EPA REGISTRATION NUMBER 1677-223

Material Sent for Data Extraction

Reg # 1677-223

Description: _____

☒ Material(s) Sent to Data Extraction Contractors:

- ☐ New Stamped Label Dated _____
- ☒ Notification Dated _____
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

_____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: D. Copeland

Phone: _____ Division: AD

Date: 5/1/12

Created February 3, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Rhonda Schulz
Director, Product Registration & Compliance
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: **Sani-Step**
EPA Registration Number 1677-223
Application Dated April 5, 2012
EPA Received Date April 10, 2012

Dear Mr. Schulz:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Add optional marketing language and graphic, French text and a Canadian address

General Comments:

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

SYMBOL								
SURNAME								
DATE								

OFFICIAL FILE COPY

ECOLAB®

Rhonda Schulz
DIRECTOR – PRODUCT
REGISTRATION & COMPLIANCE

T 651 293 4026
F 651 225 3122

370 WABASHA STREET NORTH
EUC 9
ST. PAUL, MN 55102-1390
Rhonda.Schulz@ecolab.com

April 5, 2012

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN: Velma Noble, PM-31

Re: Sani-Step, EPA Reg. No. 1677-223

Dear Ms. Noble:

Ecolab Inc. is submitting a notification per PRN 98-10 to add optional marketing language and graphic, French text and a Canadian address for EPA Reg. No. 1677-223. All changes are highlighted in red.

If you have any questions, please do not hesitate to contact me directly at the above listed number or email address.

Sincerely,

Rhonda Schulz

Rhonda Schulz
Director – Product Registration & Compliance
Law & Regulatory

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060 Approval Expires 5-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registr on
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1677-223	Velma Noble	☒ None ☐ Restricted
3. Company/Product (Name)	PM#	
Sani-Step	31	

5. Name and Address of Applicant (Include ZIP Code)
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to:
EPA Reg. No._____
Product Name _____

Section – II

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

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

This label notification per PRN 98-10 is a request to add optional marketing language and graphic, French text and a Canadian address for EPA Reg. No. 1677-223. All changes are highlighted in red.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes*	☐ Yes	☐ Yes	☐ Metal
☒ No	☒ No	☒ No	☒ Plastic lined
**** Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Package wgt. / No. Per Container	☐ Glass
			☐ Paper
			☐ Other (Specify)_____

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	30, 300 lb fiber drum	☒ On Label ☐ 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 Code)
Rhonda Schulz	Director, Product Registration & Compliance	(651) 293-4026

Certification

I certify that the statements which I have made on this form and all attachments 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
Rhonda Schulz	Director, Product Registration & Compliance
3. Typed Name	**4. Date**
Rhonda Schulz	4/5/12

EPA Form 8750-1 (Rev. 8-94) Previous editions are obsolete

White - EPA File Copy (original)

Yellow - Applicant Copy

SANI-STEP

Solid, Time-Released, Floor Sanitizer
For Use in Dairy, Food and Beverage Processing Industries
FOR INDUSTRIAL USE ~~ONLY~~

ACTIVE INGREDIENTS:

Alkyl (C_{14}, 50% C_{12}, 40% C_{16}, 10%)	
Dimethyl benzyl ammonium chloride	0.479%
Octyl decyl dimethyl ammonium chloride	0.359%
Didecyl dimethyl ammonium chloride	0.215%
Dioctyl dimethyl ammonium chloride	0.144%
OTHER INGREDIENTS:	98.803%
TOTAL:	100.00%

Keep Out of Reach of Children

CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID
IF ON SKIN OR CLOTHING: 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 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 eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison center, doctor, or going for treatment.

FOR EMERGENCY MEDICAL INFORMATION IN THE US AND CANADA, CALL TOLL-FREE 1-800-328-0026
OUTSIDE OF UNITED STATES AND CANADA CALL: 1-651-222-5352 (in USA)

NOTIFICATION
Date Reviewed: 4/26/12
Reviewed By: DC.

ENVIRONMENTAL HAZARDS: (only required for containers greater than 50 pounds) Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office of the EPA or local provincial government.

SANI-STEP is a water activated, time-released, solid sanitizer specifically formulated to improve environmental sanitation on floors where wet conditions favor microorganism growth and cause sanitation concern.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

After cleaning and sanitizing equipment, apply SANI-STEP evenly to the floor, at a rate of 1.2 grams – 2.4 grams per square foot (929 cm^2). Product may be re-applied as needed during the production process. SANI-STEP does not become active until it comes in contact with moisture on the floor.

SANI-STEP has been evaluated at a concentration that supports a dilution of 5.1 oz/gallon (39.9ml/L) in the presence of 5% soil contamination and in waters up to 500 ppm hardness (29.2 gpg calculated as CaCO3). Treated surfaces must remain wet for 5 minutes.

SANI-STEP was evaluated using the Non-Food Contact Surface Sanitizer Test and was proven to be effective against the following organisms:

Staphylococcus aureus (ATCC 6538)
Escherichia coli (ATCC 11229)
Salmonella enterica (ATCC 13311)
Enterobacter aerogenes (ATCC 13048)
Listeria monocytogenes (ATCC 49594)

STORAGE & DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.
Pesticide Storage: Store in a dry area.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your state Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Remove liner from drum and completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities.
For the outer drum, nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying.

Net Contents:
300 lb (136.2 kg)
30 lb (13.6 kg)

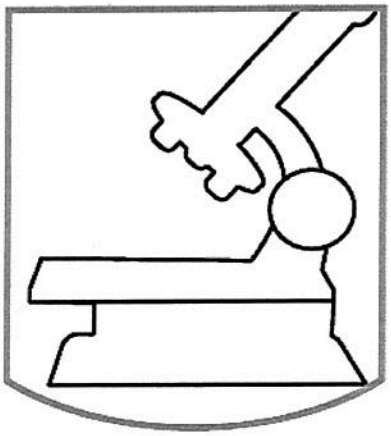
Made in USA/Fabriqué aux É-U

Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

EPA Reg. No. 1677-223
EPA Est.: 1677-MN-1 (P) ,1677-CA-2 (R),
1677-TX-1 (D), ~~1677-OH-1 (H)~~
1677-IL-2 (J), ~~1677-PR-1 (B),~~ 1677-CA-1 (S),
1677-GA-1 (M), 1677-WV-1 (V)
Superscript refers to first letter of date code

Optional marketing language:

- "See side/back panel for First Aid…"
-



Sanitizer
Desinfectante

Distributed in Canada by Ecolab Co. Food & Beverage
Distribué au Canada par Ecolab Co. Agroalimentaire et Breuvagess
5105 Tomken Rd Mississauga ON L4W 2X5
All Rights Reserved /Tous droits réservés

Sani-Step

KEEP OUT OF THE REACH OF CHILDREN.
CAUTION: Causes moderate eye irritation. Do not get in eyes, on skin or on clothing. Wear protective eyewear, clothing and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

First Aid:
IF ON SKIN OR CLOTHING: 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 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 eye. Call a poison control center or doctor for treatment advice.

SEE MATERIAL SAFETY DATA SHEET FOR THIS PRODUCT
EMERGENCY HEALTH INFORMATION: 1-800-328-0026
OUTSIDE OF UNITED STATES AND CANADA CALL: 1-651-222-5352 (in USA)

French Text (to be added)

Ecolab Co. Food & Beverage

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 29 2009

Ms. Rhonda K Schulz
Associate Director, Regulatory Affairs
Ecolab Inc.
370 Wabasha Street N
St. Paul, MN 55102

Subject: **Sani-Step**
EPA Registration Number 1677-223
Letter Dated June 2, 2009
EPA Receive Date June 10. 2009

Dear Ms. Schulz:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with comments.

Proposed Amendment:

- Update Storage and Disposal
- Add ATCC numbers to the organism
- Add metric units and Canadian (NAFTA)
- Precautionary Statement

Chemistry Review:

The product chemistry is acceptable.

Labeling:

1. Revise the "PRECAUTIONARY STATEMENT" to read as follows:

Keep Out Of Reach of Children

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: Caution: causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco or using the toilet.

2. Revise the **"FIRST AID"** read as follows:

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, and then continue rinsing.
Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison Center, doctor, or going for treatment. For emergency information Concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu)

General Comments:

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224 or Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Product Chemistry review approval Dated 9/17/09 and Product Chemistry Review 9/2/09

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 29 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1677-223

SANI-STEP

Solid, Time-Released, Floor Sanitizer
For Use in Dairy, Food and Beverage Processing Industries
FOR INDUSTRIAL USE ONLY

ACTIVE INGREDIENTS:
Alkyl (C_{14}, 50% ,C_{12}, 40% C_{16}, 10%)

Dimethyl benzyl ammonium chloride	0.479%
Octyl decyl dimethyl ammonium chloride	0.359%
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Dioctyl dimethyl ammonium chloride	0.144%
OTHER INGREDIENTS:	98.803%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION: ~~Corrosive.~~ Causes ~~skin burns and~~ moderate eye irritation. Do not get in eyes, on skin or on clothing. Wear protective eyewear, clothing and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

FIRST AID
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~~**OUTSIDE OF NORTH AMERICA, CALL 1-651-222-5352**~~

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Net Contents:
300 lb (136.2 kg)
30 lb (13.6 kg)

EPA Reg. No. 1677-223
EPA Est.: 1677-MN-1 (P),1677-CA-2 (R),
1677-TX-1 (D), 1677-OH-1 (H)
1677-IL-2 (J), 1677-PR-1 (B), 1677-CA-1 (S),
1677-GA-1 (M), 1677-WV-1 (V)
Superscript refers to first letter of date code

Made in USA

Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Distributed in Canada by Ecolab Co. Food & Beverage
Distribué au Canada par Ecolab Co. Agroalimentaire et Breuvagess
Mississauga ON L4W 2X5
All Rights Reserved /Tous droits réservés

Sani-Step

KEEP OUT OF THE REACH OF CHILDREN.
CAUTION: Causes-moderate eye irritation. Do not get in eyes, on skin or on clothing. Wear protective eyewear, clothing and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

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French Text (to be added)

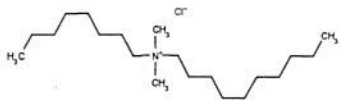
Ecolab Co. Food & Beverage

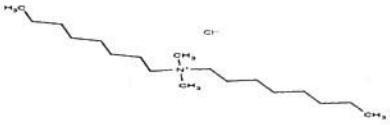
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

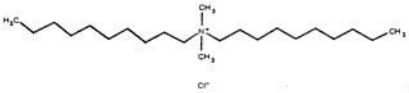
OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

September 2, 2009

DP BARCODE:	D368071
MRID:	477756-01
SUBJECT:	Sani-Step
REG. NO. OR FILE SYMBOL:	1677-223
DOCUMENT TYPE:	Product Chemistry Review
Manufacturing-use [] OR	End-use Product [X]
INGREDIENTS (PC Codes)	Alkyl dimethyl benzyl ammonium chloride (069105)







Octyl decyl dimethyl ammonium chloride (069166)

Dioctyl dimethyl ammonium chloride (069149)

Didecyl dimethyl ammonium chloride (069165)

CAS Number	68424-85-1, 7173-51-5, 32426-11-2, 5538-94-3
TEST LAB:	N/A
SUBMITTER:	Ecolab, Inc
GUIDELINE:	N/A
COMMODITIES:	Formulation
REVIEWER:	Salvador Rodríguez
ORGANIZATION:	AD
APPROVER:	Karen P. Hicks APPROVED DATE: 09/02/09

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

September 2, 2009

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 1677-223.

From: Salvador Rodríguez, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

Thru: Betty Shackleford
Associate Director
Antimicrobials Division (7510P)

To: Drusilla Copeland/ Velma Noble
PM Team 31
Antimicrobials Division (7510P)

APPLICANT: Ecolab, Inc.
Action code: A570
Due date: 11/01/09

Product Formulation
Active Ingredient(s)

% by wt.

Alkyl dimethyl benzyl ammonium chloride.....0.479
Octyl decyl dimethyl ammonium chloride 0.359
Dioctyl dimethyl ammonium chloride 0.144
Didecyl dimethyl ammonium chloride.....0.215

BACKGROUND:

The registrant, Ecolab, Inc. has submitted a storage stability and corrosion characteristic study to support the registration for the non-integrated end of use product, **Sani-Step**. The Product Chemistry Reviewer has received the following documents:

- Confidential Statement of Formula (CSF) dated on 05/23/2007, and 01/18/2007 for basic formulation.
- A transmittal letter dated on 06/02/2009.
- A letter, dated 06/02/09, application for label amendment.
- A study titled "KX-6187 Long Term Storage Stability "dated on 02/07/2008, MRID # 477756-01
- A label, dated 05/13/2007.

FINDINGS:

1. The registrant conducted the assays for (0, 3, 6, 9, 12) months. The results are as follows:

(Zero	3	6	9	12) months	
%	%	%	%	%	
1.125	1.147	1.179	1.220	1.228	
1.146	1.152	1.164	1.198	1.190	
1.178	1.246	1.225	1.191	1.186	
1.215	1.123	1.262	1.145	1.156	
1.046	1.088	1.125	1.258	1.195	
1.081					
1.099					
(1.127	1.151	1.191	1.202	1.191)	Mean

2. The registrant continues to use wider certified limits.

3. The assay results were produced using 5 batches, except for the zero day (7 assays)

5. The assay is based on the total quaternary salts of 1.197 %.

4. The one year storage stability shows that the mean assay meets the EPA standard certification limits. However, the assay shows that the use of wider certified limits is required.

5. The "830.6320 Corrosion Characteristics" study indicated that the assays were conducted at 25 °C ± 2 temperature, no physical changes were observed. The packing material used for marketing the product has not been compromised and seal remains intact.

CONCLUSIONS:

The "830.6317 Storage Stability" and the "830.6320 Corrosion Characteristics" studies are acceptable. Results show that the means (1.127, 1.151, 1.191, 1.202, 1.191) during the one-year storage stability for the AI are within the EPA standard certified limits. However, the assay shows that the use of wider certified limits is required.

The study indicates that the determinations were performed according to the requirements for the US. EPA Product Property test methods and guidelines.

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Thursday, September 17, 2009

MEMORANDUM

SUBJECT: Label Amendment for EPA Reg. No.: 1677-223 – SANI-STEP
DP Barcode: 368073

FROM: Leon Johnson, Biologist
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: Velma Noble, PM 31/ Drusilla Copeland
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Ecolab Inc.
Rhonda Schulz
Associate Director, Product Registration & Compliance
370 N. Wabasha Street
St. Paul, MN 55102-1390

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Alkyl (C14, 50%, C12, 405 C16, 10%)	
Dimethyl benzyl ammonium chloride	0.479
Octyl decyl dimethyl ammonium chloride	0.359
Didecyl dimethyl ammonium chloride	0.215
Dioctyl dimethyl ammonium chloride	0.144
Other Ingredient(s):	98.803
Total:	100.00

1) BACKGROUND:

Ecolab, Inc. is requesting to amend its product label for EPA Reg. No. 1677-223-Sani-Step. Ecolab, Inc. has submitted an acute skin irritation study "MRID No. 477756-02" to support a modification of the precautionary text on the label. Ecolab, Inc submitted a previous skin irritation study on the same product EPA Reg. No. 1677-EEG, (MRID# 470389-07) which was found to be inconsistent on June 7, 2007. This new study addresses the inconsistency that was found with the animal irritation in 2007.

2) RECOMMENDATIONS: PSB findings are:

a) The acute oral toxicity study is acceptable.
b) The acute dermal toxicity study is acceptable.
c) The acute inhalation toxicity study is acceptable.
d) The primary eye irritation study is acceptable.
e) The primary skin irritation study is acceptable.
f) The dermal sensitization study is acceptable.

The acute toxicity profile for File Symbol 1677-223 is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	470389-03	IV	Acceptable
Acute Dermal Toxicity	470389-04	IV	Acceptable
Acute Inhalation Toxicity	470389-05	IV	Acceptable
Primary Eye Irritation	470389-06	III	Acceptable
Primary Skin Irritation	477756-02	IV	Acceptable
Dermal Sensitization	470389-08	Non-sensitizer	Acceptable

3) LABELING:

a) DATE: 06/13/2007
b) EPA Reg. No. 1677-223
c) The signal word is "**CAUTION**" this is based on the results of the primary eye irritation study being placed in category III.

4) REQUIRED PRECAUTIONARY LABELING:

"Keep Out of Reach of Children"

CAUTION	Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

- No statements are required for the acute oral toxicity study, the acute dermal toxicity study, the acute inhalation toxicity study and the primary skin irritation study. However, the registrant may choose to use category three labeling. (optional)

5) REQUIRED FIRST AID STATEMENTS:

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.

- *Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu)*

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager:	Velma Noble	**Reviewer**:	L. Johnson
MRID No.:	477756-02	**Study Completion Date**:	July 17, 2008
		Lab Study No.:	EOV00063

Testing Laboratory: Charles River Laboratories, Preclinical Services
640 North Elizabeth Street, Spencerville, OH 45887
Study Director: Dawn D. Rodabaugh, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Parts160 and 792 and OECD [ENV/MC/CHEM(98)17].

Test Material: KX-6187
Lot # p11207A-CL
Light blue granules
Dosage: .5g
Species: 6 Rabbits; New Zealand White
Sex: Males
Age: 13 weeks prior to dosing
Weight: 2.9-3.1 kg prior to dosing
Source: Myrtle's Rabbitry, Thompson Station, Tennessee
Housing: Temperature Range: 67-69°F (19-21°C)
Humidity Range: 49 - 52%
Photoperiod: 12 – hour light/12 – hour dark cycle
Acclimation: 5 days

Summary:

1. **Toxicity Category**: IV
2. **Classification**: Acceptable

Procedure (Deviations from 870-2500):

No procedure deviations reported.

Results:

Exposure to the test article produced very slight erythema on 6/6 test sites at the one hour scoring interval.

The dermal irritation resolved completely at all test sites by the twenty –four scoring interval.

The Primary Irritation Index for the test article (KX-6187) was calculated to be 0.25. Under the conditions of this study, the test article (KX-6187) is considered a slight irritant to the skin of the rabbit.

AN ACUTE SKIN IRRITATION STUDY IN RABBITS

INDIVIDUAL DERMAL IRRITATION SCORES
(KX-6187)

Animal No./Sex Body Weight (Kg)	Scoring Interval	Erythema	Edema
R1241/M 3.109	1 Hour 24 Hours 48 Hours 72 Hours	1 0 0 0	0 0 0 0
R1243/M 2.901	1 Hour 24 Hours 48 Hours 72 Hours	1 0 0 0	0 0 0 0
R1244/M 2.947	1 Hour 24 Hours 48 Hours 72 Hours	1 0 0 0	0 0 0 0
R1245/M 2.916	1 Hour 24 Hours 48 Hours 72 Hours	1 0 0 0	0 0 0 0
R1246/M 3.081	1 Hour 24 Hours 48 Hours 72 Hours	1 0 0 0	0 0 0 0
R1247/M 3.075	1 Hour 24 Hours 48 Hours 72 Hours	1 0 0 0	0 0 0 0

PRIMARY IRRITATION INDEX

0.25 = SLIGHT IRRITANT

Decision #: 415089
DP #: (368071)
PRIA
Parent DP #:
Submission #: 851726

DATA PACKAGE BEAN SHEET

Date: 12-Aug-2009

* * * Registration Information * * *

Registration: 1677-223 - SANI-STEP

Company: 1677 - ECOLAB INC.

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Drusilla Copeland DCOPELAN

Sent Date: Calculated Due Date: 01-Nov-2009 OK Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A570) AMENDMENT;NON-FAST TRACK;

Ingredients: See page 3

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 12-Aug-2009 Due Back:

DP Ingredient: See page 3

DP Title:

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #:

120/90

	Assigned To	Date In	Date Out
Organization:	AD / PSB	5/12/09	
Team Name:	CTT Salvador	5/12/09	09/02/09
Reviewer Name:	~~[illegible]~~ ~~[illegible]~~	8/19/09	09/02/09
Contractor Name:		70	

Last Possible Science Due Date: 02-Oct-2009

Science Due Date: 10/27/09

Sub Data Package Due Date: 11/10/09

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Chemistry - Review cover letter, MRID 477756-01. s and label.
Note: Karen and Velma have discussed this and Karen agreed to take care of it.

RECEIVED 8/12/09

Please pull label

Decision #: 415089
DP #: (368073)
PRIA
Parent DP #:
Submission #: 851726

DATA PACKAGE BEAN SHEET

Date: 12-Aug-2009

* * * Registration Information * * *

Registration: 1677-223 - SANI-STEP

Company: 1677 - ECOLAB INC.

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Drusilla Copeland DCOPELAN

Sent Date: Calculated Due Date: 01-Nov-2009 Edited Due Date:

ok

Type of Registration: Product Registration - Section 3

Action Desc: (A570) AMENDMENT;NON-FAST TRACK;

Ingredients: See page 3

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 12-Aug-2009 Due Back:

DP Ingredient: See page 3

DP Title:

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #:

120
90

	Assigned To	Date In	Date Out
Organization:	AD / PSB → This is CII.	8/12/09	
Team Name:	~~EET~~	8/12/09	
Reviewer Name:	~~[illegible]~~	~~8/12/09~~	
Contractor Name:	LEON		

Last Possible Science Due Date: 02-Oct-2009

Science Due Date: 10/27/09

Sub Data Package Due Date: 11/10/09

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Efficacy - review cover letter, MRID#477756-02, CSFs and label.

Note: Karen and Velma have discussed this and Karen agreed to take care of it. I will give you the CFS and label when I receive the jacket.

RECEIVED 8/12/09

RHONDA SCHULZ
Associate Director, Product Registration
Regulatory Affairs
T 651.293.4026
F 651.225.3122

June 2, 2009

Document Processing Desk (E-SUB)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Velma Noble , PM 31

Re: Sani-Step (EPA Reg. No. 1677-223)
Label amendment with Data

Dear Ms. Noble:

This submission is subject to PRIA Category A570 (Amendments, non-fast track) and a copy of the check in the amount of $3,308 is enclosed. The check has been sent to the FIFRA service fees address in Missouri.

Ecolab is modifying the label to include updated empty container language, to add ATCC numbers to the organisms on the label, and to add metric units and Canadian (NAFTA) label requirements. In addition, toxicity data are being submitted to support a modification of the precautionary text on the label.

Copies of the amended labeling, with changes in red text, are enclosed. There are no other changes to the label nor are there any formulation changes.

With this submission Ecolab is also providing updated Long Term Storage Stability studies.

The following documents are enclosed to support the amendment:

1. EPA Form 8570-1 – Application for Pesticide
2. Copy of PRIA fee payment
3. Transmittal document
4. EPA Form 8570-27 - Formulator's Exemption Statement
5. EPA Form 8570-34 – Certification with Respect to Citation of Data
6. EPA Form 8570-35 - Data Matrix – file copy and public copy
7. Five copies of the revised label (revisions are highlighted in red)
8. One CD containing the electronic copy of the label.
9. Certification with Respect to Label Integrity

10. Studies for the following:
    Long Term Storage and Stability (Study # 0600021) – 3 copies
    Acute Skin Irritation Study Administered by the Dermal Route to Rabbits (0800001CL1) – 3 copies

Thank you for your attention to this matter. If you have any questions, please contact me at the above phone number or email address.

Sincerely,

Rhonda K. Schulz

Rhonda K. Schulz
Associate Director, Regulatory Affairs
Ecolab Inc.

Enclosures

TRANSMITTAL DOCUMENT

Sani-Step

EPA Registration Number 1677-223

SUBMITTER

Ecolab Inc.
Rhonda Schulz
Associate Director, Product Registration & Compliance
370 N. Wabasha Street
St. Paul, MN 55102-1390
(651) 293-4026)

REGULATORY ACTION: Amended registration application for Sani-Step to revise the product label to include updated empty container language, to add ATCC numbers to the organisms on the label and to provide toxicity information to support the modification of the precautionary statements. Ecolab is also providing updated Long Term Storage Stability.

TRANSMITTAL DATE: June 2, 2009

Volume 1 – Administrative Materials

- Cover Letter
- Application for Pesticide Registration, Form 8570-1
- Formulator's Exemption Statement, Form 8570-27
- Certification with Respect to Citation of Data, Form 8570-34
- Data Matrix, Form 8570-35 (Agency copy and Public File copy)
- Revised product label (5 copies)
- CD containing the electronic copy of the label
- Certification with Respect to Label Integrity

47775601 Volume 2 – Stability Data (3 copies)

- Long Term Storage and Stability (Study # 0600021) – 3 copies

47775602 Volume 3 –Toxicity Data (3 copies)

- An Acute Skin irritation Study of KX-6187 Administered by the Dermal Route to Rabbits (Study # 08000001CL1) – 3 copies

Company Official and Contact: Rhonda Schulz

Rhonda Schulz
Associate Director, Product Registration & Compliance
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102-1390
(651) 293-4026

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060 Approval Expires 5-31-98

EPA .ted States **Environmental Protection Agency** Washington, DC 20460

☐ Reg .ration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1677-223	Velma Noble	☒ None ☐ Restricted
4. Company/Product (Name) Sani-Step	PM# 31	

5. Name and Address of Applicant (Include ZIP Code)
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to:
EPA Reg. No._____
Product Name _____

Section – II

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

Explanation: Use additional Page(s) if necessary. (For section I and Section II)
This amendment submission is PRIA Category A570. Amended registration application for Sani-Step to revise the product label to include updated empty container language, to add ATCC numbers to the organisms on the label, to add metric units and Canadian (NAFTA) label requirements and to provide toxicity information to support the modification of the precautionary statements. Ecolab is also providing updated Long Term Storage Stability.

Section – III

Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes*	☐ Yes	☐ Yes	☐ Metal
☒ No	☒ No	☒ No	☒ Plastic
	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Package wgt. / No. Per Container	☐ Glass
			☐ Paper
			☐ Other (Specify)_____

* ***Certification must be submitted***

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	1, 5, 55 gallons	☒ On Label ☐ 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	Associate Director, Product Registration & Compliance	Telephone No. (Include Area Code)
Rhonda Schulz		(651) 293-4026

Certification
I certify that the statements which I have made on this form and all attachments 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: Associate Director, Product Registration & Compliance
Rhonda Schulz	
Typed Name: Rhonda Schulz	Date: June 2, 2009

EPA Form 8750-1 (Rev. 8-94) Previous editions are obsolete — White - EPA File Copy (original) — Yellow - Applicant Copy

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
Ecolab Inc. Attn: Rhonda Schulz 370 Wabasha St. St. Paul, MN 55102	1677-223
	Product Name Sani-Step
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 05/23/2007

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):

Alkyl (C14, 50% ,C12, 40% C 16, 10%) Dimethyl benzyl ammonium chloride
Octyl decyl dimethyl ammonium chloride
Didecyl dimethyl ammonium chloride
Dioctyl dimethyl ammonium chloride

(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
Alkyl (C14, 50% ,C12, 40% C 16, 10%) Dimethyl benzyl ammonium chloride Octyl decyl dimethyl ammonium chloride Didecyl dimethyl ammonium chloride	[redacted]	[redacted]
Signature Rhonda Schulz	Name and Title Rhonda Schulz, Associate Director	Date 06/02/2009

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 – Applicant copy

Product ingredient source information may be entitled to confidential treatment

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Ecolab Inc., 370 N. Wabasha St., St. Paul, MN 55102 651-293-4026	EPA Registration Number/File Symbol 1677-223
Active Ingredient(s) and/or representative test compound(s) Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chlorides ; Octyl decyl dimethyl a	Date 6/2/2009
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Non-Food Contact Sanitizer	Product Name Sani-Step

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 Formulator's 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 I, 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
Rhonda Schulz	6/2/2009	Rhonda Schulz, Associate Director, Reg Affairs

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

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401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. .0-0060

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DATA MATRIX

Date 6/2/2009			EPA Reg.No./File Symbol 1677-223		Page 1 of 2
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102			Product **Sani-Step**		
Ingredient:	Alkyl (C_{14} 50% C_{12} 40% C_{16} 10%) Dimethyl benzyl ammonium chloride, Octyl decyl dimethyl ammonium chloride, Didecyl dimethyl ammonium chloride, Dioctyl dimethyl ammonium chloride				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	47038901	Ecolab Inc.	OWN	
830.1600	Description of Materials used to Produce the product	47038901	Ecolab Inc.	OWN	
830.1620	Description of Production Process	47038901	Ecolab Inc.	OWN	
830.1650	Description of Formulation Process	47038901	Ecolab Inc.	OWN	
830.1670	Discussion of Formation of Impurities	47038901	Ecolab Inc.	OWN	
830.1700	Preliminary Analysis	47038901	Ecolab Inc.	OWN	
830.1750	Certified Limits	47038901	Ecolab Inc.	OWN	
830.1800	Enforcement Analytical Method	47038901	Ecolab Inc.	OWN	
830.6302	Color	47038901	Ecolab Inc.	OWN	
830.6303	Physical State	47038901	Ecolab Inc.	OWN	
830.6304	Odor	47038901	Ecolab Inc.	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	47038901	Ecolab Inc.	OWN	
830.6315	Flammability	47038901	Ecolab Inc.	OWN	
830.6316	Explodability	47038901	Ecolab Inc.	OWN	
830.6317	Accelerated Storage Stability	47038902	Ecolab Inc.	OWN	
830.6317	Long Term Storage Stability	To be assisgned	Ecolab Inc.	OWN	
830.6319	Miscibility	47038901	Ecolab Inc.	OWN	
830.6320	Corrosion characteristics	47038901	Ecolab Inc.	OWN	
830.6321	Dielectric Breakdown Voltage	47038901	Ecolab Inc.	OWN	
830.7000	pH	47038901	Ecolab Inc.	OWN	
830.7100	Viscosity	47038901	Ecolab Inc.	OWN	
830.7300	Density/Relative Density/Bulk Density	47038901	Ecolab Inc.	OWN	
Signature Rhonda Schulz			Name and Title Rhonda Schulz Associate Director, Product Registration & Compliance		Date 6/2/09

EPA For 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date 6/2/09			EPA Reg.No./File Symbol 1677-223		Page 2 of 2
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102			Product **Sani-Step**		
Ingredient:	Alkyl (C_{14}, 50%, C_{12}, 40% C_{16}, 10%) Dimethyl benzyl ammonium chloride, Octyl decyl dimethyl ammonium chloride, Didecyl dimethyl ammonium chloride, Dioctyl dimethyl ammonium chloride				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral toxicity	47038903	Ecolab Inc.	OWN	
870.1200	Acute Dermal toxicity	47038904	Ecolab Inc.	OWN	
870.1300	Acute Inhalation Toxicity	47038905	Ecolab Inc.	OWN	
870.2400	Primary Eye Irritation	47038906	Ecolab Inc.	OWN	
870.2500	Primary Dermal Irritation	47038907	Ecolab Inc.	OWN	
870.2500	Primary Dermal Irritation	To Be Assigned	Ecolab Inc.	OWN	
870.2600	Dermal Sensitization	47038908	Ecolab Inc.	OWN	
Subdivision G 91-2(j)	Non-Food Contact Surface Sanitizing - Staphylococcus aureus (ATCC 6538), Enterobacter aerogenes (ATCC 13048)	47038909	Ecolab Inc.	OWN	
Subdivision G 91-2(j)	Non-Food Contact Surface Sanitizing - Escherichia coli (ATCC 11229), Listeria monocytogenes (ATCC 49594), Salmonella typhimurium (ATCC 13311)	47038910	Ecolab Inc.	OWN	
Signature Rhonda Schulz			Name and Title Rhonda Schulz Associate Director, Product Registration & Compliance		Date 6/2/09

EPA For 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

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DATA MATRIX

Date 6/2/2009			EPA Reg.No./File Symbol 1677-223		Page 1 of 2
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102			Product **Sani-Step**		
Ingredient:	Alkyl (C_{14}, 50% C_{12}, 40% C_{16}, 10%) Dimethyl benzyl ammonium chloride, Octyl decyl dimethyl ammonium chloride, Didecyl dimethyl ammonium chloride, Dioctyl dimethyl ammonium chloride				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
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			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
Signature Rhonda Schulz			Name and Title Rhonda Schulz Associate Director, Product Registration & Compliance		Date 6/2/09

EPA For 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

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UNITED STATES ENVIRONMENTAL PROTECTION . ENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2(060

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DATA MATRIX

Date 6/2/09			EPA Reg.No./File Symbol 1677-223		Page 2 of 2
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102			Product **Sani-Step**		
Ingredient:	Alkyl (C_{14}, 50%, C_{12}, 40% C_{16}, 10%) Dimethyl benzyl ammonium chloride, Octyl decyl dimethyl ammonium chloride, Didecyl dimethyl ammonium chloride, Dioctyl dimethyl ammonium chloride				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
Signature Rhonda Schulz			Name and Title Rhonda Schulz Associate Director, Product Registration & Compliance		Date 6/2/09

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Agency Internal Use Copy

ECOLAB®

RHONDA SCHULZ
Associate Director, Product Registration
Regulatory Affairs
T 651.293.4026
F 651.225.3122

June 2, 2009

U.S. Environmental Protection Agency
Washington Finance Center
FIFRA Service Fees
P.O. Box 979074
St. Louis, MO 63197-9000

To Whom It May Concern:

The enclosed check for $3308 from Ecolab Inc. is for a PRIA fee, category A570, on a submission to the EPA for an amendment to Sani-Step (1677-223) that has been sent.

Regards,

Rhonda Schulz
Associate Director, Regulatory Affairs
Ecolab Inc.

370 Wabasha Street N St. Paul, MN 55102

ECOLAB, INC.
370 WABASHA STREET
ST. PAUL, MN 55102-1307

E: 1

DATE: June 4, 2009
TRACE NUMBER: 4026273740262737
CHECK NUMBER: 40262737
AMOUNT PAID: $3,308.00

VOID AFTER 180 DAYS

00013 CKS 6A 07154 - 0040262737 NNNN 1545100005006 X135A1 C
US ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON FINANCE CENTER
FIFRA SERVICE FEES
PO BOX 979074
ST LOUIS MO 63197-0001

VENDOR NUMBER: V000067132

ICE NUMBER	DESCRIPTION	GROSS AMOUNT	DISCOUNT AMOUNT	NET AMOUNT
02-09		$3,308.00	$0.00	$3,308.00
	TOTALS	**$3,308.00**	**$0.00**	**$3,308.00**

.EASE DETACH BEFORE DEPOSITING CHECK

ECOLAB, INC.
370 WABASHA STREET
ST. PAUL, MN 55102-1307

CHECK NUMBER 40262737

56-1544
441

June 4, 2009

*** VOID AFTER 180 DAYS ***

.Y
) THE
RDER OF:

US ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON FINANCE CENTER
FIFRA SERVICE FEES
PO BOX 979074
ST LOUIS, MO 63197-9000

CHECK AMOUNT
$3,308.00

EXACTLY *********3,308 DOLLARS AND 00 CENTS

hase Bank, N.A.
ba, OH

SECURITY FEATURES INCLUDED: SEE DETAILS ON BACK

AUTHORIZED SIGNATURE

⑈40262737⑈ [redacted]

Commercial/financial information may be entitled to confidential treatment

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL

EPA Registration #	Date Submitted to EPA	Electronic file name
1677-223	6/2/2009	001677-00223.20090602.pdf

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

Rhonda Schulz
Signature

June 2, 2009
Date

Rhonda Schulz
Name (typed)

Associate Director, Product Registrations
Title

Fee for Service

pem {8517263~

This package includes the following

- ○ New Registration
- ⊙ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ⊙ AD
- ○ BPPD
- ○ RD

Risk Mgr. 31

Receipt No.	S-	851726
EPA File Symbol/Reg. No.		1677-223
Pin-Punch Date:		6/10/2009

☐ This item is NOT subject to FFS action.

Action Code:

Requested: ~~3,308~~ A570 ant

Granted: ~~3,308~~ A570 ant

Amount Due: $ 3,308

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Tem 1 Date: 6-11-09

Remarks:

U.S. ENVIRONMENTAL PROTECTION AGENCY
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 1677-223

Date of Issuance: JUN 13 2007

Term of Issuance: Conditional

Name of Pesticide Product: SANI-STEP

NOTICE OF PESTICIDE:
_x_ Registration
__ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Ecolab
370 N. Wabasha Street
St. Paul, MN 55102

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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/reregistered 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 sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "EPA Reg. No. 1677-223".

Signature of Approving Official:

Velma Noble
Product Manager Team-31
Regulatory Management Branch I
Antimicrobials Division (7510C)

Date: JUN 13 2007

EPA Form 8570-6

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

b. According to the Acute Toxicology Profile outlined below, you must make the following revisions:

Guideline	Toxicity Category	Status
Acute Oral	IV	Acceptable
Acute Dermal	IV	Acceptable
Acute Inhalation	IV	Acceptable
Primary Eye Irritation	III	Acceptable
Primary Skin Irritation	I	Acceptable
Dermal Sensitization	Nonsenitizer	Acceptable

1) Change the SIGNAL WORD from Caution to "***DANGER.***"

2) Revise the first four sentences under the "Precautionary Statements" to read *Corrosive. Causes skin burns and moderate eye irritation. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, clothing, and gloves.*"

3) The "First Aid" statements must be reorganized such that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first. Therefore, the "IF ON SKIN" statements must precede the "IF IN EYES" text.

c. The species name for *Salmonella typhimurium* has been changed by ATCC. You must revise the label to the new designation, *Salmonella enterica*.

d. The EPA Registration Number on page 2 is incorrect and must be revised to agree with this registration notice.

General Comments

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

If you have any questions concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Sincerely,

Velma Noble
Product Manager 31
Regulatory Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label
Product Chemistry Data Evaluation
Acute Toxicology Data Evaluation
Efficacy Data Evaluation

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

SANI-STEP

Solid, Time-Released, Floor Sanitizer
For Use in Dairy, Food and Beverage Processing Industries

ACTIVE INGREDIENTS:

Alkyl (C_{14}, 50% C_{12}, 40% C_{16}, 10%)	
Dimethyl benzyl ammonium chloride	0.479%
Octyl decyl dimethyl ammonium chloride	0.359%
Didecyl dimethyl ammonium chloride	0.215%
Dioctyl dimethyl ammonium chloride	0.144%
OTHER INGREDIENTS:	98.803%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. 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 eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: 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.

FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026
OUTSIDE OF NORTH AMERICA, CALL 1-651-222-5352

ENVIRONMENTAL HAZARDS: (only required for containers greater than 50 pounds) Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Borad or Regional Office of the EPA.

FOR INDUSTRIAL USE ONLY

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 13 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1677-223

DRAFT

SANI-STEP is a water activated, time-released, solid sanitizer specifically formulated to improve environmental sanitation on floors where wet conditions favor microorganism growth and cause sanitation concern.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

After cleaning and sanitizing equipment, apply SANI-STEP evenly to the floor, at a rate of 1.2 grams – 2.4 grams per square foot. Product may be re-applied as needed during the production process. SANI-STEP does not become active until it comes in contact with moisture on the floor.

SANI-STEP has been evaluated at a concentration that supports a dilution of 5.1 oz/gallon in the presence of 5% soil contamination and in waters up to 500 ppm hardness (29.2 gpg calculated as CaCO3). Treated surfaces must remain wet for 5 minutes.

SANI-STEP was evaluated using the Non-Food Contact Surface Sanitizer Test and was proven to be effective against the following organisms:

Staphylococcus aureus
Escherichia coli
Salmonella typhimurium
Enterobacter aerogenes
Listeria monocytogenes

STORAGE & DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.
Pesticide Storage: Store in a dry area.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your state Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Net Contents:
300 lb (136.2 kg)
30 lb (13.6 kg)

EPA Reg. No. 1677-134
EPA Est.: 1677-MN-1 (P), 1677-CA-2 (R), 1677-TX-1 (D), 1677-OH-1 (H) 1677-IL-2 (J), 1677-PR-1 (B), 1677-CA-1 (S), 1677-GA-1 (M), 1677-WV-1 (V)
Superscript refers to first letter of date code

Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 14, 2007

MEMORANDUM

Subject: Efficacy Review for Sani-Step, EPA Reg. No. 1677-EEG; DP Barcode: D337447.

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510P)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Velma Noble / Jacqueline Campbell-McFarlane
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Ecolab Inc.
370 N. Wabasha Street
St. Paul. MN 55102

Formulation from the Label:

Active Ingredient(s)	% by wt.
Akyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	0.479 %
Octyl decyl dimethyl ammonium chloride	0.359 %
Didecyl dimethyl ammonium chloride	0.215 %
Dioctyl dimethyl ammonium chloride	0.144 %
Other Ingredients	98.803 %
Total	100.000 %

I. BACKGROUND

The product, Sani-Step (EPA File Symbol 1677-EEG), is a new product. The applicant requested to register the product as a non-food contact surface sanitizer for use on floors in dairy, food and beverage processing industries. Studies were conducted at Ecolab Schuman Campus, located at 655 Lone Oak Drive, Eagan, MN 55121.

This data package contained a transmittal document from the applicant to EPA (dated January 18, 2007), two studies (MRID Nos. 470389-09 and 470389-10), Statements of No Data Confidentiality Claims for both studies, and the proposed label. The registrant submitted two amendments to the two studies (dated May 10, 2007) to remove "Bardac 208M" from the final reports and replace with "Quat" for clarification (Bardac 208M diluted to lower certified limit of 1.017% active ingredient, 300 ppm quat). These amendments were attached to their respective studies.

II. USE DIRECTIONS

The product is designed to be used for sanitizing hard, non-porous surfaces such as floors. Directions on the proposed label provided the following information regarding use of the product as a sanitizer: After cleaning and sanitizing equipment, apply Sani-Step evenly to the floor, at a rate of 1.2 grams - 2.4 grams per square foot. Product may be re-applied as needed during the production process. Sani-Step does not become active until it comes in contact with moisture on the floor.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

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 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. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. These Agency standards are presented in DIS/TSS-10.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 470389-09 "Non-Food Contact Surface Sanitizing Efficacy" for Sani-Step, by Laurinda Holen; Project number: 0600036. Study conducted at Ecolab. Study completed on December 28, 2006.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. P03176A, P03176B, and

P05116A) of the product,Sani-Step (KX-6187), were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM Method E1153). The product lot P03176B was at least 60 days old at the time of testing. 300ppm use solutions were prepared by adding ~24g of the product to ~976g of 500 ppm AOAC synthetic hard water (titrated at ~485 ppm). Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. Five sterile glass carriers per product lot per organism were inoculated with 0.02 ml of a 24±4 hour old suspension of the test organism. The inoculum was spread to within 1/8 inch of the edges of the carrier. The carriers were dried at 35±2°C for 30-40 minutes. Each carrier was transferred to a sterile jar and was exposed to the use solution at for 5 minutes. After exposure, 20 ml of neutralizer was added to each jar and the jars were rotated vigorously to suspend the surviving organisms. Following neutralization, 1.0 ml and 0.1 ml the solution were plated in duplicate on Tryptone Glucose Extract Agar. All plates were incubated for 48±4 hours at 35±2°C. Controls included those for carrier quantitation, inoculum count, viability, neutralization confirmation, sterility, and purity. The average log colony forming units (CFU) per Square, for each test microorganism, are as follows: ***Enterobacter aerogenes* 2.1 x 10^7, *Staphylococcus aureus* 6.55 x 10^6.**

Note: Protocol deviations and amendments reported in the study were reviewed and found to be acceptable.

Note: The applicant provided the data for one failed trial. In that trial, the use solution was prepared at 322 ppm quat while the lower certified limit is 300 ppm. Thus, the test was invalid. These data were not used to evaluate efficacy of the test product. See Appendix B of the laboratory report.

2. MRID 470389-10 "Supplemental Non-Food Contact Surface Sanitizing Efficacy" for Sani-Step, by Laurinda Holen; Project number: 0600037. Study conducted at Ecolab. Study completed on December 26, 2006.

This study was conducted against *Escherichia coli* (ATCC 11229), *Listeria monocytogenes* (ATCC 49594), and *Salmonella typhimurium*** (ATCC 13311). Two lots (Lot Nos. P03176B, and P05116A) of the product, Sani-Step (KX-6187), were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM Method E1153). The product lot P03176B was at least 60 days old at the time of testing. 300ppm use solutions were prepared by adding ~24g of the product to ~976g of 500 ppm AOAC synthetic hard water (titrated at ~485 ppm). Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. Five sterile glass carriers per product lot per organism were inoculated with 0.02 ml of a 24±4 hour old suspension of the test organism. The inoculum was spread to within 1/8 inch of the edges of the carrier. The carriers were dried at 35±2°C for 31-37 minutes. Each carrier was transferred to a sterile jar and was exposed to the use solution at for 5 minutes. After exposure, 20 ml of neutralizer was added to each jar and the jars were rotated vigorously to suspend the surviving organisms. Following neutralization, 1.0 ml and 0.1 ml the solution were plated in duplicate. All plates were incubated for 48±4 hours at 35±2°C. Controls included those for carrier quantitation, inoculum count, viability, neutralization confirmation, sterility, and purity. The average log colony forming units (CFU) per Square, for each test microorganism, are as follows: ***Escherichia coli* 9.8 x 10^6, *Listeria monocytogenes* 8.1 x 10^7, and *Salmonella typhimurium*** 1.1 x 10^6.**

Note: Protocol deviations and amendments reported in the study were reviewed and found to be acceptable.

V. RESULTS

MRID #	Organisms	Average Number of Survivor			Initial Population	Log Reduction
		P03176A	P03176B	P05116A		
470389-09	*Staphylococcus aureus*	$< 2.7 \times 10^1$	$< 4.9 \times 10^1$	$< 2.5 \times 10^1$	$\sim 6.55 \times 10^6$	>99.9
	Enterobacter aerogenes	$< 3.9 \times 10^1$	$< 2.9 \times 10^1$	$< 1.2 \times 10^2$	$\sim 2.1 \times 10^7$	>99.9
470389-10	*Escherichia coli*		$< 2.5 \times 10^1$	$< 1.2 \times 10^1$	$\sim 9.8 \times 10^6$	>99.9
	Listeria monocytogenes		$< 2.5 \times 10^1$	$< 2.9 \times 10^2$	$\sim 8.1 \times 10^7$	>99.9
	*Salmonella typhimurium***		$< 9.0 \times 10^1$	$< 1.0 \times 10^1$	$\sim 1.1 \times 10^6$	>99.9

VI. CONCLUSIONS

1. The submitted efficacy data **support** the use of the product, Sani-Step, as a non-food contact sanitizer on floors when tested against *Enterobacter aerogenes, Staphylococcus aureus, Escherichia coli, Listeria monocytogenes,* and *Salmonella typhimurium*** 300 ppm active quat in the presence of 500 ppm hard water and 5% organic soil, for a contact time of 5 minutes.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Sani-Step, is an effective non-food contact surface sanitizer against *Enterobacter aerogenes, Staphylococcus aureus, Escherichia coli, Listeria monocytogenes,* and *Salmonella typhimurium***, **are supported** by the applicant's data.

2. The applicant must add ATCC numbers of the tested organisms to the master label.

****Please note**: The species name of this organism has been changed by ATCC. The new designation of this organism is *Salmonella* ***enterica***. This change is effective immediately, and should be used for all subsequent references to this organism in the future.

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Thursday, June 07, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 1677-EEG/ Sani-Step
DP Barcode: D337446

To: Velma Noble, PM 31/ Jacqueline Campbell-McFarlane
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: EcoLab, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Alkyl (C14 50%, C12 40%, C16 10%) dimethyl benzyl ammonium chloride	0.479
Octyl decyl dimethyl ammonium chloride	0.359
Didecyl dimethyl ammonium chloride	0.215
Dioctyl dimethyl ammonium chloride	0.144
Other Ingredient(s):	98.803
Total:	100.000

1) BACKGROUND: Ecolab, Inc., has submitted a complete set of six acute toxicity studies to support the registration of their product. The studies were conducted by Charles River Laboratories.

While the registration product is "Sani-Step", the test material has the name "KX-6187". However, the 1/18/2007 cover letter from Ecolab states: "The data was generated under the experimental name KX-6187."

2) RECOMMENDATIONS: PSB findings are:

a) The acute oral and dermal toxicity studies are acceptable.

b) The acute inhalation toxicity study is acceptable.

c) The primary eye irritation study is acceptable. However, the volume (0.0695 g) of test material used in the study was confusing. Agency guidelines state that this study is to be conducted using **0.1 mL** of test material or not more than 100 mg. The density of the product is listed on the CSF as 0.74 g/L. CTT assumes that the lab weighed the product themselves, determined a density of 0.695 g/L and used that number to determine the dosing.

d) The primary skin irritation study is acceptable.

e) The dermal sensitization study is acceptable.

The acute toxicity profile for File Symbol 1677-EEG is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	470389-03	IV	Acceptable
Acute Dermal Toxicity	470389-04	IV	Acceptable
Acute Inhalation Toxicity	470389-05	IV	Acceptable
Primary Eye Irritation	470389-06	III	Acceptable
Primary Skin Irritation	470389-07	**I**	Acceptable
Dermal Sensitization	470389-08	Nonsensitizer	Acceptable

3) LABELING:

a) The signal word is "DANGER", based upon the results of the primary skin irritation study.

b) The Precautionary Statements shall state:

"Corrosive. Causes skin burns. Causes moderate eye irritation. Do not get in eyes, on skin or on clothing. Wear protective clothing and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco. Remove and wash contaminated clothing before reuse."

c) The First Aid Statements must state:

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for treatment advice.

If on Skin:

- Take off contaminated clothing.
- Rinse immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for treatment advice.

"Note to Physician: Probably mucosal damage may contraindicate the use of gastric lavage."

d) This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary skin 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).

e) Based upon data placing it in toxicity category I for primary skin 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. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that this product be assigned Restricted-Use classification; if not, this product should at least be packaged in CRP.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 470389-03 **Study Completion Date**: 10/6/2006
Study No.: EOV00051

Testing Laboratory: Charles River Laboratories
Authors: Dawn D. Rodabaugh, B.S.

Quality Assurance (40 CFR §160.12 and OECD ENV/MC/CHEM(98)17]): Included

Test Material: KX-6187; "Blue granules"

Species: Sprague-Dawley Crl:CD (SD) rat
Weight: 187-199 grams **Age**: ~ 8 weeks
Source: Charles River Laboratories

Conclusion:

1. LD_{50} (mg/kg): **Males>** Not tested
Females> 5,000 mg/kg
Combined> N/A

2. The estimated LD_{50} is greater than 5,000 mg/kg b.w.
3. Tox. Category: IV **Classification**: Acceptable

Procedure (Deviations from §81-1): None

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000 mg/kg	---	0/3	---

Observations: The lab observed no clinical abnormalities during the study.

Gross Necropsy: No gross abnormalities were observed.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 470389-04 **Study Completion Date**: 10/6/2006
Study No.: EOV00052
Testing Laboratory: Charles River Laboratories
Author: Dawn D. Rodabaugh, B.S.
Quality Assurance (40 CFR §160.12) and OECD ENV/MC/CHEM(98)17]): Included

Test Material: KX-6187; "Blue granules"

Species: Sprague-Dawley Crl:CD (SD) rat
Weight: Males= 263-287 g **Age**: Approximately 8 weeks
Females= 189-207 g
Source: Charles River Laboratories

Summary:

1. **LD_{50} (mg/kg)**: **Males>** 5,000 mg/kg b.w.
Females> 5,000 mg/kg b.w.
Combined> 5,000 mg/kg b.w.

2. **The estimated LD_{50} is greater than 5,000 mg/kg body weight.**

3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-2): None

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,000	0/5	0/5	0/10

Observations: transient occurrences of dark material around the facial area, dermal irritation. The dermal irritation was more severe in females than the males.

Gross Necropsy Findings: Scabbing.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 470389-05 **Study Completion Date**: 11/21/06
Lab Study No.: EOV00056

Testing Laboratory: Charles River Laboratories
Author: Dawn D. Rodabaugh, B.S.

Quality Assurance (40 CFR §160.12 and OECD ENV/MC/CHEM(98)17]): Included

Test Material: KX-6187; "Blue granules"
Concentration: 2.09 mg/L (gravimetric time-weighted average)

Species: Sprague-Dawley Crl:CD (SD) rat
Weight: Males= 338-420 g Females= 218-242 g
Age: 12 weeks
Source: Charles River Laboratories

Summary:

1. **LC_{50} (mg/L):** **Males>** 2.09 mg/L
   Females> 2.09 mg/L
   Combined> 2.09 mg/L
2. **The estimated LC_{50} is greater than 2.09 mg/L of air.**
3. **MMAD**: 3.9 µm
4. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-3): None

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.09 mg/L	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles <4.0 µm
2.09 mg/L	3.9 µm	2.12 µm	52

Chamber Environment	
Chamber Volume	10 liters
Airflow	64 L/Min
Temperature	75.4 – 77.4 °C
Relative Humidity	55.3 – 59.5%
Oyxgen Content	20.9%

Clinical Observations: Abnormally colored urine, dark material around eyes, dark material around nose, congested breathing, rough fur, unkempt appearance, lack of feces, and nasal discharge.

Gross Necropsy Findings: Small testes, small epididymis, foci in thymus.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 31
MRID No.: 470389-06
Reviewer: I. Blackwell
Study Completion Date: 10/31/06
Study No.: EOV00053

Testing Laboratory: Charles River Laboratories
Author(s): Dawn D. Rodabaugh, B.S.

Quality Assurance (40 CFR §160.12 and OECD ENV/MC/CHEM(98)17]): Included

Test Material: KX-6187; "Blue granules"
Dosage: 0.0695 g

Species: New Zealand White rabbits
Weight: 3.5 – 3.9 kg
Source: Myrtle's Rabbitry
Sex: 3 males
Age: 18-19 weeks

Summary:

1. **Toxicity Category**: III
2. **Classification**: Acceptable

Procedure (Deviations From §81-4):
- The study was conducted using 0.0695 g.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	10	14
Corneal Opacity	2/3	2/3	2/3	2/3	---	0/3	0/3	0/3
Iritis	3/3	2/3	2/3	3/3	---	0/3	0/3	0/3
Conjunctivae								
Redness	3/3	3/3	3/3	2/3	---	0/3	0/3	0/3
Chemosis	3/3	3/3	3/3	2/3	---	0/3	0/3	0/3
Discharge	3/3	3/3	2/3	1/3	---	0/3	0/3	0/3

- - - = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 470389-07 **Study Completion Date**: 11/21/2006
Study No.: EOV00054

Testing Laboratory: Charles River Laboratories
Study Director: Dawn D. Rodabaugh, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: KX-6187; "Blue granules"
Dosage: 0.5 g (moistened with 2 drops of water to form a paste)

Species: New Zealand White rabbit
Weight: 2.374 – 2.484 kg **Age**: Adult
Source: Myrtle's Rabbitry

Summary:

1. **Toxicity Category**: I

2. **Classification**: Acceptable

Procedure (Deviations From §81-5): None

Results: Three animals were tested. Animals R4687 and R4688 had very slight erythema one hour after study. R4688 had very slight erythema 48 and 72 hours after exposure. However, animal 4684 had test material staining blue, grade three blanching, grade 2 superficial lightening, grade 1 and 3 **eschar**, desquamation, and **apparent new tissue growth**.

Special Comments: The results obtained from the three test animals were not consistent.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 470389-08 **Study Completion Date**: 11/21/2006
Study No.: EOV00055
Testing Laboratory: Charles River Laboratories
Author: Dawn D. Rodabaugh, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: KX-6187; "Blue granules"
Positive Control Material: HCA

Species: Hartley albino guinea pigs
Weight: 397-493 g **Age**: Young adult
Source: Charles River Laboratories

Method: Modified Buehler Design

Summary:

1. **This Product is not a dermal sensitizer.**

2. **Classification**: Acceptable

Procedure (Deviation From §81-6):

Procedure: The test animals were induced and challenged with 100% undiluted test material. The amount was 0.35 g moistened with a drop of water.

Results:
Induction: Slight patchy erythema was seen in 4/20 test material-induced animals 24 hours after the second induction treatment. No erythema was reported following the first and third induction treatments.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

May 24, 2007

DP BARCODE: D337444

MRID : 47038901, 47038902, 47038911

SUBJECT: Sani-Step

REG. NO. OR FILE SYMBOL: 1677-EEG

DOCUMENT TYPE: **Product Chemistry Review**

Manufacturing-use [ ] OR **End-use Product [X]**

INGREDIENTS (PC Codes): 069105, 069165, 069149, 069166

CAS Number: 68424-85-1, 32426-11-2, 7173-51-5, 5538-94-3

TEST LAB: Ecolab Inc.

SUBMITTER: Ecolab Inc.

GUIDELINE:

COMMODITIES:

REVIEWER: Chris Jiang **ORGANIZATION: AD**

APPROVER: Karen P. Hicks **APPROVED DATE:** 5/24/07

COMMENT: for Karen P. Hicks

TO: **Velma Noble\Jacqueline Campbell-McFarlane**
PM Team 31

FROM: Chris Jiang, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: Ecolab Inc.
Action code : A54
Due out date : 6/14/07

Product Formulation

Active Ingredient(s):	**% by wt.**
Alkyl (C_{14} 50%, C_{12} 40%, C_{16} 10%) dimethyl benzyl ammonium chloride	**0.479 %**
Octyl decyl dimethyl ammonium chloride	**0.359 %**
Didecyl dimethyl ammonium chloride	**0.215 %**
Dioctyl dimethyl ammonium chloride	**0.144 %**

BACKGROUND:

The registrant has submitted a product chemistry package in support of the registration of this floor sanitizer. The package includes a label, a Confidential Statement of Formula, and Series 830 data requirements that have been identified by the Agency as MRIDs 47038901, 47038902, and 47038911.

FINDINGS:

1. The concentrations of the active ingredients on the Confidential Statement of Formula (CSF dated 5/23/07) are consistent with the label declaration. This CSF supersedes all previous CSFs for the basic formulation.

2. All ingredients are cleared for use in pesticidal products.

3. The descriptions of the starting materials and the manufacturing\production\formulation process are **acceptable**.

4. The discussion of the formation of impurities is **acceptable**.

5. The preliminary analysis is **acceptable**.

6. The wider certified limits for the requested ingredients are **acceptable** because of variability in the raw materials and because of manufacturing flexibility. All other limits are acceptable.

7. The enforcement analytical method is **acceptable.**

8. The color, physical state, and odor are **acceptable** as the product is a dry blue granule with a slight odor.

9. The density is **acceptable** as the mean value was determined to be 0.710 g/mL.

10. The pH is **acceptable** as the mean pH of a 10% solution was determined to be 7.31.

11. The oxidation/reduction potential is **acceptable** as the product is slightly reactive to metals, acids, and alkalis.

12. The flammability is **acceptable** as the product does not contain any flammable ingredients.

13. The explodability is **acceptable** as the product does not contain any potentially explosive ingredients.

14. A joint study for corrosion characteristics and storage stability is ongoing.

15. The viscosity is **acceptable** as this guideline is not applicable to solids.

16. The miscibility is **acceptable** as the product is not intended to be used with oil or nonpolar solvents.

17. The dielectric breakdown voltage is **acceptable** as the product is not to be used around electrical equipment.

CONCLUSIONS:

1. Product Science Branch of Antimicrobials Division finds the submission for 1677-EEG to be acceptable.

Fee for Service

{804440S~

This package includes the following

- (•) New Registration
- ( ) Amendment

✓ Studies? ☐ Fee Waiver?

✓ volpay % Reduction: ____

for Division

- (•) AD
- ( ) BPPD
- ( ) RD

Risk Mgr. 31

Receipt No.	S- 804440
EPA File Symbol/Reg. No.	1677-EEG
Pin-Punch Date:	1/24/2007

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A54

Granted: A54

Amount Due: $ 4200

Parent/Child Decisions:

Reviewer: McFarlane Date: 1/26/07

Remarks:

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

January 29, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-374147
EPA File Symbol or Registration Number: 1677-EEG
Product Name: SANI-STEP
EPA Receipt Date: 24-Jan-2007
EPA Company Number: 1677
Company Name: ECOLAB INC.

JOY SALVERDA
ECOLAB INC.
370 WABASHA ST. ECOLAB CENTER
ST PAUL, MN 55102

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 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: A54

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Please remit payment in the amount of: $ 4,200 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1801 S. Bell St.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6432.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

ECOLAB

Regulatory Affairs

Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Fax: (651) 225-3122

Writer's Direct Dial Number:
(651) 293-2848
e-mail: joy.salverda@ecolab.com

January 18, 2007

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22022

ATTN: Velma Noble, PM-31

Subject: Sani-Step Registration Application, EPA Reg. No. 1677-

Ecolab Inc. is submitting a registration application for the new end use product Sani-Step. This product is a non-food contact surface sanitizer. Ecolab believes that this product will be considered PRIA category A55 (New Product, Non-fast Track, Other uses) with a review timeline of 6 months.

The certified limit ranges for [redacted] on the Confidential Statement of Formulas (CSFs) adhere to the limit guidelines outlined in 40 CFR 158.175. Expanded ranges have been requested for the quat and colorant. Please refer to page 28 of the Chemical Characterization study for an explanation regarding the designation of the certified limits.

The administrative package contains the final proposed label and confidential statement of formula (CSF). The studies contain an earlier proposed version of the label and CSF. All CSF changes were minor (include additional suppliers). The label was revised to ensure that the language complied with EPA guidelines. Email correspondence with the Agency regarding the efficacy test method is included with the administrative documents.

Enclosed is the data to support the registration of Sani-Step. The data was generated under the experimental name KX-6187. The data requirements are satisfied by the submission of efficacy, toxicology, chemistry and accelerated storage stability data reports. Please see the transmittal document for the list of specific studies. A copy of the transmittal document is included in the front of each volume of data.

Sincerely,

ECOLAB INC.

Joy A. Salverda (J.SW)

Joy A. Salverda
Manager, Product Registration & Compliance

Inert ingredient information may be entitled to confidential treatment

TRANSMITTAL DOCUMENT

Sani-Step

EPA Registration Number 1677-

SUBMITTER:

Ecolab Inc.
Joy A. Salverda
Manager, Product Registration & Compliance
370 N. Wabasha Street
St. Paul, MN 55102-1390
(651) 293-2848

REGULATORY ACTION:
New registration application for Sani-Step, a non-food contact surface sanitizer.

TRANSMITTAL DATE: 01/18/07

SUBMITTED DOCUMENTS:

Volume 1 – Administrative Materials

- Cover Letter
- Application for Pesticide Registration, Form 8750-1.
- Confidential Statement of Formula, Form 8570-4 (3 copies).
- Certification with Respect to Citation of Data, Form 8570-34.
- Formulator's Exemption Statement, Form 8570-27
- Agency correspondence regarding efficacy test method
- Data Matrix, Form 8570-35 (Agency copy and Public File copy).
- Proposed end-use product label (5 copies).

Volume 2 – Product Chemistry and Accelerated Storage Stability Studies (3 Copies)

47038901 Chemical Characterization: EPA Guidelines – OPPTS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7100, 830.7300.

47038902 Accelerated Storage Stability: EPA Guidelines – OPPTS 830.6317, 830.6320, 830.1550.

Volume 3 – Acute Toxicity Studies (3 Copies)

47038903 Acute Oral LD_{50}: EPA Guideline – OPPTS 870.1100

47038904 Acute Dermal LD_{50}: EPA Guideline – OPPTS 870.1200

47038905 Acute Inhalation LC_{50}: EPA Guideline – OPPTS 870.1300

Volume 4 – Acute Toxicity Studies (3 Copies)

47038906 Primary Eye Irritation: EPA Guideline – OPPTS 870.2400

47038907 Primary Dermal Irritation: EPA Guideline OPPTS 870.2500

47038908 Dermal Sensitization: EPA Guideline OPPTS 870.2600

Volume 5 –Non-Food Contact Surface Sanitizing Efficacy Studies (3 Copies)

47038909 Non-Food Contact Surface Sanitizing: EPA Guideline – Subdivision G 91-2(j): Staphylococcus aureus (ATCC 6538), Enterobacter aerogenes (ATCC 13048)

47038910 Non-Food Contact Surface Sanitizing: EPA Guideline – Subdivision G 91-2(j): Escherich coli (ATCC 11229), Listeria monocytogenes (ATCC 7644), Salmonella typhimurium (ATCC 13311),

47038911 KX-6187 Chemical Quality Verification Study # 0600019

COMPANY OFFICIAL AND CONTACT: Joy A. Salverda (JAS)

Joy A. Salverda
Manager, Product Registration & Compliance
370 N. Wabasha Street
St. Paul, MN 55102-1390
(651) 293-2848

TRANSMITTAL DOCUMENT

Sani-Step

EPA Registration Number 1677-

SUBMITTER: Ecolab Inc.
Joy A. Salverda
Manager, Product Registration & Compliance
370 N. Wabasha Street
St. Paul, MN 55102-1390
(651) 293-2848

REGULATORY ACTION:
New registration application for Sani-Step, a non-food contact surface sanitizer.

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- Chemical Characterization: EPA Guidelines – OPPTS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7100, 830.7300.
- Accelerated Storage Stability: EPA Guidelines – OPPTS 830.6317, 830.6320, 830.1550.

Volume 3 – Acute Toxicity Studies (3 Copies)
- Acute Oral LD_{50}: EPA Guideline – OPPTS 870.1100
- Acute Dermal LD_{50}: EPA Guideline – OPPTS 870.1200
- Acute Inhalation LC_{50}: EPA Guideline – OPPTS 870.1300

Volume 4 – Acute Toxicity Studies (3 Copies)
- Primary Eye Irritation: EPA Guideline – OPPTS 870.2400
- Primary Dermal Irritation: EPA Guideline OPPTS 870.2500
- Dermal Sensitization: EPA Guideline OPPTS 870.2600

Volume 5 –Non-Food Contact Surface Sanitizing Efficacy Studies (3 Copies)

- Non-Food Contact Surface Sanitizing: EPA Guideline – Subdivision G 91-2(j): Staphylococcus aureus (ATCC 6538), Enterobacter aerogenes (ATCC 13048)
- Non-Food Contact Surface Sanitizing: EPA Guideline – Subdivision G 91-2(j): Escherich coli (ATCC 11229), Listeria monocytogenes (ATCC 7644), Salmonella typhimurium (ATCC 13311),

COMPANY OFFICIAL AND CONTACT: Joy A. Salverda (JAS)

Joy A. Salverda
Manager, Product Registration & Compliance
370 N. Wabasha Street
St. Paul, MN 55102-1390
(651) 293-2848

Please read instructions on reverse before complet[illegible]m. [illegible]rm Approved. OMB No. 2070-0060 Approval Expires 5-31-98

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

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

440

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
1677- EEG	Velma Noble	☒ None ☐ Restricted
3. Company/Product (Name) Sani-Step	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102 ☐ Check if this is a new address	6. **Expedited Review.** In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No.____ Product Name ____	

Section – II

☐ Amendment - Explain below.
☐ Final printed labels in response to
☐ Resubmission in response to Agency letter dated ____
☐ "Me Too" Application.
☐ Notification – Explain below.
☒ Other – Explain below.

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

Ecolab Inc. is submitting a registration application for the new end use product Sani-Step. This product is an antimicrobial non-food contact surface sanitizer for use in food processing plants. Ecolab believes that this product will be considered PRIA category A55 (New Product, Non-fast Track, Other uses) with a review timeline of 6 months.

The certified limit ranges for all ingredients on the Confidential Statement of Formulas (CSFs) adhere to the limit guidelines outlined in 40 CFR 158.175, except for the active ingredient. Please refer to page 28 of the Chemical Characterization study for an explanation regarding [illegible]e designation of the asymmetrical certified limits.

[illegible]e administrative package contains the final proposed label and con[illegible]dential statement of formula (CSF). The studies contain an earlier proposed version of the label and CSF. All CSF changes were minor [illegible]r revised to adhere to 40 CFR 158.175. The label was revised to ensure that the language complied with EPA guidelines.

Enclosed is the data to support the registration of Sani-Step. The data was generated under the experimental name KX-6187. The data requirements are satisfied by the submission of efficacy, toxicology, chemistry and accelerated storage stability data reports.

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)____
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Package wgt. / No. Per Container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	300 lb tote	☒ On Label ☐ 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 Code)
Joy A. Salverda	Manager, Product Registration & Compliance	(651) 293-2848

Certification

I certify that the statements which I have made on this form and all attachments 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
Joy A. Salverda (JAS)	Manager, Product Registration & Compliance
3. Typed Name: Joy A. Salverda	4. Date: 1/18/07

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.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, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.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 Ecolab Inc., 370 N. Wabasha St., St. Paul, MN 55102-1390	EPA Registration Number/File Symbol 1677-
Active Ingredient(s) and/or representative test compound(s) n-Alkyl dimethyl benzyl ammonium chloride, octyl decyl dimethyl ammonium chloride, didecyl dime	Date 1/18/07
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Non-food contact surface sanitizer	Product Name Sani-Step

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 Formulator's 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 I, 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
Joy A. Salverda	1/18/07	Joy A. Salverda, Manager - Product Registration

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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
Ecolab Inc. 370 North Wabasha Street St. Paul, MN 55102	1677-
	Product Name Sani-Step
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 01/18/2007

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):

n-Alkyl(50%C14, 40%C12, 10%C16)dimethyl benzyl ammonium chloride, octyl decyl dimethyl ammonium chloride, didecyl dimehtyl ammonium chloride, dioctyl dimethyl ammonium chloride

(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
n-Alkyl(50%C14, 40%C12, 10% C16)dimethyl benzyl ammonium chloride, octyl decyl dimethyl ammonium chloride, didecyl dimehtyl ammonium chloride, dioctyl dimethyl ammonium chloride	[redacted]	[redacted]

Signature	Name and Title	Date
Joy A. Salverda	Joy A. Salverda, Manager	01/18/2007

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

Pages 76-79 Non-Responsive/Pending registration information may be entitled to confidential treatment

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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 1/18/07

EPA Reg.No./File Symbol 1677-

Applicant/Registrant Name & Address
Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102

Product
Sani-Step

Ingredient: Alkyl (C_{14}, 50% C_{12}, 40% C_{16}, 10%) Dimethyl benzyl ammonium chloride, Octyl decyl dimethyl ammonium chloride, Didecyl dimethyl ammonium chloride, Dioctyl dimethyl ammonium chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	To be assisgned	Ecolab Inc.	OWN	
830.1600	Description of Materials used to Produce the product	To be assisgned	Ecolab Inc.	OWN	
830.1620	Description of Production Process	To be assisgned	Ecolab Inc.	OWN	
830.1650	Description of Formulation Process	To be assisgned	Ecolab Inc.	OWN	
830.1670	Discussion of Formation of Impurities	To be assisgned	Ecolab Inc.	OWN	
830.1700	Preliminary Analysis	To be assisgned	Ecolab Inc.	OWN	
830.1750	Certified Limits	To be assisgned	Ecolab Inc.	OWN	
830.1800	Enforcement Analytical Method	To be assisgned	Ecolab Inc.	OWN	
830.6302	Color	To be assisgned	Ecolab Inc.	OWN	
830.6303	Physical State	To be assisgned	Ecolab Inc.	OWN	
830.6304	Odor	To be assisgned	Ecolab Inc.	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	To be assisgned	Ecolab Inc.	OWN	
830.6315	Flammability	To be assisgned	Ecolab Inc.	OWN	
830.6316	Explodability	To be assisgned	Ecolab Inc.	OWN	
830.6317	Accelerated Storage Stability	To be assisgned	Ecolab Inc.	OWN	
830.6317	Long Term Storage Stability	To be assisgned	Ecolab Inc.	OWN	
830.6319	Miscibility	To be assisgned	Ecolab Inc.	OWN	
830.6320	Corrosion characteristics	To be assisgned	Ecolab Inc.	OWN	
830.6320	Corrosion characteristics	To be assisgned	Ecolab Inc.	OWN	
830.6321	Dielectric Breakdown Voltage	To be assisgned	Ecolab Inc.	OWN	
830.7000	pH	To be assisgned	Ecolab Inc.	OWN	
830.7100	Viscosity	To be assisgned	Ecolab Inc.	OWN	
830.7300	Density/Relative Density/Bulk Density	To be assisgned	Ecolab Inc.	OWN	

Signature Joy A. Salverda

Name and Title Joy A. Salverda
Manager, Product Registration & Compliance

Date 1/18/07

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DATA MATRIX

Date 1/18/07			EPA Reg.No./File Symbol 1677-		Page 2 of 2
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102			Product **Sani-Step**		
Ingredient:	Alkyl (C_{14}, 50% C_{12}, 40% C_{16}, 10%) Dimethyl benzyl ammonium chloride, Octyl decyl dimethyl ammonium chloride, Didecyl dimethyl ammonium chloride, Dioctyl dimethyl ammonium chloride				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral toxicity	To be assigned	Ecolab Inc.	OWN	
870.1200	Acute Dermal toxicity	To be assigned	Ecolab Inc.	OWN	
870.1300	Acute Inhalation Toxicity	To be assigned	Ecolab Inc.	OWN	
870.2400	Primary Eye Irritation	To be assigned	Ecolab Inc.	OWN	
870.2500	Primary Dermal Irritation	To be assigned	Ecolab Inc.	OWN	
870.2600	Dermal Sensitization	To be assigned	Ecolab Inc.	OWN	
Subdivision G 91-2(j)	Non-Food Contact Surface Sanitizing - Staphylococcus aureus (ATCC 6538), Enterobacter aerogenes (ATCC 13048)	To be assigned	Ecolab Inc.	OWN	
Subdivision G 91-2(j)	Non-Food Contact Surface Sanitizing - Escherichia coli (ATCC 11229), Listeria monocytogenes (ATCC 49594), Salmonella typhimurium (ATCC 13311)	To be assigned	Ecolab Inc.	OWN	
Signature Joy A. Salverda			Name and Title Joy A. Salverda Manager, Product Registration & Compliance		Date 1/18/07

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DATA MATRIX

Date 1/18/07		EPA Reg.No./File Symbol 1677-	Page 1 of 4
Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102		Product **Sani-Step**	
Ingredient:	Alkyl (C_{14}, 50% C_{12}, 40% C_{16}, 10%) Dimethyl benzyl ammonium chloride, Octyl decyl dimethyl ammonium chloride, Didecyl dimethyl ammonium chloride, Dioctyl dimethyl ammonium chloride		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
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			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	

Signature	Name and Title Joy A. Salverda Manager, Product Registration & Compliance	Date 1/18/07

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Applicant/Registrant Name & Address Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102			Product **Sani-Step**		
Ingredient:	Alkyl (C_{14}, 50% C_{12}, 40% C_{16}, 10%) Dimethyl benzyl ammonium chloride, Octyl decyl dimethyl ammonium chloride, Didecyl dimethyl ammonium chloride, Dioctyl dimethyl ammonium chloride				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
			Ecolab Inc.	OWN	
Signature			Name and Title Joy A. Salverda Manager, Product Registration & Compliance		Date 1/18/07

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Pages 84-89 Confidential Statement of Formula may be entitled to confidential treatment