UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

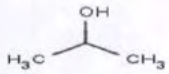
OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

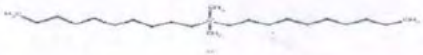
April 19, 2011.

DP BARCODE:	D373641
MRID:	483439-00, 483439-02, 483439-03, & 483439-04.
SUBJECT:	**Cavicide 1**
REG. NO. OR FILE SYMBOL:	46781-RE
DOCUMENT TYPE:	Product Chemistry Review
Manufacturing-use [] OR	End-use Product [X]

INGREDIENTS (PC Codes)

Isopropyl alcohol (047501) (67-63-0)	Didecyl dimethyl ammonium chloride (069149) CAS Number: (7173-51-5)	Ethanol (001501) CAS Number: (64-17-5)





TEST LAB:	Metrex Research, LLC
SUBMITTER:	Metrex Research
GUIDELINE:	OPPTS 830 Guidelines.
COMMODITIES:	Formulation
REVIEWER:	Salvador Rodriguez
ORGANIZATION:	AD
APPROVER:	Karen P. Hicks APPROVED DATE: 04/19/11.

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April 19, 2011.

MEMORANDUM

Subject:	Product Chemistry Review for EPA Reg # 46781-RE.
From:	Salvador M. Rodriguez Product Science Branch, CT Team Antimicrobials Division (7510P)
Thru:	Karen P. Hicks, CT Team Leader Product Science Branch Antimicrobials Division (7510P)
To:	Zebora Johnson PM Team 33
APPLICANT:	Metrex Research
Action code:	362
Due date:	05/27/11.

Product Formulation
Active Ingredient(s)

	% by wt.
Isopropyl alcohol	15.0
Ethanol	7.5
Didecil dimethyl ammonium chloride	0.76

BACKGROUND:

Metrex Research, LLC has submitted an application for registration of a new end-use product, CaviCide 1. The product is a disinfectant (bactericide, fungicide, tuberculocide, and virucide) and deodorizer for use on hard, non-porous surfaces in institutional, commercial, animal care, and hospital or medical environments. The product is produced by a non-integrated formulation system (i.e., the product contains an active ingredient that is not an EPA-registered product). The source of the active ingredient, DDAC, is the registered product, [redacted] EPA Reg. No. [redacted]). Ethanol and Isopropanol are obtained from non-registered products.

The data package included a list of documents submitted to support the new product registration, undated; a Confidential Statement of Formula (CSF) for the basic formulation, dated January 4, 2011; a draft label, dated January 4, 2011; and three studies (MRID 483439-02 through 483439-04), plus three more studies, pin punched 04/13/11, which they are already in the process to be assigned the particular MRID #s.

FINDINGS:

1. The CSFs, dated 01/04/11, for basic formulation is revised

2. All the certified limits meet the EPA standard certified limits.

3. The CSFs and the label have the same nominal.

4. Group A product chemistry data requirements applicable to end-use products have been Met. MRID #s: 483439-03, 483439-04.

5. Group B product chemistry data requirements applicable to end-use products have been met. MRID #s: 483439-02. The registrant has submitted to the Front End Processing Department the three new studies in order to be assigned an MRID # for each study. The titles of the studies are:

   - Storage Stability & Corrosion Characteristics.
   - Description of the Formulation Process.
   - Dielectric Breakdown Voltage

6. A statement of Good Laboratory Practice (GLP) compliance was provided for the study assigned MRID 483439-02. The study is said to meet the requirements of 40 CFR Part 160. It is questionable whether testing was conducted in compliance with GLP standards. A study director was identified; however, a Quality Assurance Statement was not provided.

7. The assay is based on the total active ingredients (AI)s of 23.26 %.

8. The registrant conducted the assays for the active ingredients (AI)s concentration as follows:

(A I) Concentration of Expresed Liquid of Cavicide 1 over time.

Sample	Iso-Prpopanol (%/wt)	DDAC (%/wt)	Ethanol (%/wt)
Initial	15.11	0.722	7.44
4-month	14.63	0.734	7.795
7-month	14.74	0.727	7.425
10-month	14.84	0.720	7.757
14-month	15.14	0.759	7.673

9. The registrant indicated that under the conditions of this study, the product sample "Cavicide 1" shows no physical changes such as phase separation or "clumping" and demonstrated no corrosion of the storage commercial containers throughout the course of the one year storage stability study.

10. Labeling meets the guidelines. However it could be improved. See recommendation section.

CONCLUSIONS:

The results of the storage stability study for the product Cavicide1, indicate that: a) the concentration of active ingredients are within the certified limits or b) no degradation of toxicological significance was detected. The OPPTS Guideline Series 830.1650 Group A, and Guideline Series 830.6317, 830.6320 & 830.6321 Group B product chemistry data requirements, applicable to end-use products are acceptable.

RECOMMENDATIONS:

- The following revisions to the product label are recommended
  - Relocate the "Physical or Chemical Hazards" section so that it is immediately beneath the "Environmental Hazards" section of the product label.
  - Under the "Pesticide Disposal" section on the product label, provide instructions for disposing of unused product.
  - Revise the "Physical or Chemical Hazards" statements to read: "**Combustible**. Do not use or store near heat or open flame." Note the use of boldface type.
  - Place the "Storage and Disposal" section of the product label in a text box for prominence.
  - Under the "Pesticide Storage" section of the product label, add instructions that specify what to do if the product leaks or spills from the product container.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAIs used registered? Yes [X] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [X] No [ ]

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredients	NC (%)	LCL (%)	UCL (%)
Didecyldimethylammonium chloride	0.76	0.68	0.84
Ethanol	8.70	8.27	9.14
Isopropanol	14.6	13.87	15.33

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of $\geq 0.1\%$ in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No []

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statements regarding flammability or explosive characteristics of the product are listed on the label.
Yes [X] No [ ] Not applicable [ ]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [ ] No [X]

Note: Disposal options for unused pesticide must be identified. See the "Recommendations" section of this report.

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [X]

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	483439-03 483439-04
830.1600 Description of Materials	A	483439-03 483439-04
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A	MRID# To be assigned
830.1670 Formation of Impurities[4]	NA	
830.1700 Preliminary Analysis[5]	A	MRID# To be assigned
830.1750 Certified Limits[6]	A	CSF
830.1800 Enforcement Analytical Method[7]	A	483439-03 483439-04
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The product is clear, colorless.	483439-02
830.6303 Physical State	A	The product is a liquid.	483439-02
830.6304 Odor	A	The product has an alcohol odor.	483439-02
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	N/A	The product does not contain oxidizing or reducing agents	
830.6315 Flammability/ Flame Extension	A	The product was reported to have a flashpoint of 34.43°C (93.9°F).	483439-02
830.6316 Explodability	N/A	This is a water-based product.	
830.6317 Storage Stability	A	The product is stable.	MRID# To be assigned
830.6319 Miscibility[1]	NA	The product is ready-to-use.	
830.6320 Corrosion Characteristics	A	The product & container are stable	MRID# To be assigned
830.6321 Dielectric Breakdown Voltage	A	The product is not to be used on electrical equipment.	MRID# To be assigned
830.7000 pH[2]	A	The pH range of the product was reported to be 11.0 to 12.49.	MRID# To be assigned
830.7050 UV/Visible Absorption	NA	*[Not required for end-use products.]*	
830.7100 Viscosity	N/A	TGAI registered product.	
830.7200 Melting Point/Melting Range	NA	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NA	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	The specific gravity of the product was reported to be 0.960.	483439-02
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water