

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

June 8, 2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
AM 3651P

DP Barcode: 273613
Manufacturing-use [] OR

Reg. No. Or File Symbol: 70871-RL
End-use Product [X]

TO: Velma Noble/Tracy Lantz
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Product Formulation

Active Ingredient(s)	% by wt.
3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride.....	35.60%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride.....	6.40%
Octyl decyl dimethyl ammonium chloride.....	4.80%
Didecyl dimethyl ammonium chloride.....	2.88%
Diocetyl dimethyl ammonium chloride.....	1.92%

BACKGROUND:

The registrant has submitted an application for a new end-use product, dispensed as a

spray, for a disinfectant for use in a wide variety of commercial, institutional, and educational areas, as well as for household use. Data submitted in nine (9) documents (MRID Nos. 448766-01C, 448766-03, 448859-01, 448859-02, 449291-01, 449724-01C, 451213-01C, 451213-02, and 451213-02) were the same as that submitted to the Agency to support the registration of the manufacturing-use product AM 3651PI (EPA Reg. #70871-13).

FINDINGS:

1. The label is making a claim as a sanitizer, but the efficacy data submitted does not support a sanitization claim for non-food use hard non-porous surfaces.
2. The combined quaternary ammonium chloride active ingredient has not been cleared by Code of Federal Regulations for food use.
3. The product contains $\geq 6\%$ methanol. The directions specify the use of protective eyewear and gloves when using the product.
4. One of the components in the combined active ingredients was not correctly listed on the label. The carbon chain link must be included in the listing of n-alkyl dimethyl benzyl ammonium chloride whenever the compound is named.
5. All ingredients have been approved for use in pesticides for non-food contact.
6. The certified upper and lower limits have been correctly calculated and appear on the Confidential Statement of Formula.
7. The nominal concentration of the active ingredients listed on the Confidential Statement of Formula are in agreement with those appearing in the label ingredient claims statement, conforming to PR Notice 91-2.
8. Most of the product chemistry data had previously been accepted at the time of the registration of the MUP. The product specific data was submitted as a self-certification. Attached below is a summary of all the product chemistry data.

RECOMMENDATIONS:

1. The product chemistry data submitted to support registration of this end-use product is acceptable.
2. The label claims for the product as a sanitizer against all organisms and a disinfectant against *E. coli* must be omitted. The label must be revised to meet the requirements listed in the efficacy review.

3. The complete chemical name (including the chain link distribution of the carbon atoms) of the first active ingredient must appear on the label. The correct name is as follows:
n-Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₆) dimethyl benzyl ammonium chloride
4. The Confidential Statement of Formula, dated February 28, 2001 is acceptable.

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system ☒ [X]
- Are all TGAI used registered? Yes ☐ [] No ☐ []
- Integrated formulation system ☐ []
- if "ME-TOO", specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:

Cleared for food use under 40 CFR §180.1001: Yes ☐ [] No ☒ [X] NA ☐ []

4c. Physical state of product: Liquid

4d. The chemical IDs and analytical information (including that for the TGAI), density, pH, and flammability are consistent with that given in 830.1000, Series A and 830.7300, .7000 and .6315 respectively: Yes ☒ [X] No ☐ []

4h. NCs and CLs are acceptable: ☒ [X] Not acceptable ☐ []

4i. Active ingredient (s)

	NC	UCL	LCL
A. 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride	35.6%	36.67%	34.53%
B. n-Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	6.40%	6.72%	6.18%
C. Octyl decyl benzyl ammonium chloride	4.80%	5.04%	4.54%
D. Didecyl dimethyl ammonium chloride	2.88%	3.02%	2.74%
E. Dioctyl dimethyl ammonium chloride	1.92%	1.82%	2.02%

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
Yes ☐ [Y] No ☐ [] Not applicable ☐ []
- All impurities of $\geq 0.1\%$ in the product have been identified?
Yes ☒ [X] No ☐ [] Not applicable ☐ []

5. PRODUCT LABEL

- 5a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [X] No []
- 5b. The formulation contains one of the following:
- 10% or more of a petroleum distillate: Yes [] No []
 - 1.0% or more of methyl alcohol: Yes [X] No [] $\geq 6\%$
 - Sodium nitrite at any level: Yes [] No []
 - a toxic List 1 inert at any level: Yes [] No []
 - arsenic in any form: Yes [] No []
- 5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [X] No [] Not applicable []
- 5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [X] No [] Not applicable []
- 5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes [X] No []
- 5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
Yes [] No [X]

PRODUCT CHEMISTRY (Series 830 Part A)

	Acceptance of Information	MRID No.
830.1550 Chemical ID (See Appendix) ¹	A	448859-01C
830.1600 Description of Materials	A	448859-01C, 449724-01C
830.1620 Manufacturing Process ²	A	448859-01C, 449724-01C

	Acceptance of Information	MRID No.
830.1650 Formulation Method ³	A	449724-01C
830.1670 Discussion of Impurities ⁴	A	451213-01C
830.1700 Analysis ⁵	A	448766-01C
830.1750 Certified Limits ⁶	A	451213-01C
830.1800 Analytical Method for AIs ⁷	A Titration of Quat	448766-01C

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required, G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information

²For MP/EP products produced by an integrated formulation system.

³For products from a TGA I or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLS recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR),

Physical and Chemical Characteristics (Series 830, Part B)

6b. <u>Physical/Chemical Properties*</u>	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	Light yellow	452457-01
830.6303 Physical State	A	Cloudy liquid	452457-01
830.6304 Odor	A	Mild sweet soap	452457-01
830.6314 Oxidation/Reduction	A	Contains no oxidizer of reducing agent	452457-01
830.6315 Flammability/Flash Pt.	A	Flash pt. 28° C.	452457-01
830.6316 Explodability	A	Not explosive	452457-01
830.6317 Storage Stability	A	Stable for 12 months	452457-02
830.6320 Corrosion Character.	A	Not corrosive	452457-02
830.7000 pH	A	6% at 20° C	452457-01
830.7100 Viscosity	A	Sl.viscous 55.8 mPs	452457-01
830.7300 Density/rel. or bulk	A	9.44 gm/ml	452457-02

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= Not required
G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

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

Product Manager Please Note:

This product is labeled for household use, but inasmuch as it contains greater than 6% methanol, goggles and gloves are required for using it, and children and pets must be removed from the vicinity while it is being used and until surfaces are dry, shouldn't there be restrictions on the label against household use? Please advise. N.