

7. Vol. 3 Product Chemistry (MRID 49795303)
   OCSPP 830.1800- Enforcement Analytical Titration Validation for Chemical Characterization (A18858) – Sodium Percarbonate

8. Vol. 4 Product Chemistry (MRID 49795304)
OCSPP 830.1800- Enforcement GC Method Validation for Chemical Characterization (A18859) – TAED

9. Vol. 5 Product Chemistry (MRID 49737305)
OCSPP 830.6302-7300- Product Chemistry Testing (A19924)

10. Vol. 6 Product Chemistry (MRID 49795306)
40 CFR Part 160.105 – Active Ingredient Chemical Characterization – Capricorn-9 Lot # 4562-113 and Lot # 4562-114 (A18996)

11. Vol. 7 Product Chemistry (MRID 49795307)
40 CFR Part 160.105 – Active Ingredient Chemical Characterization – Capricorn-9 Lot # 4562-124 (A19265)

12. Vol. 8 Storage Stability and Corrosion Characteristics (MRID 49795308)
OCSPP 830.6317 and 6320- Long Term Storage Stability of Test Substances Interim Report (A19554)

13. Vol. 9 Storage Stability and Corrosion Characteristics (MRID 49795309)
OCSPP 830.6317 and 6320- Long Term Storage Stability of Test Substances Interim Report (A19553)

14. Vol. 10 Toxicity (MRID 49795310)
Acute Toxicity Discussion Volume

15. Vol. 11 Toxicity (MRID 49795311)
OCSPP 870.1100- Acute Oral Toxicity (UDP) in Rats (19321-15)

16. Vol. 12 Toxicity (MRID 49795312)
OCSPP 870.1200- Acute Dermal Toxicity in Rats (19322-15)

17. Vol. 13 Toxicity (MRID 49795313)
OCSPP 870.1300- Acute Inhalation Toxicity in Rats (19323-15)

18. Vol. 14 Toxicity (MRID 49795314)
OCSPP 870.2400- Acute Eye Irritation in Rabbits (19099-15)

19. Vol. 15 Toxicity (MRID 49795315)
OCSPP 870.2500- Acute Dermal Irritation in Rabbits (19324-15)

20. Vol. 16 Toxicity (MRID 49795316)
OCSPP 870.2600- Skin Sensitization in Guinea Pigs (19325-15)

21. Vol. 17 Efficacy (MRID 49795317)
OCSPP 810.2200- AOAC Use-Dilution Method – *Pseudomonos aeruginosa, Salmanella enterica, Staphylococcus aureus* (A19644)

22. Vol. 18 Efficacy (MRID 49795318)
OCSPP 810.2200- AOAC Use-Dilution Method – *Escherichia coli* O157:H7 (A19755)

23. Vol. 19 Efficacy (MRID 49795319)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – 2009-H1N1 Influenza A virus (Novel H1N1) (A19752)

24. Vol. 20 Efficacy (MRID 49795320)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Herpes simplex virus type 1 (A19753)

25. Vol. 21 Efficacy (MRID 49795321)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rotavirus (A19771)

26. Vol. 22 Efficacy (MRID 49795322)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rhinovirus type 39 (A19772)

27. Vol. 23 Efficacy (MRID 49795323)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Immunodeficiency Virus type 1 (A19736)

28. Vol. 24 Efficacy (MRID 49795324)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Klebsiella pneumoniae, Staphylococcus aureus* (A19683)

29. Vol. 25 Efficacy (MRID 49795325)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Escherichia coli* O157:H7 (A19767)

30. Vol. 26 Efficacy (MRID 49795326)
OCSPP 810.2400- Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Dilutable) – *Klebsiella pneumoniae, Staphylococcus aureus* (A19691)

31. Vol. 27 Efficacy (MRID 49795327)
OCSPP 810.2400- Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Dilutable) – *Escherichia coli* O157:H7 (A19902)

32. Vol. 28 Efficacy (MRID 49795328)
OCSPP 810.2400- Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces – *Salmonella enterica* (A19900)

33. Vol. 29 Efficacy (MRID 49795329)
Subdivision G 93-30 – EPA Hard Surface Mildew-Fungistatic Test – *Aspergillus niger* (A19759)

34. Vol. 30 Efficacy (MRID 49795330)
Subdivision G 93-30 – Fabric Mildew Fungistatic Test – *Aspergillus niger, Penicillium variabile* (A19758)

35. Vol. 31 Efficacy (MRID 49795331)
OCSPP 810.2200- AOAC Use-Dilution Method – *Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus* (A19659)

36. Vol. 32 Efficacy (MRID 49795332)
OCSPP 810.2200- AOAC Use-Dilution Method – *Escherichia coli* O157:H7 (A19757)

37. Vol. 33 Efficacy (MRID 49795333)
OCSPP 810.2200- AOAC Use-Dilution Method – *Klebsiella pneumoniae* (A19756)

38. Vol. 34 Efficacy (MRID 49795334)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – 2009-H1N1 Influenza A virus (Novel H1N1) (A19760)

39. Vol. 35 Efficacy (MRID 49795335)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Herpes simplex virus type 1 (A19761)

40. Vol. 36 Efficacy (MRID 49795336)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rotavirus (A19770)

41. Vol. 37 Efficacy (MRID 49795337)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rhinovirus type 39 (A19769)

42. Vol. 38 Efficacy (MRID 49795338)
OCSPP 810.2200- Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Immunodeficiency Virus type 1 (A19728)

43. Vol. 39 Efficacy (MRID 49795339)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Klebsiella pneumoniae, Staphylococcus aureus* (A19679)

44. Vol. 40 Efficacy (MRID 49795340)
OCSPP 810.2300- Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Dilutable) – *Escherichia coli* O157:H7 (A19749)

45. Vol. 41 Active Ingredient Product Chemistry (MRID 49795341)
OCSPP 830.1700- Provox Preliminary Analysis of Test Substance (5 Batch Analysis) (19490-15)

46. Vol. 42 Active Ingredient Toxicity (MRID 49795342)
OCSPP 870.1100- Provox Acute Oral Toxicity (UDP) in Rats (19318-15)

47. Vol. 43 Active Ingredient Toxicity (MRID 49795343)
OCSPP 870.1200- Provox Acute Dermal Toxicity in Rats (19319-15)

48. Vol. 44 Active Ingredient Toxicity (MRID 49795344)
OCSPP 870.2600- Provox Skin Sensitization: Local Lymph Node Assay in Mice (19320-15)

49. Vol. 45 Active Ingredient Waivers (MRID 49795345)
OCSPP Guidelines Provox (Sodium Percarbonate Active Ingredient Source) Waiver Requests


| | |
|---|---|
| Company Official: | David Swain |
| Company Name: | Agent for Church & Dwight Co., Inc. |
| Company Contact: | David Swain<br>Phone: (260) 244-6270<br>Email: dswain@srcconsultants.com |

Form Approved OMB No. 2070-0060

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

## Certification with Respect to Citation of Data

| | |
|---|---|
| Applicant's/Registrant's Name, Address, and Telephone Number<br>Church & Dwight Co., Inc., 500 Charles Ewing Blvd. Ewing, NJ 08628 | EPA Registration Number/File Symbol<br>10772-X |
| Active Ingredient(s) and/or representative test compound(s)<br>Sodium percarbonate and Tetraacetylethylenediamine | Date<br>Mar. 08, 2016 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)<br>Laundry & hard surface disinfectant/sanitizer, soft surface sanitizer - healthcare, residential, I&I | Product Name<br>Capricorn |

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

### SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

### SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method. or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

### SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

**I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.**

| Signature | Date | Typed or Printed Name and Title |
|---|---|---|
| | Mar. 08, 2016 | David Swain, Agent |

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M Street, S.W.**
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

## Certification with Respect to Citation of Data

| | |
|---|---|
| Applicant's/Registrant's Name, Address, and Telephone Number<br>Church & Dwight Co., Inc., 500 Charles Ewing Blvd. Ewing, NJ 08628 | EPA Registration Number/File Symbol<br>10772-X |
| Active Ingredient(s) and/or representative test compound(s)<br>Sodium percarbonate | Date<br>Mar. 08, 2016 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)<br>Laundry & hard surface disinfectant/sanitizer, soft surface sanitizer - healthcare, residential, I&I | Product Name<br>Capricorn (Sodium Percarbonate AI source) |

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

**I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.**

| | | |
|---|---|---|
| Signature | Date<br>Mar. 08, 2016 | Typed or Printed Name and Title<br>David Swain, Agent |

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

# A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

| Guideline No. | Group A: Product Chemistry Data Study Title | EP Data Submitted | MP Data Submitted | TGAI Data Submitted |
|---|---|---|---|---|
| 830.1550 | Product Identity & Composition | ✓ | | |
| 830.1600 | Description of materials used to produce the product | ✓ | | |
| 830.1650 | Description of formulation process | ✓ | | |
| 830.1670 | Discussion on the formation of impurities | ✓ | | |
| 830.1700 | Preliminary analysis | ✓ | | |
| 830.1750 | Certified limits (158.345) | ✓ | | |
| 830.1800 | Enforcement analytical method | ✓ | | |

| Guideline No. | Group B: Product Chemistry Data Study Title | EP Data Submitted | MP Data Submitted | TGAI Data Submitted |
|---|---|---|---|---|
| 830.6302 | Color | ✓ | | |
| 830.6303 | Physical State | ✓ | | |
| 830.6304 | Odor | ✓ | | |
| 830.6313 | Stability to normal and elevated temperatures metal and metal ions | | | |
| 830.6314 | Oxidation/Reduction (Chemical incompatibility) | ✓ | | |
| 830.6315 | Flammability | ✓ | | |
| 830.6316 | Explodability | ✓ | | |
| 830.6317 | Storage stability* | ✓ | | |
| 830.6319 | Miscibility | ✓ | | |
| 830.6320 | Corrosion Characteristics* | ✓ | | |
| 830.6321 | Dielectric Breakdown Voltage | ✓ | | |
| 830.7000 | pH | ✓ | | |
| 830.7050 | UV/ Visible Absorption | | | |
| 830.7100 | Viscosity | ✓ | | |
| 830.7200 | Melting Point | | | |
| 830.7220 | Boiling Point | | | |
| 830.7300 | Density | ✓ | | |
| 830.7370 | Dissociation Constant | | | |
| 830.7550 | Partition Coefficient | | | |
| 830.7840 | Water Solubility | | | |
| 830.7950 | Vapor Pressure | | | |

Grayed out = data not required *May not be included with initial application

# A540 – Acute Toxicity Requirements

New products must either:
1) supply the product specific acute toxicity 6 pack data (listed below),
2) provide a bridging rationale document or waiver request or,
3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

| Guideline No. | Acute toxicity (6 pack) Study Title | Cite All | Selective | Waiver Request | Bridging Rational |
|---|---|---|---|---|---|
| 870.1100 | Acute Oral (LD50) | | ✓ | | |
| 870.1200 | Acute Dermal (LD50) | | ✓ | | |
| 870.1300 | Acute Inhalation (LC50) | | ✓ | | |
| 870.2400 | Acute Eye Irritation | | ✓ | | |
| 870.2500 | Acute Dermal Irritation | | ✓ | | |
| 870.2600 | Dermal Sensitization | | ✓ | | |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 29, 2017 | | EPA Reg. No./File Symbol 10772-23 | Page 1 of 10 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.1550 (*61-1*) | Product Identity and Composition | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1600 (*61-2a*) | Description of Materials Used to Produce the Product | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1620 (*61-2b*) | Description of Production Process | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1650 (*61-2b*) | Description of Formulation Process | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1670 (*61-3*) | Discussion of Formation of Impurities | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1700 (*62-1*) | Preliminary Analysis | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1750 (*62-2*) | Certified Limits | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1800 (*62-3*) | Enforcement Analytical Method Sodium percarbonate | 49795303 | Church & Dwight Co., Inc. | OWN | |
| 830.1800 (*62-3*) | Enforcement GC Method Validation TAED | 49795304 | Church & Dwight Co., Inc. | OWN | |
| 830.6302 (*63-2*) | Color | 49795305 | Church & Dwight Co., Inc. | OWN | |
| 830.6303 (*63-3*) | Physical state | 49795305 | Church & Dwight Co., Inc. | OWN | |
| 830.6304 (*63-4*) | Odor | 49795305 | Church & Dwight Co., Inc. | OWN | |
| 830.6313 (*63-13*) | Stability to Normal and Elevated Temperature Metals and Metal Ions | 49795302 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/29/2017 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

**Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 29, 2017 | | EPA Reg. No./File Symbol 10772-23 | Page 2 of 10 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient | Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.6314 (*63-14*) | Oxidation /Reduction: Chemical Incompatibility | 43232902 | Church & Dwight Co., Inc. | OWN | |
| 830.6315 (*63-15*) | Flammability | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.6316 (*63-16*) | Explodability | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.6317 (*63-17*) | Storage Stability | 49795308 | Church & Dwight Co., Inc. | OWN | |
| 830.6317 (*63-17*) | Storage Stability | 49795309 | Church & Dwight Co., Inc. | OWN | |
| 830.6319 (*63-19*) | Miscibility | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.6320 (*63-20*) | Corrosion Characteristics | 49795308 | Church & Dwight Co., Inc. | OWN | |
| 830.6320 (*63-20*) | Corrosion Characteristics | 49795309 | Church & Dwight Co., Inc. | OWN | |
| 830.6321 (*63-21*) | Dielectric Breakdown Voltage | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7000 (*63-12*) | pH | 49795305 | Church & Dwight Co., Inc. | OWN | |
| 830.7050 [*None*] | UV/Visible Absorption | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7100(*63-18*) | Viscosity | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7200 (*63-5*) | Melting Point/ Melting Range | 49795302 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/29/2017 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

**Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 29, 2017 | | EPA Reg. No./File Symbol 10772-23 | Page 3 of 10 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |

Ingredient Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860)

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.7220 (*63-6*) | Boiling Point/Boiling Range | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7300 (*63-7*) | Density/ Relative Density/Bulk Density | 49795305 | Church & Dwight Co., Inc. | OWN | |
| 830.7370 (*63-10*) | Dissociation Constants in Water | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7520 [*None*] | Particle Size Fiber Length and Diameter Distribution | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7550 (*63-11*) | Partition Coefficient (*n*-Octanol/Water) Shake Flask Method | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7560 (*63-11*) | Partition Coefficient (*n*-Octanol/Water) Generator Column Method | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7570 (*63-11*) | Partition Coefficient (*n*-Octanol/Water) Estimation By Liquid Chromatography | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7840 (*63-8*) | Water Solubility: Column Elution Method; Shake Flask Method | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7860 (*63-8*) | Water Solubility (Generator Column Method) | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7950 (*63-9*) | Vapor Pressure | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 40 CFR § 160.105 | Active Ingredient Chemical Characterization | 49795306 | Church & Dwight Co., Inc. | OWN | |
| 40 CFR § 160.105 | Active Ingredient Chemical Characterization | 49795307 | Church & Dwight Co., Inc. | OWN | |
| 870 Series | Acute Toxicity Discussion Volume | 49795310 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/29/2017 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

**Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 29, 2017 | | EPA Reg. No./File Symbol 10772-23 | Page 4 of 10 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |

Ingredient Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860)

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 870.1100 (*81-1*) | Acute oral toxicity, rat | 49795311 | Church & Dwight Co., Inc. | OWN | |
| 870.1200 (*81-2*) | Acute dermal toxicity, rat | 49795312 | Church & Dwight Co., Inc. | OWN | |
| 870.1300 (*81-3*) | Acute inhalation toxicity, rat | 49795313 | Church & Dwight Co., Inc. | OWN | |
| 870.2400 (81-4) | Acute eye irritation, rabbit | 49795314 | Church & Dwight Co., Inc. | OWN | |
| 870.2500 (*81-5*) | Acute dermal irritation, rabbit | 49795315 | Church & Dwight Co., Inc. | OWN | |
| 870.2600 (*81-6*) | Skin Sensitization, Guinea pig | 49795316 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | AOAC Use Dilution Method *Staphylococcus aureus* [ATCC 6538], *Pseudomonas aeruginosa* [ATCC 15442], *Salmonella enterica* [ATCC 10708] ; A19644 | 49795317 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | AOAC Use Dilution Method *Escherichia coli* O157:H7 [ATCC 43888]; A19755 | 49795318 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – 2009-H1N1 Influenza A virus (Novel H1N1); Strain A/Mexico/4108/2009, [CDC #2009712192]; A19752 | 49795319 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Herpes simplex virus type 1 Strain F(1) [ATCC VR-733]; A19753 | 49795320 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Rotavirus, Strain WA [ATCC VR-2018]; A19771 | 49795321 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/29/2017 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

## DATA MATRIX

| | | | |
|---|---|---|---|
| Date March 29, 2017 | | EPA Reg. No./File Symbol 10772-23 | Page 5 of 10 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient | Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 810.2200 | Virucidal Efficacy – Rhinovirus type 39 Strain 209; [ATCC VR-340]; A19772 | 49795322 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$; A19736 | 49795323 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Klebsiella pneumoniae* [ATCC 4352], *Staphylococcus aureus* [ATCC 6538]; A19683 | 49795324 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Escherichia coli* O157:H7 [ATCC 43888]; A19767 | 49795325 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Soft non-food contact sanitizer efficacy - *Klebsiella pneumoniae* [ATCC 4352], *Staphylococcus aureus* [ATCC 6538] ; A19691 | 49795326 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Soft non-food contact sanitizer efficacy - *Escherichia coli* O157:H7 [ATCC 43888]; A19902 | 49795327 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Soft non-food contact sanitizer efficacy - *Salmonella enterica* [ATCC 10708]; A19900 | 49795328 | Church & Dwight Co., Inc. | OWN | |
| Sub G 93-30 | EPA Hard Surface Mildew Fungistatic Test - *Aspergillus niger* [ATCC 6275]; A19759 | 49795329 | Church & Dwight Co., Inc. | OWN | |
| Sub G 93-30 | Fabric Mildew Fungistatic Test - *Aspergillus niger* [ATCC 6275]; *Penicillium variabile* [ATCC 32333] A19758 | 49795330 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/29/2017 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 29, 2017 | | EPA Reg. No./File Symbol 10772-23 | Page 6 of 10 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient | Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 810.2200 | AOAC Use Dilution Method *Staphylococcus aureus* [ATCC 6538], *Pseudomonas aeruginosa* [ATCC 15442], *Salmonella enterica* [ATCC 10708] ; A19659 | 49795331 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | AOAC Use Dilution Method *Escherichia coli* O157:H7 [ATCC 43888]; A19757 | 49795332 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | AOAC Use Dilution Method *Klebsiella pneumoniae* [ATCC 4352]; A19756 | 49795333 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – 2009-H1N1 Influenza A virus (Novel H1N1); Stra n A/Mexico/4108/2009, [CDC #2009712192]; A19760 | 49795334 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Herpes simplex virus type 1 Strain F(1) [ATCC VR-733]; A19761 | 49795335 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Rotavirus, Strain WA [ATCC VR-2018]; A19770 | 49795336 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Rhinovirus type 39 Strain 209; [ATCC VR-340]; A19769 | 49795337 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$; A19728 | 49795338 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Klebsiella pneumoniae* [ATCC 4352], *Staphylococcus aureus* [ATCC 6538]; A19679 | 49795339 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/29/2017 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 29, 2017 | | EPA Reg. No./File Symbol 10772-23 | Page 7 of 10 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 810.2300 | Non-food contact sanitizer efficacy - *Escherichia coli* O157:H7 [ATCC 43888]; A19749 | 49795340 | Church & Dwight Co., Inc. | OWN | |
| 830.1550 (*61-1*) | Product Identity and Composition | 50209701 | Church & Dwight Co., Inc. | OWN | |
| 830.1600 (*61-2a*) | Description of Materials Used to Produce the Product | 50209701 | Church & Dwight Co., Inc. | OWN | |
| 830.1620 (*61-2b*) | Description of Production Process | 50209701 | Church & Dwight Co., Inc. | OWN | |
| 830.1650 (*61-2b*) | Description of Formulation Process | 50209701 | Church & Dwight Co., Inc. | OWN | |
| 830.1670 (*61-3*) | Discussion of Formation of Impurities | 50209701 | Church & Dwight Co., Inc. | OWN | |
| 830.1750 (*62-2*) | Certified Limits | 50209701 | Church & Dwight Co., Inc. | OWN | |
| 870 Series | Acute Toxicity Discussion Volume | 50209702 | Church & Dwight Co., Inc. | OWN | |
| 870.1100 (*81-1*) | Acute oral toxicity, rat | 50209703 | Church & Dwight Co., Inc. | OWN | |
| 870.1200 (*81-2*) | Acute dermal toxicity, rat | 50209704 | Church & Dwight Co., Inc. | OWN | |
| 870.1300 (*81-3*) | Acute inhalation toxicity, rat | 50209705 | Church & Dwight Co., Inc. | OWN | |

| Signature | Name and Title | Date |
|---|---|---|
| | David Swain, Agent | 03/29/2017 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 29, 2017 | | EPA Reg. No./File Symbol 10772-23 | Page 8 of 10 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |

Ingredient Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860)

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 870.2500 (*81-5*) | Acute dermal irritation, rabbit | 50209706 | Church & Dwight Co., Inc. | OWN | |
| 870.2600 (*81-6*) | Skin Sensitization, Guinea pig | 50209707 | Church & Dwight Co., Inc. | OWN | |
| 810 Series | Efficacy Discussion Volume | 50209708 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | AOAC Use Dilution Method *Klebsiella pneumoniae* [ATCC 4352]; A19754 | 50209709 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Pseudomonas aeruginosa* [ATCC 15442]; A19766 | 50209710 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Salmonella enterica* [ATCC 10708]; A19768 | 50209711 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Soft non-food contact sanitizer efficacy - *Pseudomonas aeruginosa* [ATCC 15442]; A19901 | 50209712 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Fungicidal Use-Dilution Method - *Trichophyton mentagrophytes* [ATCC 9533]; (A20050) | 50209713 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Pseudomonas aeruginosa* [ATCC 15442]; A19763 | 50209714 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Salmonella enterica* [ATCC 10708]; A19762 | 50209715 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Klebsiella pneumoniae* [ATCC 4352], *Staphylococcus aureus* [ATCC 6538]; A19796 | 50209716 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/29/2017 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

## DATA MATRIX

| | | | |
|---|---|---|---|
| Date March 29, 2017 | | EPA Reg. No./File Symbol 10772-23 | Page 9 of 10 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 810.2300 | Non-food contact sanitizer efficacy - *Escherichia coli* O157:H7 [ATCC 43888]; A19793 | 50209717 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Pseudomonas aeruginosa* [ATCC 15442]; A19794 | 50209718 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Salmonella enterica* [ATCC 10708]; A19795 | 50209719 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Standard Test Method for the Evaluation of Laundry Disinfectants - *Klebsiella pneumoniae* [ATCC 4352], *Staphylococcus aureus* [ATCC 6538]; A22530 {HE} | 50209720 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Virucidal Efficacy of a Laundry Additive - Human Coronavirus (A22316) {HE} | 50209721 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Virucidal Efficacy of a Laundry Additive - Influenza A (H1N1) virus (A22317) {HE} | 50209722 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Virucidal Efficacy of a Laundry Additive - Rhinovirus type 37 [VR-1147]; (A22318) {HE} | 50209723 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Virucidal Efficacy of a Laundry Additive - Influenza A (H1N1) virus (A22464) {TL} | 50209724 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Virucidal Efficacy of a Laundry Additive - Rhinovirus type 37; [VR-1147]; (A22536) {TL} | 50209725 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Standard Test Method for the Evaluation of Laundry Sanitizers - *Klebsiella pneumoniae* [ATCC 4352], *Staphylococcus aureus* [ATCC 6538]; A22333 {HE} | 50209726 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/29/2017 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| Date March 29, 2017 | EPA Reg. No./File Symbol 10772-23 | Page 10 of 10 |
|---|---|---|
| Applicant's/Registrant's Name & Address: Church & Dwight Co., Inc. 500 Charles Ewing Blvd. Ewing, NJ 08628 | Product: Capricom | |
| Ingredient: Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 810.2400 | Standard Test Method for the Evaluation of Laundry Sanitizers - *Klebsieila pneumoniae* [ATCC 4352], *Staphylococcus aureus* [ATCC 6538]; A22601 {TL} | 50209727 | Church & Dwight Co., Inc. | OWN | |
| EPA Carpet Sanitizer methodology | Carpet Sanitizer - *Enterobacter aerogenes* [ATCC 13048], *Staphylococcus aureus* [ATCC 6538]; A21720 | 50209728 | Church & Dwight Co., Inc. | OWN | |

| Signature | Name and Title | Date |
|---|---|---|
| David Swain | David Swain, Agent | 03/29/2017 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

**Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 1 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.1550 (*61-1*) | Product Identity and Composition | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1600 (*61-2a*) | Description of Materials Used to Produce the Product | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1620 (*61-2b*) | Description of Production Process | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1650 (*61-2b*) | Description of Formulation Process | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1670 (*61-3*) | Discussion of Formation of Impurities | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1700 (*62-1*) | Preliminary Analysis | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1750 (*62-2*) | Certified Limits | 49795301 | Church & Dwight Co., Inc. | OWN | |
| 830.1800 (*62-3*) | Enforcement Analytical Method Sodium percarbonate | 49795303 | Church & Dwight Co., Inc. | OWN | |
| 830.1800 (*62-3*) | Enforcement GC Method Validation TAED | 49795304 | Church & Dwight Co., Inc. | OWN | |
| 830.6302 (*63-2*) | Color | 49795305 | Church & Dwight Co., Inc. | OWN | |
| 830.6303 (*63-3*) | Physical state | 49795305 | Church & Dwight Co., Inc. | OWN | |
| 830.6304 (*63-4*) | Odor | 49795305 | Church & Dwight Co., Inc. | OWN | |
| 830.6313 (*63-13*) | Stability to Normal and Elevated Temperature Metals and Metal Ions | 49795302 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/08/2016 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

**Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 2 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient | Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.6314 (*63-14*) | Oxidation /Reduction: Chemical Incompatibility | 43232902 | Church & Dwight Co., Inc. | OWN | |
| 830.6315 (*63-15*) | Flammability | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.6316 (*63-16*) | Explodability | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.6317 (*63-17*) | Storage Stability | 49795308 | Church & Dwight Co., Inc. | OWN | |
| 830.6317 (*63-17*) | Storage Stability | 49795309 | Church & Dwight Co., Inc. | OWN | |
| 830.6319 (*63-19*) | Miscibility | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.6320 (*63-20*) | Corrosion Characteristics | 49795308 | Church & Dwight Co., Inc. | OWN | |
| 830.6320 (*63-20*) | Corrosion Characteristics | 49795309 | Church & Dwight Co., Inc. | OWN | |
| 830.6321 (*63-21*) | Dielectric Breakdown Voltage | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7000 (*63-12*) | pH | 49795305 | Church & Dwight Co., Inc. | OWN | |
| 830.7050 [*None*] | UV/Visible Absorption | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7100(*63-18*) | Viscosity | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7200 (*63-5*) | Melting Point/ Melting Range | 49795302 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/08/2016 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

**Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 3 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.7220 (*63-6*) | Boiling Point/Boiling Range | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7300 (*63-7*) | Density/ Relative Density/Bulk Density | 49795305 | Church & Dwight Co., Inc. | OWN | |
| 830.7370 (*63-10*) | Dissociation Constants in Water | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7520 [*None*] | Particle Size Fiber Length and Diameter Distribution | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7550 (*63-11*) | Partition Coefficient (*n*-Octanol/Water) Shake Flask Method | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7560 (*63-11*) | Partition Coefficient (*n*-Octanol/Water) Generator Column Method | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7570 (*63-11*) | Partition Coefficient (*n*-Octanol/Water) Estimation By Liquid Chromatography | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7840 (*63-8*) | Water Solubility: Column Elution Method; Shake Flask Method | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7860 (*63-8*) | Water Solubility (Generator Column Method) | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 830.7950 (*63-9*) | Vapor Pressure | 49795302 | Church & Dwight Co., Inc. | OWN | |
| 40 CFR § 160.105 | Active Ingredient Chemical Characterization | 49795306 | Church & Dwight Co., Inc. | OWN | |
| 40 CFR § 160.105 | Active Ingredient Chemical Characterization | 49795307 | Church & Dwight Co., Inc. | OWN | |
| 870 Series | Acute Toxicity Discussion Volume | 49795310 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/08/2016 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 4 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient | Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 870.1100 (*81-1*) | Acute oral toxicity, rat | 49795311 | Church & Dwight Co., Inc. | OWN | |
| 870.1200 (*81-2*) | Acute dermal toxicity, rat | 49795312 | Church & Dwight Co., Inc. | OWN | |
| 870.1300 (*81-3*) | Acute inhalation toxicity, rat | 49795313 | Church & Dwight Co., Inc. | OWN | |
| 870.2400 (81-4) | Acute eye irritation, rabbit | 49795314 | Church & Dwight Co., Inc. | OWN | |
| 870.2500 (*81-5*) | Acute dermal irritation, rabbit | 49795315 | Church & Dwight Co., Inc. | OWN | |
| 870.2600 (*81-6*) | Skin Sensitization, Guinea pig | 49795316 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | AOAC Use Dilution Method *Staphylococcus aureus* [ATCC 6538], *Pseudomonas aeruginosa* [ATCC 15442], *Salmonella enterica* [ATCC 10708] ; A19644 | 49795317 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | AOAC Use Dilution Method *Escherichia coli* O157:H7 [ATCC 43888]; A19755 | 49795318 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – 2009-H1N1 Influenza A virus (Novel H1N1); Strain A/Mexico/4108/2009, [CDC #2009712192]; A19752 | 49795319 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Herpes simplex virus type 1 Strain F(1) [ATCC VR-733]; A19753 | 49795320 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Rotavirus, Strain WA [ATCC VR-2018]; A19771 | 49795321 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/08/2016 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 5 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient | Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 810.2200 | Virucidal Efficacy – Rhinovirus type 39 Strain 209; [ATCC VR-340]; A19772 | 49795322 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$; A19736 | 49795323 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Klebsiella pneumoniae* [ATCC 4352], *Staphylococcus aureus* [ATCC 6538]; A19683 | 49795324 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Escherichia coli* O157:H7 [ATCC 43888]; A19767 | 49795325 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Soft non-food contact sanitizer efficacy - *Klebsiella pneumoniae* [ATCC 4352], *Staphylococcus aureus* [ATCC 6538] ; A19691 | 49795326 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Soft non-food contact sanitizer efficacy - *Escherichia coli* O157:H7 [ATCC 43888]; A19902 | 49795327 | Church & Dwight Co., Inc. | OWN | |
| 810.2400 | Soft non-food contact sanitizer efficacy - *Salmonella enterica* [ATCC 10708]; A19900 | 49795328 | Church & Dwight Co., Inc. | OWN | |
| Sub G 93-30 | EPA Hard Surface Mildew Fungistatic Test - *Aspergillus niger* [ATCC 6275]; A19759 | 49795329 | Church & Dwight Co., Inc. | OWN | |
| Sub G 93-30 | Fabric Mildew Fungistatic Test - *Aspergillus niger* [ATCC 6275]; *Penicillium variabile* [ATCC 32333] A19758 | 49795330 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/08/2016 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 6 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient | Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 810.2200 | AOAC Use Dilution Method *Staphylococcus aureus* [ATCC 6538], *Pseudomonas aeruginosa* [ATCC 15442], *Salmonella enterica* [ATCC 10708] ; A19659 | 49795331 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | AOAC Use Dilution Method *Escherichia coli* O157:H7 [ATCC 43888]; A19757 | 49795332 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | AOAC Use Dilution Method *Klebsiella pneumoniae* [ATCC 4352]; A19756 | 49795333 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – 2009-H1N1 Influenza A virus (Novel H1N1); Strain A/Mexico/4108/2009, [CDC #2009712192]; A19760 | 49795334 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Herpes simplex virus type 1 Strain F(1) [ATCC VR-733]; A19761 | 49795335 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Rotavirus, Strain WA [ATCC VR-2018]; A19770 | 49795336 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Rhinovirus type 39 Strain 209; [ATCC VR-340]; A19769 | 49795337 | Church & Dwight Co., Inc. | OWN | |
| 810.2200 | Virucidal Efficacy – Human Immunodeficiency Virus type 1, Strain HTLV-$III_B$; A19728 | 49795338 | Church & Dwight Co., Inc. | OWN | |
| 810.2300 | Non-food contact sanitizer efficacy - *Klebsiella pneumoniae* [ATCC 4352], *Staphylococcus aureus* [ATCC 6538]; A19679 | 49795339 | Church & Dwight Co., Inc. | OWN | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/08/2016 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 7 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn | |
| Ingredient | Tetraacetylethylenediamine (4115) and Sodium percarbonate (128860) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 810.2300 | Non-food contact sanitizer efficacy - *Escherichia coli* O157:H7 [ATCC 43888]; A19749 | 49795340 | Church & Dwight Co., Inc. | OWN | |

| Signature | Name and Title | Date |
|---|---|---|
| | David Swain, Agent | 03/08/2016 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

**Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 1 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn – Sodium Percarbonate Active Ingredient Source | |
| Ingredient Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.1550 (*61-1*) | Product Identity and Composition | 44593001 | Solvay Chemicals, Inc. | OLD | |
| 830.1600 (*61-2a*) | Description of Materials Used to Produce the Product | 44593001 | Solvay Chemicals, Inc. | OLD | |
| 830.1620 (*61-2b*) | Description of Production Process | 44593001 | Solvay Chemicals, Inc. | OLD | |
| 830.1650 (*61-2b*) | Description of Formulation Process | 44593001 | Solvay Chemicals, Inc. | OLD | |
| 830.1670 (*61-3*) | Discussion of Formation of Impurities | 44593001 | Solvay Chemicals, Inc. | OLD | |
| 830.1700 (*62-1*) | Preliminary Analysis | 49795341 | Church & Dwight Co., Inc. | OWN | |
| 830.1750 (*62-2*) | Certified Limits | 44593002 | Solvay Chemicals, Inc. | OLD | |
| 830.1800 (*62-3*) | Enforcement Analytical Method | 44714101 | Biosafe Systems, LLC | OLD | |
| 830.6302 (*63-2*) | Color | [1] N/R | | | [1] PRN 92-5 |
| 830.6303 (*63-3*) | Physical state | 44714101 | Biosafe Systems, LLC | OLD | |
| 830.6304 (*63-4*) | Odor | [2] N/R | | N/A | [2] PRN 92-5 |
| 830.6313 (*63-13*) | Stability to Normal and Elevated Temperature Metals and Metal Ions | [3] N/R | | | [3] N/A - not expected to come in contact with metals. |

| Signature | Name and Title | Date |
|---|---|---|
| | David Swain, Agent | 03/08/2016 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

**Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 2 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn – Sodium Percarbonate Active Ingredient Source | |
| Ingredient Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.6314 (*63-14*) | Oxidation /Reduction: Chemical Incompatibility | 44714101 | Biosafe Systems, LLC | OLD | |
| 830.6315 (*63-15*) | Flammability | 44995601 | Solvay Chemicals, Inc. | OLD | |
| 830.6316 (*63-16*) | Explodability | 44995601 | Solvay Chemicals, Inc. | OLD | |
| 830.6317 (*63-17*) | Storage Stability | 44995601 | Solvay Chemicals, Inc. | OLD | |
| 830.6319 (*63-19*) | Miscibility | 44995601 | Solvay Chemicals, Inc. | OLD | |
| 830.6320 (*63-20*) | Corrosion Characteristics | 44995601 | Solvay Chemicals, Inc. | OLD | |
| 830.6321 (*63-21*) | Dielectric Breakdown Voltage | 44995601 | Solvay Chemicals, Inc. | OLD | |
| 830.7000 (*63-12*) | pH | 44995601 | Solvay Chemicals, Inc. | OLD | |
| 830.7050 [*None*] | UV/Visible Absorption | 44995601 | Solvay Chemicals, Inc. | OLD | |
| 830.7100(*63-18*) | Viscosity | 44995601 | Solvay Chemicals, Inc. | OLD | |
| 830.7200 (*63-5*) | Melting Point/ Melting Range | 44995601 | Solvay Chemicals, Inc. | OLD | |
| 830.7220 (*63-6*) | Boiling Point/Boiling Range | [4] N/R | Church & Dwight Co., Inc. | OWN | [4] not a liquid at room temperature |
| 830.7300 (*63-7*) | Density/ Relative Density/Bulk Density | 44995601 | Solvay Chemicals, Inc. | OLD | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/08/2016 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

**Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 3 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product | Capricorn – Sodium Percarbonate Active Ingredient Source |
| Ingredient Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.7370 (*63-10*) | Dissociation Constants in Water | [5] N/R | | | [5] substance does not have acid, base or alcohol functionality |
| 830.7520 [*None*] | Particle Size Fiber Length and Diameter Distribution | [6] N/R | | | [6] not insoluble |
| 830.7550 (*63-11*) | Partition Coefficient (*n*-Octanol/Water) Shake Flask Method | [7] N/R | | | [7] substance is not organic and non-polar |
| 830.7560 (*63-11*) | Partition Coefficient (*n*-Octanol/Water) Generator Column Method | [7] N/R | | | [7] substance is not organic and non-polar |
| 830.7570 (*63-11*) | Partition Coefficient (*n*-Octanol/Water) Estimation By Liquid Chromatography | [7] N/R | | | [7] substance is not organic and non-polar |
| 830.7840 (*63-8*) | Water Solubility: Column Elution Method; Shake Flask Method | 49795345 | Church & Dwight Co., Inc. | OWN | |
| 830.7860 (*63-8*) | Water Solubility (Generator Column Method) | 49795345 | Church & Dwight Co., Inc. | OWN | |
| 830.7950 (*63-9*) | Vapor Pressure | 49795345 | Church & Dwight Co., Inc. | OWN | |
| **ECOLOGICAL EFFECTS** | | | | | |
| 850.1010 | Invertebrate Toxicity | 45771601 | Biosafe Systems, LLC | PAY | |
| 850.1075 | Fish Toxicity Bluegill Sunfish | 45554901 | Biosafe Systems, LLC | PAY | |

| Signature | Name and Title | Date |
|---|---|---|
| | David Swain, Agent | 03/08/2016 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 4 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn – Sodium Percarbonate Active Ingredient Source | |
| Ingredient Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 850.1075 | Fish Toxicity Rainbow Trout | 46667311 | Winston Company, Inc. | PAY | |
| 850.1075 | Fish Toxicity Rainbow Trout | 46806402 | Winston Company, Inc. | PAY | |
| 850.2100 | Acute Avian Oral - Quail | 46756501 | Biosafe Systems, LLC | PAY | |
| 850.2200 | Acute Avian Dietary - Quail | 46667309 | Winston Company, Inc. | PAY | |
| 850.2200 | Acute Avian Dietary - Duck | 46667309 | Winston Company, Inc. | PAY | |
| 850.1400 | Early Life Stage Fish | 45526401 | Solvay Chemicals, Inc. | PAY | |
| 850.1300 | Life cycle Invertebrate | 45526401 | Solvay Chemicals, Inc. | PAY | |
| **TOXICOLOGY** | | | | | |
| 870.1100 (*81-1*) | Acute oral toxicity, rat | 49795342 | Church & Dwight Co., Inc. | OWN | |
| 870.1200 (*81-2*) | Acute dermal toxicity, rat | 49795343 | Church & Dwight Co., Inc. | OWN | |
| 870.1300 (*81-3*) | Acute inhalation toxicity, rat | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.2400 (81-4) | Acute eye irritation, rabbit | 42545401 | Wexford Labs | OLD | |

| | | |
|---|---|---|
| Signature | Name and Title<br>David Swain, Agent | Date<br>03/08/2016 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 5 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product | Capricorn – Sodium Percarbonate Active Ingredient Source |
| Ingredient Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 870.2500 (*81-5*) | Acute dermal irritation, rabbit | 42545401 | Wexford Labs | OLD | |
| 870.2600 (*81-6*) | Skin Sensitization, Guinea pig | 49795344 | Church & Dwight Co., Inc. | OWN | |
| 870.2600 | Acute Neurotoxicity-Rat | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.3100 | 90-Day Oral Toxicity-Rodent | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.3150 | 90-Day Oral Toxicity-Nonrodent | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.3200 | 21/28-Day Dermal Toxicity | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.3250 | 90-Day Dermal Toxicity | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.3465 | 90-Day Inhalation Toxicity-Rat | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.6200 | 90-Day Neurotoxicity-Rat | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.4100 | Chronic Oral Toxicity-Rodent | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.4200 | Carcinogenicity-Two Rodent Species – Rat and Mouse | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |

| Signature | Name and Title | Date |
|---|---|---|
| | David Swain, Agent | 03/08/2016 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 6 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product<br>Capricorn – Sodium Percarbonate Active Ingredient Source | |
| Ingredient Sodium percarbonate (128860) | | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 870.3700 | Prenatal Developmental Toxicity – Rat and Rabbit | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.3800 | Reproduction and Fertility Effects | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.5100 | Bacterial Reverse Mutation Assay | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.5300 | In Vitro Mammalian Cell Gene Mutation Test | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.5375 | In Vitro Mammalian Chromosome Aberration Test | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 870.5385 | Mammalian Bone Marrow Chromosomal Aberration Test | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| **APPLICATOR EXPOSURE** | | | | | |
| 875.1100 | Dermal Exposure | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 875.1300 | Inhalation Exposure | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 875.1500 | Biological Monitoring | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 875.1600 | Data Reporting and Calculations | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |

| Signature | Name and Title | Date |
|---|---|---|
| | David Swain, Agent | 03/08/2016 |

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M. Street, S.W.**
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137)U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.Do not send the form to this address.

**DATA MATRIX**

| | | | |
|---|---|---|---|
| Date March 8, 2016 | | EPA Reg. No./File Symbol 10772-xx | Page 7 of 7 |
| Applicant's/Registrant's Name & Address | Church & Dwight Co., Inc.<br>500 Charles Ewing Blvd.<br>Ewing, NJ 08628 | Product | Capricorn – Sodium Percarbonate Active Ingredient Source |
| Ingredient | Sodium percarbonate (128860) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 875.1700 | Product Use Information | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| **POST-APPLICATOR EXPOSURE** | | | | | |
| 875.2300 | Indoor Surface Residue Dissipation | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 875.2400 | Dermal Exposure | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 875.2500 | Inhalation Exposure | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 875.2800 | Description of Human Activity | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |
| 875.2900 | Data Reporting and Calculations | 49795345 | Church & Dwight Co., Inc. | OWN | Waiver |

| Signature | Name and Title | Date |
|---|---|---|
| | David Swain, Agent | 03/08/2016 |

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

**Agency Internal Use Copy**

# Request for Waiver of Chronic Toxicity and Exposure Data Requirements

Chronic Toxicity (OCSPP Test Guideline 870 Series, Group C)
Occupational and Residential Exposure (OCSPP Test Guideline 875 Series, Groups A and B)

**Waiver Request:**

Church & Dwight is requesting the waiver of the requirement to submit data for the Chronic Toxicity (OCSPP Test Guideline 870 Series, Group C) and Occupational and Residential Exposure (OCSPP Test Guideline 875 Series, Groups A and B). EPA has previously granted waiver of these data requirements in support of the registration of sodium percarbonate, including waiver by EPA's Antimicrobials Division (AD) supporting the registration of the identical antimicrobial uses requested here (indoor residential surfaces and laundry) for Sterilex Ultra Powder (EPA Reg. No. 63761-5)(29.75% sodium percarbonate). No additional data have been requested by EPA in support of these existing, approved antimicrobial uses as part of Registration Review, as EPA has yet to issue a preliminary work plan for sodium percarbonate (PC Code 128860). As a result, we ask that EPA apply the same rationale in support of waiver of these data requirements for this application.

In addition to EPA AD's prior determination to waive these data requirements for antimicrobial uses, EPA did not require these data to support registration of sodium percarbonate for algaecidal and fungicidal uses. Specifically, on September 16, 2002, the Biopesticides and Pollution Prevention Division (BPPD) issued a BRAD for sodium carbonate peroxyhydrate (PC Code 128860) stating that "[t]he overall toxicological risk from human exposure to sodium carbonate peroxyhydrate is negligible." *See* BRAD at page 10.

We provide below a brief discussion of sodium percarbonate and its negligible toxicological risk.

**Background on Sodium Percarbonate:**

Sodium percarbonate is a reactive oxidant that dissolves into hydrogen peroxide and sodium carbonate (washing soda) upon contact with physiological fluids and/or water. The hydrogen peroxide oxidizes the critical cellular components of the target organism and kills them. Both carbonate and sodium that result from intake of sodium percarbonate are not expected to be systemically available in the human body. Both substances are regulated through normal physiological processes.[1]

[1] *See* Massachusetts Department of Environmental Protection (MDEP) review of products containing "Hydrogen Peroxide, Peracetic Acid and Sodium Percarbonate", dated October 2010, explaining that, "[w]ith regard to carbonate, normal physiological pH is 7.4, with a range of 7.0 to 7.8. If pH of the blood decreases (i.e. , metabolic acidosis) it results in hyperventilation (increased excretion of carbon dioxide) and increased renal absorption of HCO-3. If pH of the blood increases (i.e., metabolic alkalosis), it results in hypoventilation (decreased excretion of carbon dioxide) and increased excretion of HCO-3. In addition, if sodium percarbonate is ingested, gastric acid, with a pH close to 2, will easily neutralize percarbonate to bicarbonate and/or carbon dioxide. With regard to sodium, the main regulation of sodium concentrations in the body occurs in the kidney. The amount of sodium that would be contributed through an oral intake of sodium percarbonate would not be expected to cause an increase in physiological sodium level (HERA, 2002)."

With respect to hydrogen peroxide, in a final rule issued December 1, 2000 (65 Federal Register, 75174-75179), EPA agreed that waivers should be granted for all acute, 90-day subchronic, chronic, oncogenicity, developmental, reproductive, mutagenicity, neurotoxicity and metabolism requirements for hydrogen peroxide. In its decision, the Agency stated that no additional toxicology data are required for hydrogen peroxide, in part, because of the following:

1. Hydrogen peroxide is highly reactive, with a short half-life due to the inherent instability of the peroxide bond (*i.e.*, the O-O bond). Agitation or contact with rough surfaces, sunlight, organics and metals accelerates decomposition. The instability of hydrogen peroxide, along with detoxifying enzymes found in cells (e.g., catalase, glutathione peroxidase), reduces potential residues of hydrogen peroxide in or on foods below the limits of detection of conventional analytical methods. Residues are expected to be short-lived, based on half-lives for hydrogen peroxide that are as short as a few minutes under certain conditions. Additionally, the primary degradates are oxygen and water, which are not of toxicological concern.

2. There are acceptable acute generic data referenced in the Reregistration Eligibility Document for Peroxy Compounds (December 1993, Case 4072).

Id. at 75175.

EPA also cited to an extensive data base assembled by the Agency's Office of Water, which included some data showing toxicological effects but only at high doses. In addition, the rapid decomposition of hydrogen peroxide into oxygen and water, which are not of toxicological concern, mitigates any concern about residues.

While EPA is in the process of assessing whether additional data may be required as part of Registration Review of hydrogen peroxide (the Peroxy Compounds case), it has determined that sodium percarbonate is not to be regulated in the same Peroxy Compounds case. As a result, this decision does not affect the registration of sodium percarbonate.

**Conclusion**

Church & Dwight respectfully requests the waiver of all chronic toxicity and exposure data requirements for the antimicrobial active ingredient, sodium percarbonate. EPA AD has waived these requirements previously for this active ingredient in a currently registered product with the same uses requested herein, Sterilex Ultra Powder (EPA Reg. No. 63761-5)(29.75% sodium percarbonate). Further, EPA BPPD has determined that sodium percarbonate poses negigible toxicological risk.

**END**

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Capricorn

{Alternate Brand Names}

OXICLEAN™ Antibacterial Cleaner

OXICLEAN™ Antibacterial Laundry Additive

OXICLEAN™ Antibacterial [Chlorine]Bleach Alternative

OXICLEAN™ White Revive Laundry Stain Remover [with Disinfection]

OXICLEAN™ Color Safe Disinfection

KABOOM™ Plus Disinfex [Toilet Bowl Cleanser]

**Active Ingredient:**

| | |
|---|---|
| Sodium Percarbonate | 18.50% |
| Tetraacetylethylenediamine | 4.44% |
| Other ingredients | 77.06% |
| Total: | 100.00% |

**FRONT PANEL:**

**DANGER**
KEEP OUT OF REACH OF CHILDREN

**See back panel for First Aid and additional Precautionary Labeling.**
EPA Reg. No. #10772-XX

EPA Establishment #XXXXX-XX-XXX, #XXXXX-XX-XXX

Manufactured [by] [for]:
Church & Dwight Co., Inc.
500 Charles Ewing Blvd.
Ewing, NJ 08628

Net contents:
1.7 LB (0.77kg)
2.0 LB (0.90kg)
2.5 LB (1.13kg)
2.6 LB (1.17kg)
3.0 LB (1.36kg)
4.0 LB (1.81kg)
4.5 LB (2.04kg)
5.0 LB (2.26kg)
6.5 LB (2.94kg)
10.0 LB (4.53kg)
10.5 LB (4.76kg)
11.0 LB (4.98kg)
13.5 LB (6.123kg)

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

*{NOTE TO REVIEWER: This product meets the EPA's criteria of Toxicity Category 1 for the eye route of exposure, Toxicity Category 3 for oral route of exposure and Toxicity Category 4 for all other routes of exposure. Therefore a Signal Word, Precautionary Language and First Aid Statements are required in accordance with EPA Label Review Manual: Chapter 7. The Precautionary Statements and First Aid Statements below are mandatory and will appear on the container labeling. The skin and inhalation first aid statements below are optional as the corresponding acute toxicity studies were Toxicity Category 4.}*

**BACK PANEL:**

**PRECAUTIONARY STATEMENTS: Hazardous to Humans and Domestic Animals**

**Danger.** Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**FIRST AID. If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. **If swallowed:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person. [**If on skin:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.][If **inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.] Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, call the National Pesticides Information Center at 1-800-858-7378. For emergencies, call the poison control center 1-800-222-1222.

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label.

[[1]] Always ensure powder is fully dissolved.

[[2] [Always test [product] [powder] on an inconspicuous area first.]

[[3] [Follow manufacturer's instructions for cleaning.]

[[4] [Do not use on] [wool] [wool blends], [silk], [silk blends], [leather], [or on] [fabrics labeled dry clean only.] [Not for use on] [jewelry], [latex paints], [woven baskets], [unpainted wicker]. [jute], [teak], [or] [unfinished wood]. [Metal must not be soaked and must be rinsed immediately and thoroughly.] [Not for use on] [rust], [dried paint], [or bleach damage].]

[[5] [Treat stains while fresh. Do not place fabric that has not been thoroughly rinsed into dryer.]]

[[6] [Some stains require repeated or longer treatments.] [Adding more [powder] [product] than directed increases the risk of color loss.] [Do not rinse or soak overnight.]]

**[Shake container before pouring.]**
**[[Before pouring,] [G][g]ently tap container on a [hard] surface.]**

## LAUNDRY [USE]

[To] Clean [and] [&] [Remove Stains]: [Soak [1- 6 hours] for best results]
TOP LOADER: Fill washer [drum] with water. Add up to [1] [2] [scoop] [scoops] [cap] [caps] [capful] [capfuls] [of product] [of powder] [into] [to] [washing machine] BEFORE adding laundry. [Add detergent directed.] [Add regular laundry detergent.]
HE WASHER[**]: Add up to [1] [2] [scoop] [scoops] [cap] [caps] [capful] [capfuls] [of product] [of powder] [into] [to] washer [drum] BEFORE adding laundry. [**Do not mix [powder] [product] with detergent in the dispenser.]

**[LAUNDRY] [SANITIZATION] [and] [DISINFECTION]**

[To] Sanitize [Laundry]:
[Pre-soak [Use]:] *{Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}*[in washing machine]. Immerse laundry for [at least] 10 minutes prior to starting the wash cycle. [Light soils do not require precleaning.] Effective against *{insert laundry sanitization bacteria from Table 7.}*

[To] Disinfect [Laundry]:
[To kill] bacteria and viruses†[:] *{Insert directions for 1X dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}* [in washing machine]. Immerse laundry for [at least] 15 minutes prior to starting the wash cycle. [Light soils do not require precleaning.] Effective against *{insert laundry disinfection bacteria and/or viruses from Table 7}.*

[Post-Wash [Sanitization/Disinfection] [Use]: For additional sanitization/disinfection, refill washing machine with [clean] water. *{insert directions for "1X" and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}* in washing machine. Immerse laundry for [at least] 10 minutes for sanitization or 15 minutes for disinfection. Rinse thoroughly.]

[Safe for colorfast fabrics][Follow manufacturer's instructions for water temperature and for cleaning garment or item.]

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

## HOUSEHOLD USE

### HARD NON-POROUS [SURFACES]

[To] Clean [and] [&] [Remove Stains]:
[1] *{Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [using a] [cloth] [sponge] [brush] [mop] [or by] [pouring] [solution] directly onto surface.
[3] Let stand 5-30 [minutes] [min]. Scrub as needed.
[4] Rinse thoroughly [with] [cool] [water] [and let air dry].

[[For use on] [Use only on] {Insert hard non-porous surfaces from Table 3 and/or S}]

[To] Sanitize [Hard Surfaces]:
[1] *{Insert directions for "1X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 5 minutes.
[3] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop]. [Pre-clean heavily soiled surfaces.] [*Effective against {Insert non-food contact sanitization bacteria from Table 7}.]*

[To] Disinfect [Hard Surfaces]:
[1] Pre-clean surface.
[2] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[3] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet. Let stand 10 [minutes] [min.] for bacteria and 5 [minutes] [min.] for viruses†.
[4] Wipe clean [using a] [with a] [damp] [cloth] [sponge] [or] [mop]. [Effective against *{Insert disinfection bacteria and/or viruses from Table 7}.]*

[To] Prevent Mold [and Mildew]:
[1] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [using a] [cloth] [sponge] [brush] [mop] [or] [by] [pouring] [solution on surface] until thoroughly wet.
[3] Air dry. Repeat [application] every 7 days [to inhibit] [mold] [and mildew] [growth]. [Effective against Aspergillus [A.] niger [(black mold)] [mildew].

### SOFT SURFACES [AND] [&] [FABRICS]

[To] Clean [and] [&] [Remove Stains]:
[1] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Apply [only] [enough] solution to saturate [the] stain. Let stand 1-5 [minutes] [min].
[3] Blot [stained] [area] [gently] with a [white] [dye-free] cloth. Repeat [steps 2 and 3] until stain is no longer visible.
[4] Rinse [surface] with [clean] water and pat dry.

[To] [Spot] Sanitize [Soft Surfaces]:
[1] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] Saturate [fabric] surface until it is thoroughly wet. Let stand 5 minutes.
[3] [Blot] [stained] [area] [gently] with a [white] [dye-free] [cloth] [or sponge]. [Pre-clean heavily soiled surfaces.] *[Effective against {Insert soft surface sanitization bacteria from Table 7}.]* [Blot dry with cloth.]

[To] Prevent Mold [and Mildew] [growth] [on Fabric] [on cotton] [and] [polyester]:
[1] *{Insert directions for "2X" dilution type and applicable measuring device from Table 9 (scoops) or Table 10 (caps)}.*
[2] [Saturate] [Mop, spray, wipe or sponge on] [fabric] surface until thoroughly wet.

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

[3] Air dry. [Pre-clean heavily soiled surfaces.] Repeat [application] every 28 days [to inhibit] [mold] [and mildew] [growth]. [Effective against Aspergillus [A.] niger [(black mold)] [mildew] and Penicillium [P.] variable.

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1 AIDS Virus] ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids; and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV-1 [associated with AIDS].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface/object to remain wet for 5 minutes for HIV-1 on hard non-porous surfaces. For laundry allow object to pre-soak for 15 minutes for HIV-1.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

***{Residential Containers}***

**STORAGE AND DISPOSAL:**
Nonrefillable container. Do not contaminate water, food or feed by storage and disposal. Store in original container in areas inaccessible to small children. Keep securely closed. Do not reuse or refill this container. Place [container] in trash or offer for recycling, if available.

***{Institutional Containers}***

*{Nonrefillable containers}*

**STORAGE AND DISPOSAL:**
Do not contaminate water, food or feed by storage and disposal.
**PESTICIDE STORAGE:** Store in original container in areas inaccessible to children. Keep securely closed.
**PESTICIDE DISPOSAL:** To avoid waste, use all material in this container according to label directions. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.
**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse [or equivalent]. Follow pesticide disposal instructions for rinsate. Then discard in trash or offer for recycling, if available.

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Questions or Comments:
[Call]1.XXX.XXX.XXXX
Mon-Fri 9AM-5PM ET

Website:
www.oxiclean.com/XXXXXXX
www.kaboomkaboom.com/XXXXXXX

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

*NOTE: Any claim may appear on either FRONT / BACK panel in bullet / paragraph format*

**Marketing Claims:**
[Clean & Simple] [Complete] [Complete OXICLEAN™ Clean] [Easy] [Easy to use] [Everyday Cleaner] [Everyday Use][Effective] [$O_2$ Powered] [Oxygen Powered] [Modern] [Multi-Action] [Multi-Clean] [Multi-Purpose] [Multi-Surface] [Multi-Task] [Power & Clear] [Simple Power] [Triple Action] [Ready to use][Streak-Free] [Versatile][with Oxygen] [Beautiful] [Bright][Brilliant][Glistening] [Shine] formula
[Cleaner] [Cleans] [Cleaning][Degreaser] [Degreases] [Grease releaser][with Grease Release Action][Deodorize] [Deodorizer][Deodorizes] [Deodorizing][Bathroom] [Floor] [Kitchen][Multi-Purpose] [Cleaner] [Disinfectant] [Deodorant] [Cleans][Cuts][Cuts through] [Degreases] [Destroys] [Dissolves][Eliminates] [Penetrates] [[Removes][the following] {*Insert one or more items from Table 1*}} [tough] [the toughest] [even the toughest] [stubborn] [everyday] [stains] [with no] [without] [chlorine bleach] [with no] [without] [chlorine bleach]
[Effective] [Effectively] [Effortlessly] [Fresh] [Good][Great][Maximum Cleaning Power][Smell][Smelling] [Smells] [Clean] [Cleans] [Cleaner] [Cleaning]

New [!] {*to be used as a claim descriptor only for the first 6 months on shelf*}

From OXICLEAN™, your stain removal partners

It's from OXICLEAN™, removing stains *{insert stain from Table 1}* for over XX years

From the makers of OXICLEAN™, tackles the toughest stains *{insert stain from Table 1}* all around the house [in the home]

From OXICLEAN™, tackling the toughest stains *{insert stain from Table 1}* all around the house [in the home] for XX years

Leaves surfaces sparkling

Clear drying formula for multiple surfaces

Clean the OXICLEAN™ way

[Clean] with the power of Oxygen

Bleach like whitening

From couch to counter

*{Insert number of loads according to package weight and corresponding value on Table 11}*. [Mix until powder is fully dissolved]{Laundry] [Disinfecting] [Disinfection] Loads

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

**Fragrance Claims**
Fresh Scent
Fresh Water Splash
Fresh Water Sparkle
Fresh Water Springs
Arctic Chill
Arctic Splash
Blue Wave
Cool Summer Shower
Classic Clean
Crisp Morning Air
Ocean Air
Moonlit Ocean
Rain Mist
Refreshing spring
Sparkling Water
Summer Dew
Waterfall
Water Lily

**Packaging Claims**
[Bonus] [Bonus x%] [Bonus x oz.] [X% Discount] [X% More Free] [X oz. Free]
[X oz. at x oz. Price] [X oz. for the x oz. Price] [X oz. at the Price of x oz.] [X oz. for the Price of x oz.]
[More than] [Over] [Great] [Mega] [Super] [Trial] [Value] [Pack] [Refill] [Size] [Money back guarantee] [Satisfaction guaranteed] [Your # 1 choice][For more stain fighting ideas visit [website]]

**Cleaning Claims**
[A] friendly [cleaner] [cleaning]
A shining [beautiful] clean you can see/trust
All-in-1 [complete] [cleaning] [action]
Alternative [chlorine] bleach cleaner
[Available in] [Economy] Economical refill
Bathrooms, sinks and faucets and floor areas
Better than ever on {stains} *{insert stain from Table 1 below}*
Bleach-free
Bleach power without the damaging effects and chlorine [fumes] [smell]
Boost Laundry Cleaning Power
Breaks down [and lifts out] tough stains with supercharged OXICLEAN™ Stain Fighters
Brightens
[Chlorine] Bleach alternative
Chlorine bleach alternative cleaner
[Chlorine] bleach free
Chlorine free
Chlorine free bleach
[OXICLEAN™] [a clean] you can trust
Cleans
Cleans bathroom soils
Cleans blood
Cleans everyday messes
Cleans fingerprints

Cleans food
Cleans mildew [stains] [odor]
Cleans rust stains
Cleans to a shine
Cleans [up] grease and grime
Cleans x [countertops] [floors] [square feet] [area]
Cleans and shines
Cleans [and smells] [great] [fantastic]
Cleans non-food contact surfaces
Cleans [tough] grease [better than] [ever] [before]
Cleans with a [sparkling] [fresh] [floral] [citrus] scent
Cleans without leaving a [dull] residue [behind]
Clings to surfaces for a powerful clean
Color safe
Compatible with equipment surfaces *{insert surface/site from Table 3, 5, 6}*
[Compatible with -or- Suitable] [for use on] equipment surfaces
Compatible with -or- Suitable –or compatible with equipment surfaces for computer surfaces
VOC Compliant
Confidence in cleaning
Contains [just enough] [cleaning] ingredients for [those] everyday touch ups
Contains maximum stain fighting power
Contains [effective] [fast-acting] [grease cutters] [cleaning agents]
Contains no [chlorine] bleach
Contains [water] and [active] [oxygen]
Controls [pet] [smoke] [cooking] odors [fast] [quickly]
Convenient [surface] cleaner *{insert surface/site from lists below}*
Convenient [kitchen] [and] [bathroom] surface cleaner *{insert surface/site from lists below}*
Customize your cleaning
Cuts -and/or- removes grease -and/or grime-and/or- sweat
Cuts Tough Grime without Scrubbing
Cuts cleaning time
Deep down clean
Designed -or- Ideal for daily [cleaning] [use]
Designed – or – Ideal for in home cleaning
Does not contain [chlorine] bleach
Does not contain [dyes]
Dye free
Easy [cleaning]
Easy to use [formula] [formulation]
[Easily] removes soap scum
Easily removes soap scum, hard water stains, and [dirt][grime]
Effective [cleaner -or- cleaning] [formula]
Effective cleaning [without chlorine bleach]
Effectively works on [many] [hard] non-porous surfaces
Efficacious cleaner [without compromise]
[OXICLEAN™] essential for oxygen clean
Foaming action penetrates your toughest messes
Foams [and] [bubbles] so you know it's working
For a deep down clean
For a deep clean

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

For easy cleaning
For everyday [use] [usage] [touch-ups]
For multiple cleaning [tasks]
Free from [chlorine] bleach
Free of chemical residue
Friendly to your [floor] surfaces
Friendly to your clothes
Get a true clean [with] [this product]
Gives you multiple cleaning actions [-] [removes] [eliminates] [cuts through] [stains] *{insert stain from Table 1}* (and] (deodorizes]
Go ahead [use around the house on floors] [and counters]
Good for use with microfiber cloths
Grease cut [-ter] [-ting] formula
Groundbreaking formula [is a] cleaner + stain remover + antibacterial protection
Help[s] make your room OXICLEAN™ clean
Ideal for larger soft surface areas like [couches, throw rugs, curtains] [sanitize and] to remove stains
Ideal for larger surface areas like couches, rugs and countertops
Ideal for use in gyms -and/or- health clubs-and/or- wellness centers
Ideal for use in schools -and/or- offices -and/or- public places
Ideal for use on high touch surfaces
Just [apply] mixture[,] wipe. rinse [and you're done] [; no scrubbing required!]
Knocks out the toughest kid and pet messes, removing stains and odor [on carpet] [in laundry]
Knocks out the toughest kid and pet messes, removing stains and odor [fabrics]
Labor saving no-rinse formula
Leaves a [long-lasting] [fresh] [clean] scent
Leaves a [whitening] shine
Leaves no [dull] [filmy] [sticky] residue
Leaves nothing behind [except] [but] [the] [smell] [of clean] [shine]
Leaves [virtually] no [annoying] [chemical] [scum] [residue] [film]
Leaves your *{insert surface/site from Table 3, 5, 6}* [fresh] [clean] [and] [fragrant]
Leaves your *{insert surface/site from Table 3, 5, 6}* [fresh] [clean] [and] [sparkling] [shiny]
Leaves your *{insert surface/site from Table 3, 5, 6}* [with a] [fresh] [and] [clean] scent
Lifts out [and breaks down] tough stains with supercharged OXICLEAN™ Stain Fighters
Light touch-up quick cleaning
Makes your [floor] cleaning job easier [in the] [kitchen] [and] [bathroom]
Makes grout and hard surfaces look radiant
Makes cleaning easier
Money-saving formula [use everywhere] [use in laundry & to clean surfaces]
[Multipurpose][Versatile] Cleaner
No [chlorine] bleach harshness
No [chlorine] bleach [fumes] [smell]
No harsh chemical residue
No harsh chlorine [bleach] fumes -or- smell –or odor-and/or- build-up -and/or- residue
No mess [cleaner] [cleaning]
No mixing, measuring, or rinsing required
No phosphates
No scrubbing necessary!
No sorting necessary!
No [sticky] [tacky] [residue] [film]
Non-abrasive

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Non-[chlorine] bleach
Now cleans [tough] grease [better than] [ever] [before]
Packaging made with [x%] recycled –or recyclable plastic
Pleasant smell
Powerful [cleaner] [additive]
Proof is in the clean
Quickly deodorizes
[Quickly] removes dirt and grime
Radiant shine
Releases powerful cleaning agents [on contact]
Releases powerful OXICLEAN™ Stain Fighters [on contact]
Removes offensive odors from *{insert surface/site from Table 3, 5, 6}*
Removes [oxidizable] stains
Removes stains
Shine[s] like new
Smell of clean
Sparkling shine
Stain remover
Stains disappear [before your eyes]
Starts cleaning on contact
Starts to work before you do [on]
Starts to work before [you do] [your eyes]
Strong cleaning
Strong [effective] cleanser
Strong effective cleanser [with a] [non-chemical] [fresh] [scent]
Strong effective cleanser [with a non-chemical scent]
Suitable for everyday use
[The] smell of clean
The smell of [OXICLEAN™] [clean]
The toughest stains [instantly] disappear
[This product] cleans and shines
This product's formula cleans and shines
This room is OXICLEAN™ clean
Tough on grime
Tough stains [instantly] disappear
Trusted heritage [of] [Oxygen Cleaning]
Versatile for all bathroom surfaces
Watch [this] [these] stains [start to] [disappear] [dissolve] [breakdown] right before your eyes
Watch [this] [the] [tough] [toughest] stains disappear
Works great [smells great]

**Stain Claims**
Removes -and/or- Cleans the following: *[insert stain(s)/soil(s) from Table 1]*
Removes dried on [blood]
Removes grease and grime
Removes *[insert stain(s)/soil(s) fram Toble 1]*
Removes [tough] *[insert stain(s)/soil(s) from Table 1]*
Use it [in the wash or] [as a] pre-treater [with it] to remove more stains

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

**Deodorizing Claims**
Deodorizer
Deodorizes
Deodorizes food odors [like garlic and onion] [left behind on kitchen surfaces] [after cooking]
Eliminates odors [as it cleans]
No harsh chlorine [fumes] [smells]
No harsh alcohol smell
Pleasant odor
Removes odors
[This product] will deodorize hard, nonporous surfaces from [where obnoxious odors may develop]
[This product] will deodorize surfaces in [and] [other] places bacteria growth can cause malodors

**General Antimicrobial Claims**
[3-in-1] [clean –s, -er, -ing][deodorize –s, -er, -ing][disinfect –s, -ant, -ing]
[3x Cleaning Power] [clean -s][deodorize -s][disinfect -s]
3 [cleaning] actions [in one bottle] [clean –s, -er, -ing] [deodorize -s, -er, -ing] [disinfect -s, -ant, -ing]
3 [cleaning] actions [in one bottle] [remove -s stains] [clean -s] [disinfect –s] [deodorize -s]
[4-in-1] [clean–s, -er, -ing][disinfect –s, -ant, -ing][remove -s non-living allergens][sanitize -s hard surfaces][sanitize -s fabric -s]
[4x Cleaning Power] [cleans]][disinfects][removes non-living allergens][sanitizes hard surfaces][sanitizes fabrics]
[4-in-1] [cleans][disinfects][removes non-living allergens][sanitizes hard surfaces][sanitizes fabrics]
4 [cleaning] actions [in one bottle] [disinfects] [removes non-living allergens] [sanitizes hard surfaces] [sanitizes fabrics]
3-in-1 Bathroom Cleaner [Disinfectant] [Cleaner] [Deodorizer]
A convenient way to [clean] [disinfect] [and] [deodorize]
[All-in-1] [cleaner][deodorizer][disinfectant]
[All-in-1 Complete] [cleaner/cleans][deodorizer/deodorizes][disinfectant/disinfects]
For a better [4-in-1] [kind of] clean [disinfects] [removes non-living allergens] [sanitizes hard surfaces] [sanitizes fabrics]
For [a] complete [clean] [cleaning action]
[Antibacterial] [Antibacterial Action] [Bactericidal] [Bactericide] [Germicidal*] [Virucidal†]
[Disinfect] [Disinfects] [Disinfectant] [Disinfecting]
Antibacterial Cleaner cleans and kills bacteria
Antibacterial [surface] *{insert surface/site from Table 3, 5, 6}* cleaner
Antibacterial [kitchen] [and] [bathroom] surface *{insert surface/site from Table 3, 5, 6}* cleaner
Antibacterial 4-in-1 action [disinfects] [removes non-living allergens] [sanitizes hard surfaces] [sanitizes fabrics]
Can help prevent cross-contamination by [household] bacteria
Cleans & Disinfects *{insert hard nonporous surfaces from Table 5}*
Cleans as it disinfects
Cleaner + stain fighting power + antibacterial protection for all around the house
Combines [streak-free] cleaning with antibacterial action
[Kills][Effective against] [Controls] odor-causing bacteria
[Kills][Effective against] [Controls] odor-causing bacteria in the [kitchen] [and] [bathroom]
Designed as a general [multipurpose] [multi surface] [versatile] cleaner and disinfectant
Disinfection for your [kitchen] [and] [bathroom] [floors]
Disinfects [and] [deodorizes]
Disinfects [and] [deodorizes] hard, non-porous surfaces
[Disinfectant] [Cleaner] [Deodorizer]
Helps prevent the spread of cold° and flu' viruses†
Multi surface [multipurpose] [versatile] cleaner disinfectant
Oxygen-based formula cleans and sanitizes
Surface cleaner [with antibacterial formula]

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

[This product] deodorizes areas that are hard to keep fresh smelling [or other areas prone to odors caused by microorganisms]
[This product] will help [you] keep your [surfaces] clean [and disinfected]
Three steps to clean [Disinfectant] [Cleaner] [Deodorizer]
Use [only] one product to get a streak-free shine [plus antibacterial action]
Deodorizes odors caused by bacteria
Kills odor causing bacteria in the kitchen -or- bathroom

**Hard Non-Porous Surface Sanitizing Claims**
Sanitization [against bacteria]
Oxygen based formula cleans and sanitizes
Kills [and] [Sanitizes] 99.9% of bacteria [including] [*Insert 1 or more strains from Table 7 under non-food contact sanitization]*
Powers out the toughest stains and bacteria without stripping color
Sanitizer [Sanitizes]
[5 minute] [One Step] [1 Step] Sanitizer
[5 minute] [One Step] [1 Step] Non-Food Contact Sanitizer
Cleans and sanitizes [in One Step]
Cleans, deodorizes, and sanitizes in one step
When you need sanitization!
When you need to kill bacteria [in one [easy] step]!
Kills 99.9% bacteria [in 5 minutes]!
In 5 minutes, 99.9% bacteria are dead!
Kills 99.9% {*Insert bacteria from Table 7 list under non-food contact sanitizer}* [in 5 minutes]
{Non-Food Contact Sanitizer] Effective against {*Insert bacteria from Table 7 list under non-food contact sanitizer}*
Kill bacteria where you need it most
Eliminates 99.9% of [household] bacteria in 5 minutes

**Hard Non-Porous Surface Disinfecting Claims**
[Chlorine] Bleach-free
Broad spectrum [general] [hospital] disinfectant
Destroys bacteria on {*insert site from Table 3, 5, 6*}
Disinfectant [&] Cleaner
Disinfects bathroom bacteria
Kills [*insert organism(s) from Table 7*)]
Kills bacteria on {*{insert surface/site from Table 3, 5, 6*}
Oxygen-based [disinfectant] kills [99.9%] of bacteria/viruses
Oxygen-based [disinfectant] [cleaner] kills [99.9%] of bacteria/viruses/germs*
Reduces bacteria on {*{insert surfoce/site from Table 3, 5, 6*}
Kills 99.9% of [bacteria,] [germs*] [virus†] [and], [Influenza A plus H1N1 virus†]
Kills [99.9%] [99.99%] of odor causing bacteria
Kills [99.9%] of odor causing [germs*] [With Germfighter* Technology]
Designed as a general [versatile] [multipurpose] [multi surface] cleaner and disinfectant [/sanitizer]
Cuts tough dirt [grease] and grime and kills 99.9% [99.99%] of bacteria [in the bathroom] [on] *{insert surface/site from Table 3, 5, 6}*
Cuts tough grease and grime [killing] 99.9% of bacteria [germs*] [in the kitchen] [on] {*insert surface/site from Table 3, 5, 6}*
Destroys germs* [bacteria] [that ordinary cleaners [can't] [don't]]
Disinfects *{insert surface/site from Table 3, 5, 6}*

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Disinfects and removes offensive odors from *{insert surface/site from Table 3, 5, 6}*
*Disinfects bacteria and viruses {in {insert location from Table 6}} {on {Insert items from Table 3 or 5}}*
Effective against *{Insert organisms from Table 7 under disinfection}*
Eliminates 99.9% of bacteria [germs*] [virus†]
Eliminates [99.9% of] [99.99% of] [household] bacteria [in] [10 minutes]
Eliminates 99.9% of [household] germs* [in] [10 minutes]
Eliminates [99.9% of] [99.99% of] bacteria from [kitchen] [and] [bathroom] *{insert surface/site from Table 3, 5, 6}*
Eliminates [99.9% of] [99.99% of] bacteria [in] [the] [kitchen] [and] [bathroom]
Eliminates [99.9% of] germs* [that ordinary cleaners [can't] [don't]]
Eliminates [99.9% of] [99.99% of] of hidden bacteria
Eliminates [99.9% of] [99.99% of] [kitchen] [and] [bathroom] bacteria
Kills [99.9% of] [99.99% of] bacteria
Kills [99.9% of] [99.99% of] bacteria in one step
Kills [99.9% of] [99.99% of] bacteria and leaves surfaces sparkling
Kills [99.9% of] germs*
Kills [99.9% of] bacteria and [&] viruses†
Kills [99.9% of] [99.99% of] bacteria for a deep down clean
Kills [99.9% of] [99.99% of] bacteria for a healthy home [environment]
Kills [99.9% of] [99.99% of] [Escherichia coli O157:H7 (E. coli)] [and] [Salmonella enterica] [other organisms] *{insert organism from Table 7 under disinfection}*
Kills [99.9% of] germs* [including [the] cold° and flu[‡] viruses†]
Kills [99.9% of] [99.99% of] [household] bacteria [in] [10 minutes]
Kills [99.9% of] [99.99% of] the following [household] bacteria commonly found in kitchens on hard, non-porous surfaces in 10 minutes:{organisms} *{insert organism from Table 7 under disinfection}*
Kills [99.9% of] [99.99% of] the following [household] bacteria commonly found in bathrooms on hard, non-porous surfaces in 10 minutes:{organisms} *{insert organism from Table 7 under disinfection}*
Kills [99.9% of] viruses† and [&] bacteria
Kills [99.9% of] viruses† and [&] bacteria [including [the] cold° and flu[‡] viruses]
Kills bacteria on hard, non-porous [kitchen] [and] [bathroom] surfaces in 10 minutes
Kills viruses† on hard, non-porous [kitchen] [and] [bathroom] surfaces in 5 minutes
Kills bacteria on hard, non-porous [kitchen] surfaces in 10 minutes
Kills viruses† on hard, non-porous [kitchen] surfaces in 5 minutes
Kills bacteria commonly found in [the] [kitchen] [and] [bathroom] [in] [10 minutes]
Kills bacteria for a deep down clean
Kills germs* [that ordinary cleaners] [don't] [can't]
Kills germs*
Kills [household] bacteria [germs*]
Kills [household] bacteria [commonly found in] [bathrooms] [and] [kitchens] [on hard, non-porous surfaces] [in] [10 minutes]
Kills [household] bacteria [in] [10 minutes] [commonly found in] [bathrooms] [and] [kitchens] [and on] [floors]
Kills [kitchen] [and] [bathroom] germs*
Kills [kitchen] [household] bacteria [germs*]
Kills more than 99.9% of bacteria and viruses†
Kills Viruses†
Reduces the amount of bacteria [germs*] on a surface
Removes bacteria [germs*]
Designed as a general [versatile] [multi-surface] [multipurpose] cleaner and disinfectant

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

*{Qualified "germs" claim: One of the two following footnotes must appear wherever "germs*" or related words (e.g. Germicidal*) is used on label:*

***[Kills] {*insert at least one bacteria and one virus from Table 7*}**
***Insert Table 7**

**Soft Surface Sanitizer Claims**
[Oxygen based] Soft Surface Sanitizer [Sanitization]
[Oxygen based] Soft Surface [Spot] [Fabric] Sanitizer [Sanitization]
Kills 99.9% of bacteria on soft surfaces [fabric] [upholstery] [{*insert one or more items from Table 4*}]
Oxygen based formula cleans and [spot] sanitizes soft surfaces [fabric] [upholstery] [{*insert one or more items from Table 4*}]
Powers out the toughest stains and bacteria without stripping color in fabrics
[5 minutes] [bacteria] [*Insert 1 or more strains from Table 7 under soft surfoce sonitization]* soft surface sanitization [Sanitizer]
[*Insert 1 or more stroins from Table 7 under soft surface sanitization]* soft surface [spot] sanitizer
Soft Surface [Fabric] Sanitizer [Sanitizes]
[5 minutes] [One Step] [1 Step] Soft Surface [Fabric] Sanitizer
[5 minutes] [One Step] [1 Step] soft surface sanitizer [for the [*Insert one or more locations from {Table 6}*]]
Cleans and sanitizes fabrics [soft surfaces] [soft and hard surfaces] [in One Step]
Cleans, deodorizes, and sanitizes fabrics [soft surfaces] and [hard surfaces] in one [easy] step
When you need fabric [and surface] sanitization[!]
When you need to kill bacteria on soft and hard surfaces[!]
Kills 99.9% bacteria [in] [5 minutes]
In 5 minutes, 99.9% bacteria are dead on soft surfaces[!]
Kills 99.9% {*Insert bacteria from Table 7 list under soft surface sanitizer}* [in] [5 minutes]
[Soft Surface Sanitizer] Effective against {*Insert bacteria from Table 7 list under soft surface sanitizer}*
Eliminates 99.9% of [household] bacteria on fabric [soft surfaces] in 5 minutes

**Laundry Disinfection**
Antibacterial [laundry] additive cleans and kills bacteria [germs*]
Can help prevent cross-contamination in laundry
Cleaner + stain fighting power + antibacterial protection for all your laundry needs
[Kills][Eliminates]Controls odor-causing bacteria
[Kills][Eliminates]Controls odor-causing bacteria in the [laundry]
Deodorizes odors causing bacteria
Disinfection for all your laundry needs
Disinfects [and] [deodorizes]
Disinfects your clothes
[Disinfecting] [Antibacterial] [laundry] presoak
Dissolve and eliminate tough stains
Eliminates 99.9% of bacteria [germs*] [virus†] in your laundry
Eliminates [99.9% of] [99.99% of] bacteria [in] [15 minutes] [on your clothing]
Eliminates 99.9% of germs* [in] [15 minutes] [on] [{*insert surfoce/site from Table 4}*
Eliminates [99.9% of] [99.99% of] bacteria from *{insert surfoce/site from Table 4}*
Eliminates [99.9% of] [99.99% of] bacteria [in] [the] [laundry] [and] [on] [soft surface]
Eliminates [99.9% of] germs* [that ordinary additives [can't] [don't]]
Eliminates [99.9% of] [99.99% of] of hidden bacteria
Eliminates [99.9% of] [99.99% of] bacteria

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Freshens while killing bacteria [germs*] [virus†]
Helps prevent the spread of cold° and flu[i] viruses†
Kills odor causing bacteria in the [wash and/or laundry]
[Kills] [Eliminates] [Destroys] [99.9% of] [99.99% of] bacteria in your laundry
[Kills] [Eliminates] [Destroys] [99.9% of][germs*] in your laundry
[Kills] [Eliminates] [Destroys] odor causing bacteria on *{Insert soft surface from Table 4 list under soft surface sanitizer}*
[Kills] [Eliminates] [Destroys] [99.9% of] viruses, bacteria, and in your laundry [or on *{Insert soft surface from Table 4 list under soft surface sanitizer}*
Kills [99.9%] of odor causing bacteria [germs*] [With Germfighter* Technology]
Kills 99.9% of [bacteria,] [germs*] [virus†] [and], [Influenza A plus H1N1 virus†] in your laundry
Kills [99.9% of] germs*
Kills [99.9% of] bacteria and [&] viruses†
Kills [99.9% of] [99.99% of] bacteria for a deep clean
Kills [99.9% of] [99.99% of] [Escherichia coli O157:H7 (E. coli)) [and) [Salmonella enterica] [other organisms] *{insert organism from Table 7 under disinfection}*
Kills [99.9% of] germs* [including [the] cold° and flu[i] viruses†]
Kills [99.9% of] [99.99% of] [odor causing] bacteria [in] [15 minutes]
Kills [99.9% of] viruses† and [&] bacteria
Kills [99.9% of] viruses† and [&] bacteria [including [the] cold° and flu[i] viruses]
Kills bacteria [on] [laundry] [and] [soft surfaces] in 15 minutes
Kills viruses† [on] [laundry] [and] [soft surfaces] in 15 minutes
Kills germs* [that ordinary cleaners] [don't] [can't]
Kills germs*
Kills [household] bacteria [germs*]
Oxygen-based formula cleans and sanitizes
[This product] [even] deodorizes areas that are hard to keep smelling fresh [or other areas prone to odors caused by microorganisms]
[This product] will help [you] remove stains from your [laundry] and [and disinfect]
Versatile for [all colors] [and loads] [use on *{Insert from Table 1,2,3,4,5,6,7 list under soft surface sanitizer}]*

**Hard Surface Non-Porous Mildewstat Claims**
Inhibits [the growth of] [mold] [and] [mildew] for [up to] [7 days]
Inhibits [the growth of] [mold] [and] [mildew] for [up to] [7] days on hard surfaces
[Controls] [Inhibits][Prevents] [the growth of] [mold] [and] [mildew] for [up to] [7] days on hard surfaces
[Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] days on hard surfaces]
[Controls][Inhibits][Prevents] [the growth of] [mold] [and] [mildew] for [up to] [7] days on *{Insert one or more of the items in Table 3}*
[Controls] [Inhibits] [Prevents] [the growth of] [mold] [and] [mildew] on *{Insert one or more of the items in Table 3}*
[Controls] [Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] days on hard surfaces] on *{Insert one or more of the items in Table 3}*
[Controls] [Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on *{Insert one or more of the items in Table 3}*
[Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] days on [hard] [surfaces] on *{Insert one or more of the locations in Table 3}*
[Controls][Inhibits][Prevents] [the growth of] [mold] [and] [mildew] on [hard surfaces] like *{Insert one or more of the locations in Table 3}*
[Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] days on hard surfaces] on *{Insert one or more of the locations in Table 3}*

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

[Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on [hard surfaces] [like] [including] *{Insert one or more of the locations in Table 3}*
[Controls][Inhibits][Prevents] [the growth of] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on hard and [soft] [fabric] surfaces] [like] [including] *{Insert one or more of the locations in Table 3}*
[Controls][Inhibits][Prevents] [the growth of] [mold] [and] [mildew] on hard and [soft] [fabric] surfaces]

**Fabric Mildewstat Claims**
Fabric Mildewstat [fungistat]
[Controls] [Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] [28] days on fabric
[Controls][Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] [28] days on fabric]
[Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] [28] days on {*Insert one or more of the items in Table 4*}
[Controls] [Inhibits] [Prevents] [the growth of mold] [and] [mildew] on *{Insert one or more of the items in Table 4}*
[Controls] [Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] {28} days on fabric] on {*Insert one or more of the items in Table 4*}
[Controls] [Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on {*Insert one or more of the items in Table 4*}
[Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] for [up to] [7] [28] days on [fabric] [soft surfaces] in {*Insert one or more of the locations in Table 6*}
[Controls][Inhibits][Prevents] [the growth of mold] [and] [mildew] on [fabric] [soft surfaces] in *{Insert one or more of the locations in Table 6}*
[Controls][Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] [for [up to] [7] [28] days on fabric] in *{Insert one or more of the locations in Table 6}*
[Controls][Inhibits][Prevents] [the growth of mold] [fungi] [fungus] [fungal spores] [mold spores] [mold & mildew spores] on [fabric] [soft surfaces] in *{Insert one or more of the locations in Table 6}*

**Non-Pesticidal Allergen Claims**
Breaks Down non-living Allergens[!][including {*insert one or more items from Table 2*}][in {*insert one or more locations from Table 6*}][on *{insert one or more items from Table 3 or 5}]*
Controls [the most] [common] non-living allergens [including {*insert one or more items from Table 2*}] [in {*insert one or more locations from Table 6*}] [on {*insert one or more items from Table 3 or 5*}]
Destroys [Eliminates] non-living Allergens[!][including {*insert one or more items from Table 2*}][in{*insert one or more locations from Table 6*}][on *{insert one or more items from Table 3 or 5}]*
Destroys -or- deactivates dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens [found in dust] [in{*insert one or more locations from Table 6*}][on *{insert one or more items from Table 3 or 5}]*
[Penetrates and] breaks down dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens [found in dust] [in {*insert one or more locations from Table 6*}] [on {*insert one or more items from Table 3 or 5*}]
Reduces dust mite matter -or- particles, cockroach matter –or particles, and pet dander allergens [found in dust]
Reduces non-living Allergens[!][in {*insert one or more locations from Table 6*}][on {*insert one or more items from Table 3 or 5*}]
Reduces up to XX% of [inanimate] [non-living] allergens [that become airborne from {*insert one or more items from Table 3, 4 or 5*}], [such as {*insert one or more items from Table 2*}]
[This product] kills germs* and destroys non-living allergens [while cleaning hard, nonporous surfaces.]
[This product] kills germs* on surfaces, controls mold & mildew on fabric, and destroys non-living allergens.
[Deodorizes] [Disinfects][controls mold & mildew on fabric], and destroys non-living allergens

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

{Table 1:} Soils / Odors: (Graphic - depicting soil)

| | | | | |
|---|---|---|---|---|
| Baby food | Dirt (greasy dirt) | Hard water stains | Outdoor grime | Tomato / spaghetti sauce |
| Bacon fat | Dust | Heel / scuff marks | Pancake mix | Toothpaste |
| Bathtub rings | Eggs | Juice / wine stains | Pen / Ink mark | Tough soils / stains |
| BBQ Sauce | Fingerprints | Lime scale | Pet odors | |
| Beverage stains | Food odors | Makeup | Pet stains | |
| Blood stains | Food stains | Mildew stains | Smears / smudges | |
| Blueberry | Grass | Mold stains | Smoke / smoking odors | |
| Chocolate syrup | Gravy | Motor Oil | Soap scum | |
| Coffee | Grease (splatter) | Mud | Stains / soils | |
| Cooking odors | Grime | Mustard | Sweat odors | |
| Cosmetic stains | Hair dye | Musty odors | Sweat stains | |
| Crayon / pencil marks | Handprints | Organic soils / stains | Tea | |

{Table 2:} Non-living Allergens:

| | | |
|---|---|---|
| Cat dander | Dog dander | Hair |
| Cockroach debris | Dust mite debris | Pet dander |
| Cockroach matter | Dust mite matter | Pet hair |
| Cockroach particles | Dust mite particles | Pollen particles |

{Table 3:} Hard Non-Porous Surface Types:

| | | |
|---|---|---|
| Chrome | Glazed granite | Sealed Marble |
| Corian® | Glazed porcelain | Silestone® |
| Countertop [surfaces] | Glazed tile | Stainless steel |
| Crystal | Laminate | Vinyl |
| Enamel | Linoleum | |
| Formica® | Plastic laminate | |
| Glazed ceramic | Sealed Fiberglass fixtures | |

{Table 4:} Soft Surface Types:

| | | | |
|---|---|---|---|
| Baby carriages | Curtains [Draperies] | Seat cushion [kitchen] | Suitcase [luggage] |
| Baby prams | Cushion [Pillow] | Shoes [canvas] [fabric] | Throw rug |
| Backpack[/School bag] | Dog [Pet] bed | Shoe interior | [Upholstered] booster seat |
| Bathroom mat | Diaper bag | Shower curtain [fabric] | [Upholstered] chairs |
| Bedding [Bedspread] | Duvet cover | Slippers | [Upholstered] couches |
| Box spring [cover] | Gym bag [fabric] | Sneakers [canvas] [fabric] | [Upholstered] furniture |
| Car [seat] [upholstery] | [Upholstered] Highchair seat | Sponges [rags] | Upholstery |
| Clothing | Laundry bag [fabric] | Sport[s] [bag[s]] [equipment] | Window treatments [fabric] |
| Cotton [fabric] purse | Mattress [cover] | Soft [fabric] surfaces | |
| Cots | Mop [/ broom] | Stroller [seats] | |
| Couch [Sofa] | Seat cushion [household] | Stuffed [Plush] toys | |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

{Table 5:} Hard Non-porous Surfaces: (Graphic - depicting use site)

| | | | |
|---|---|---|---|
| Appliance exterior | Fixture [chrome/stainless steel] | Microwave exterior | Shower [stall] [area] |
| Bathtub [tub] | Floor [linoleum] | Non-medical [chrome/stainless steel] | Sink [basin] |
| Bed frame | Floor [glazed ceramic/porcelain tile] | Outdoor patio furniture [non-wood] | Stove [stovetop] |
| Cabinet [non-wood] | Floor [laminate] | Oven [door] | Table [tabletop] [non-wood] |
| Chair [non-wood] | Floor [sealed marble] | Patio door | Telephone |
| Changing table [non-wood] | Floor [vinyl] | Picnic table [non-wood] | Toilet bowl exterior [Urinal] |
| Counter [Countertop] | Garbage [can] [pail] [container] | Plastic laundry [basket] [hamper] | Water fountain |
| Crib [non-wood] | Glazed ceramic tile | Range hood [stove hood] | Window [windowsill] |
| Diaper pail [non-wood] | Glazed porcelain tile | Refrigerator Shelves [drawers] | Vanity top |
| Exhaust [fan] [hood] | Grill [Barbecue] exterior | Sealed granite | |
| Faucet | Highchair [non-food contact area] | Shower [door] [curtain] | |

{Table 6: Use Sites (Graphic - depicting use site)}:

| | | | |
|---|---|---|---|
| Basement | High-touch areas | Nursery | Dining room |
| Bathroom | Home [House] | Outdoor area | Game room |
| Bedroom | Household areas | Storage [area] [room] | Rec room |
| Den [/Study] | Laundry [room] | Lodging establishments | Public transportation Terminals [air/bus/train/car] |
| Family room | Education [schools, colleges, preschools] | Locker rooms etc. | Pet shops |
| Athletic/Recreational facilities [fitness facilities, gyms] | Entertainment [Theaters, Parks, Playgrounds, etc.] | Manufacturing facilities | Retail locations [Grocery stores, Shops, Malls] |
| Automotive interiors [seats, handles, etc.] | Food service establishments [Restaurants] [Commercial Kitchens] | Other commercial facilities | Shower rooms |
| Breakrooms | Government facilities | Offices | Zoos |
| Churches | Hospitality areas [hotel, motels, extended stay, time share] | Office buildings | Cruise ships |
| Commercial laundry | Living room | Tool shed | Hotel [motel] |
| Garage | Mud room | Kitchen | |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

**Table 7: List of Organisms***

**Hard Surface Non-Porous DISINFECTANT**

| Contact Time | Bacteria |
|---|---|
| 10 minutes | *Pseudomonas aeruginosa*[P.][ATCC 15442]<br>*Salmonella enterica* [S.][ATCC 10708]<br>*Staphylococcus aureus* [(*Staph*)][S][ATCC 6538]<br>*Escherichia coli O157:H7[E.][ATCC43888]* |
| 5 minutes | **Viruses†**<br>†°Rhinovirus [(type 39)][ATCC VR-340] [Strain 209]<br>†[i]Influenza A [Pandemic] [(H1N1)] [CDC #2009712192] [A/Mexico/4108/2009]<br>†Herpes Simplex Virus, Type 1 [ATCC VR-733]<br>† Rotavirus [ATCC VR-2018]<br>†† Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus] |

**Hard Surface Non-Food Contact Non-Porous SANITIZER**

| Contact Time | |
|---|---|
| 5 minutes | *Staphylococcus aureus* [(*Staph*)] [S.][ATCC 6538]<br>*Klebsiella pneumoniae [K.][ATCC 4352]*<br>*Escherichia coli O157:H7[E.][ATCC43888]* |

**Hard Surface Non-Porous MILDEWSTAT**

| | |
|---|---|
| 7 day | *Aspergillus niger[A.]*[ATCC 6275] |

**Soft Surface [Fabric] SANITIZER**

| Contact Time | |
|---|---|
| 5 minutes | *Salmonella enterica* [S.][ATCC 10708]<br>*Staphylococcus aureus* [(*Staph*)] [S.][ATCC 6538]<br>*Klebsiella pneumoniae[K.][ATCC 4352]*<br>*Escherichia coli* [E.] [ATCC 11229] |

**FABRIC MILDEWSTAT**

| | |
|---|---|
| 28 day | *Aspergillus niger[A.]*[ATCC 6275]<br>*Penicillium voriable* [P.][ATCC 32333] |

**Laundry Pre-Soak DISINFECTANT**

| Contact Time | Bacteria |
|---|---|
| 15 minutes | *Pseudomonas aeruginosa*[P.][ATCC 15442]<br>*Salmonella enterica* [S.][ATCC 10708]<br>*Staphylococcus aureus* [(*Staph*)][S][ATCC 6538]<br>*Klebsiella pneumoniae[K.][ATCC 4352]*<br>*Escherichia coli O157:H7[E.][ATCC43888]* |
| | **Viruses†**<br>†°Rhinovirus [(type 39)][ATCC VR-340] [Strain 209]<br>†[i]Influenza A [Pandemic] [(H1N1)] [CDC #2009712192]<br>†Herpes Simplex Virus, Type 1 [ATCC VR-733]<br>† Rotavirus [ATCC VR-2018]<br>† Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus] |

**Laundry Pre-Soak SANITIZER**

| Contact Time | |
|---|---|
| 10 minutes | *Staphylococcus aureus* [(*Staph*)] [S.][ATCC 6538]<br>*Klebsiella pneumoniae [K.][ATCC 4352]*<br>*Escherichia coli O157:H7[E.][ATCC43888]* |

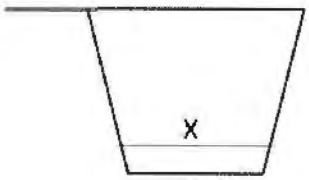
[Table 8: Testing and Dilution Type]

| Testing Type | Type of Organism | Dilution Type | Efficacy Study Dilution Rate | Gallon Conversion |
|---|---|---|---|---|
| Hard Surface Disinfection | Bacteria<br>Viruses | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Hard Surface Mildewstat | Fungi | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Non-Food Contact Sanitization | Bacteria | 1X | 31.2 grams Product / 1 liter water | 118 grams Product / 1 gallon water |
| Soft Surface Sanitization | Bacteria | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Soft Surface Mildewstat | Fungi | 2X | 62.4 grams Product / 1 liter water | 236 grams Product / 1 gallon water |
| Laundry Pre-Soak Disinfection | Bacteria<br>Viruses | 1X | 31.2 grams Product / 1 liter water | 118 grams Product / 1 gallon water |
| Laundry Pre-Soak Sanitization | Bacteria | 1X | 31.2 grams Product / 1 liter water | 118 grams Product / 1 gallon water |

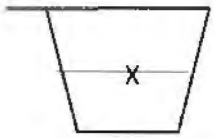
[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

| [Table 9: Scoop Directions for Use Table {[X] can equal any letter or number }]**Scoop Scenario** | **Directions for Use for insertion depending on Measuring Device and Dilution Type** | **Measuring Device** | **Dilution Type** | **grams product per measuring device** | **Total grams product per gallon of water** | **Total grams product per liter of water** |
|---|---|---|---|---|---|---|
| **Scoop X (118 grams)** | | | | | | |
| 1 | "Add 1 scoop of product to 1 gallon of water" | Scoop [X] | 1X | 118 | 118 | 31.2 |
| 2 | "Add 2 scoops of product to 1 gallon of water" | Scoop [X] | 2X | 118 | 236 | 62.4 |
| 3 | "Fill scoop to line [X] and add to 16 ounces of water." | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (59 grams)** | | | | | | |
| 4 | "Add 2 scoops of product to 1 gallon of water" | Scoop [X] | 1X | 59.0 | 118 | 31.2 |
| 5 | "Add 4 scoops of product to 1 gallon of water" | Scoop [X] | 2X | 59.0 | 236 | 62.4 |
| 6 | "Fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (118 grams @ line [X])** | | | | | | |
| 7 | "Fill scoop to line [X] and add to 1 gallon of water" | Scoop [X] Line [X] | 1X | 118 | 118 | 31.2 |
| 8 | "Fill scoop to line [X] 2 times and add to 1 gallon of water" | Scoop [X] Line [X] | 2X | 118 | 236 | 62.4 |
| 9 | "Fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Scoop [X] (59 grams @ line [X])** | | | | | | |
| 10 | "Fill scoop to line [X] 2 times and add to 1 gallon of water" | Scoop [X] Line [X] | 1X | 59.0 | 118 | 31.2 |
| 11 | "Fill scoop to line [X] 4 times and add to 1 gallon of water" | Scoop [X] Line [X] | 2X | 59.0 | 236 | 62.4 |
| 12 | "Fill scoop to line [X] and add to 16 ounces of water" | Scoop [X] Line [X] | 2X | 29.5 | 236 | 62.4 |

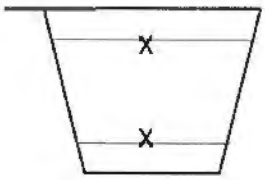
[bracketed text] is optional; *italicized* text and {bracketed text} is informational.



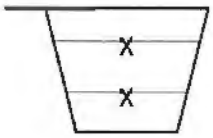

Scoop type X




Scoop type X




Scoop type X

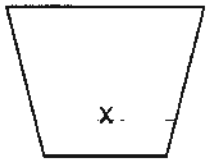



Scoop type X

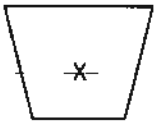
[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

[Table 10: Cap Directions for Use {[X] can equal any letter or number}]

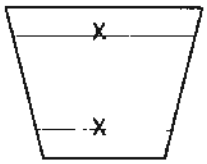
| Cap Scenario | Directions for Use for insertion depending on Measuring Device and Dilution Type | Measuring Device | Dilution Type | grams product per measuring device | Total grams product per gallon of water | Total grams product per liter of water |
|---|---|---|---|---|---|---|
| **Cap [X] (118 grams)** | | | | | | |
| 1 | "Add 1 capful of product to 1 gallon of water" | Cap [X] | 1X | 118 | 118 | 31.2 |
| 2 | "Add 2 capfuls of product to 1 gallon of water" | Cap [X] | 2X | 118 | 236 | 62.4 |
| 3 | "Fill cap to line 'X' and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 4 | "Add 2 capfuls of product to 1 gallon of water" | Cap [X] | 1X | 59.0 | 118 | 31.2 |
| 5 | "Add 4 capfuls of product to 1 gallon of water" | Cap [X] | 2X | 59.0 | 236 | 62.4 |
| 6 | "Fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 7 | "Fill cap to line [X] and add to 1 gallon of water" | Cap [X] Line [X] | 1X | 118 | 118 | 31.2 |
| 8 | "Fill cap to line [X] 2 times and add to 1 gallon of water" | Cap [X] Line [X] | 2X | 118 | 236 | 62.4 |
| 9 | "Fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |
| **Cap [X] (59 grams)** | | | | | | |
| 10 | "Fill cap to line [X] 2 times and add to 1 gallon of water" | Cap [X] Line [X] | 1X | 59.0 | 118 | 31.2 |
| 11 | "Fill cap to line [X] 4 times and add to 1 gallon of water" | Cap [X] Line [X] | 2X | 59.0 | 236 | 62.4 |
| 12 | "Fill cap to line [X] and add to 16 ounces of water" | Cap [X] Line [X] | 2X | 29.5 | 236 | 62.4 |



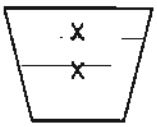

Cap type X




Cap type X




Cap type X




Cap type X

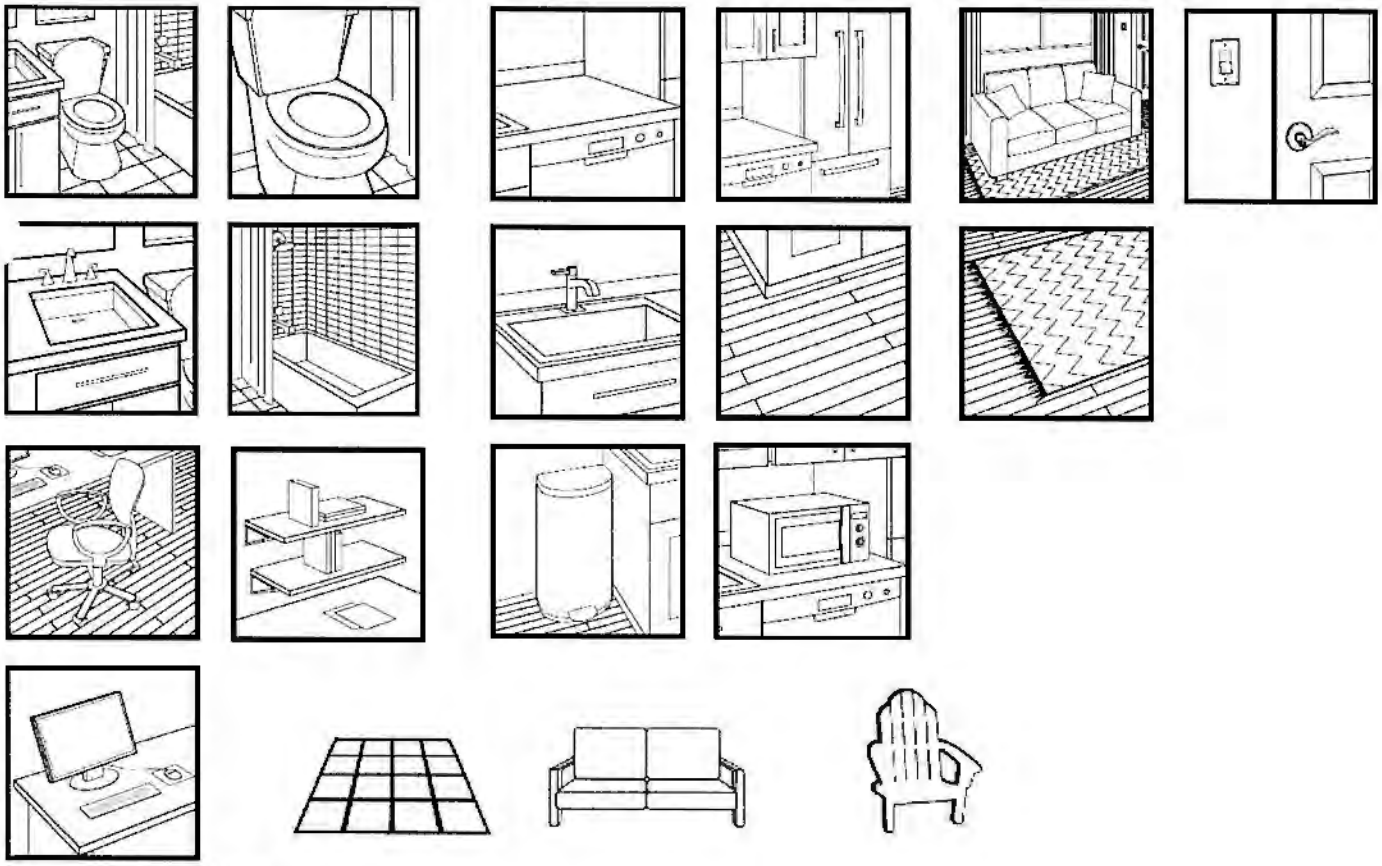
[Table 11: Package dose quantities]

| Content Wt. (lbs.) | Content Mass (kg) | Number of loads (assuming 118 grams in 1 gallon = 1 load) |
|---|---|---|
| 1.7 | 0.77 | 6 |
| 2.5 | 1.13 | 9 |
| 3.0 | 1.36 | 11 |
| 4.5 | 2.04 | 17 |
| 5.0 | 2.27 | 19 |
| 6.5 | 2.95 | 25 |
| 10.0 | 4.54 | 38 |
| 10.5 | 4.76 | 40 |
| 11.0 | 4.99 | 42 |
| 13.5 | 6.12 | 51 |

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

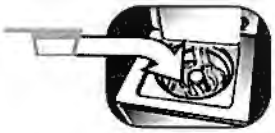
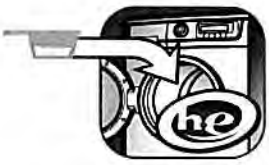
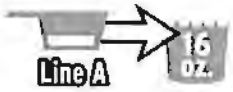
Optional Pictograms- Safety

Optional Pictograms- Locations usage (Bathroom, Kitchen, Living Room, Office, Grout, Soft Surface, Hard Surface)



Laundry compatible

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.

Optional Pictograms- Usage

[bracketed text] is optional; *italicized* text and {bracketed text} is informational.