UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

June 23, 2000

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
Z-1

DP Barcode: 260931 **Reg. No. Or File Symbol: 3573-AO**
Manufacturing-use [ ] OR **End-use Product [X]**

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PM team No. 31

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6/23/00

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Product Formulation	**Active Ingredient**
Didecyl dimethyl ammonium chloride	0.139%

BACKGROUND:

This is a new product designed to eliminate odors from fabrics which are difficult to launder. It makes no public health claims. One basic formula and seven (7) alternate formulations were submitted for review. The primary review of the product chemistry data required for a new product registration by 40 CFR, Part 158 was conducted at the Oak Ridge National Laboratories. The additional review was done in the Antimicrobial Division.

FINDINGS:

1. The formulations differ only in the concentration of the active ingredient [redacted] and in minor adjustments of the inert ingredients.

2. All upper and lower certified limits meet the Agency standards set forth in 40 CFR, *Part* 158.175, or the registrant has provided data to provide support for the wider range of limits by explanatory statements on the Confidential Statements of Formula.

3. All ingredients have been cleared by the Agency for use in pesticides. Four fragrances not previously approved have been entered into the Agency database for Pesticide Chemical codes.

4. The label ingredient claims statement and the nominal concentration of the active ingredient are in agreement and conform to the recommendations of PR Notice 91-2.

5. All product chemistry data for Series 830, Part A and B are complete. The one-year storage stability (830.6317) and corrosion characteristics (830.6320) studies are still underway. Results of the accelerated studies were submitted and final results are pending the completion of the study period.

RECOMMENDATIONS:

1. The data requirements for product chemistry for registration are complete with exceptions noted in #5 above, and are acceptable. (See attached)

2. The Confidential Statements of Formula for one basic formula and seven (7) alternate formulations are acceptable.

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
  - Are all TGAIs used registered? Yes [X] 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 [ ] NA[X]
]

4c. Physical state of product: liquid

4d. The chemical IDs and analytical information (including that for the TGAIs), 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 [ ]
wider range for fragrances and pH adjuster approved

4i. Active ingredient (s)	NC	LCL	UCL
A. Didecyl dimethyl ammonium chloride	0.139	0.125	0.153

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

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

  Yes [ ] No [ ] Not applicable [X]

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 [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]

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [ ] No [ ] Not applicable [X]

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]

6. **PRODUCT CHEMISTRY (Series 830 Part A)**

	Acceptance of Information	MRID No.
830.1550 Chemical ID (See Appendix)[1]	A	449560-01
830.1600 Description of Materials	A	449560-01
830.1620 Manufacturing Process[2]	A	449560-01
830.1650 Formulation Method[3]	NA	
830.1670 Discussion of Impurities[4]	NA	

	Acceptance of Information	MRID No.
830.1700 Analysis[5]	NA	
830.1750 Certified Limits[6]	A	449560-01
830.1800 Analytical Method for AIs[7]	A Titration	449560-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; 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 tox concern.

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

[6]If different from standard CIs 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),

Physical and Chemical Characteristics (Series 830, Part B)

6b. Physical/Chemical Properties*	Acceptance of data	Value or qualitative description	MRID No.
830.6303 Physical State	A	Liquid.	449560-03
830.6315 Flammability	A	Above 150 deg. C	449560-06
830.6316 Explodability	NA		
830.6317 Storage Stability	A	Complete study pending	449560-02
830.6320 Corrosion Character.	A	Complete study pending	449560-02
830.7000 pH	A	6.22 +/- 0.142	449560-03
830.7100 Viscosity	A	1.3 +/- 0.0 cP @ 30 rpm	449560-04
830.7300 Density/rel. or bulk	A	1.0003 +/- 0.0001	449560-03

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; 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/