UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
**Antimicrobials Division**

**March 10, 2006**

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF:**
**Aegis 444-02 RTU Antimicrobial**

**DP Barcode: D324449** **Reg. No. Or File Symbol: 64881-A**
**TGAI\MUP** **[]** OR **End-use Product [X]**

**TO:** Velma Noble\Jacqueline Campbell-McFarlane
PM Team No. 31

**FROM:** Chris Jiang, Chemist
Product Science Branch
Antimicrobials Division (7510C)

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

3/14/06

**THRU:** Michele Wingfield, Branch Chief
Product Science Branch
Antimicrobials Division (7510C)

**Product Formulation from label**

| **Active Ingredient(s)** | **% by wt.** |
|---|---|
| 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride | 0.84 % |

**BACKGROUND:**

The registrant has submitted a product chemistry package in support of a new registration of an end-use product. The package contains a label, a Confidential Statement of Formula, and studies that have been identified by the Agency as MRID #'s 46693801 and 46693802. The contractor has done the primary review of this submission and Product Science Branch of Antimicrobials Division has done a secondary review which supersedes the primary review.

**FINDINGS:**

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated November 10, 2005) is consistent with the label declaration. It is suggested that the registrant write the name of the active ingredient and the purity of the source on the CSF.

2. All the ingredients with the exception of the active ingredient and [redacted] are cleared for use in pesticidal products. The registrant must either substitute the uncleared inerts with already cleared inerts or have the suppliers send the complete compositional information of the uncleared ingredients to the Agency. The information must include the product name (which must exactly match the name on the CSF), manufacturer name/address and complete chemical composition including the chemical name, CAS Reg. No. and percentage by weight for each component of the mixture. This information must be typed on manufacturer's letterhead and accompanied by a signature.

3. The descriptions of the starting materials and the manufacturing\production\formulation process are **acceptable**, pending clearance of the uncleared inerts.

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

5. The certified limits cannot be determined because of the uncleared inerts. The registrant may wish to alter the formulation with other inerts and this would necessitate recalculation of the certified limits.

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

7. The physical state is **unacceptable** because it is not addressed in the submission. It constitutes a data gap.

8. The density is **acceptable**. The density was determined at 21 °C to be 0.998 g/mL (8.321 lbs/gal) using a method based on ASTM Method D 891-89, Method B.

9. The pH is **acceptable** as it was determined to be 3.81 at 25 °C using a procedure based on ASTM Method E 70.

10. The oxidation/reduction potential is **unacceptable** because it is not addressed in the submission. It constitutes a data gap. The test must be done under GLP compliance.

11. The flammability is **acceptable** as no flash point was observed when the product was heated to 100 °C using a method based on ASTM Method D 56.

12. The explodability is **unacceptable** because it is not addressed in the submission. It constitutes a data gap. The test must be done under GLP compliance.

13. The storage stability is **unacceptable** because it is not addressed in the submission. It constitutes a data gap. The test must be done under GLP compliance.

14. The viscosity is **acceptable** as the kinematic viscosity was determined to be 1.179 cSt at 21 °C using ASTM Methods D 445 and D 446.

15. The miscibility is **unacceptable** because it is not addressed in the submission. It constitutes a data gap. The test must be done under GLP compliance.

16. The corrosion characteristics are **unacceptable** because they are not addressed in the submission. They constitute a data gap. The test must be done under GLP compliance.

17. The dielectric breakdown voltage is **unacceptable** because it is not addressed in the submission. It constitutes a data gap. The test must be done under GLP compliance.

**RECOMMENDATIONS:**

1. Product Science Branch of Antimicrobials Division finds this submission in support of the registration of 64881-A to be unacceptable for the reasons stated in the findings. The registrant must remedy the problems stated in the findings before registration can proceed.

**February 7, 2006**

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF** Aegis 444-02 RTU Antimicrobial

**DP Barcode:** D324449 **Reg. No. Or File Symbol:** 64881-A
**Manufacturing-use** [ ] **End-use Product** [X]

**TO:** Wallace Powell, EPA Work Assignment Manager
**FROM:** John S. Chandler, CSS Work Assignment Manager

This is a review of the following Product Chemistry 830 Series study packages provided to CSC Systems & Solutions LLC (CSS) for preliminary review:

**Product Identity and Composition** (MRID 466938-01)

830 Series, Group A: 830.1550 (Product Identity and Composition), 830.1600 (Description of Materials Used to Produce the Product), 830.1620 (Description of Manufacturing Process), 830.1670 (Discussion of Formation of Impurities), 830.1700 (Preliminary Analysis), 830.1750 (Certified Limits), and 830.1800 (Enforcement Analytical Method).

**Product Chemistry Discussion** (MRID 466938-02)

830 Series, Group B: 830.6315 (Flammability), 830.7000 (pH), 830.7100 (Viscosity), and 830.7300 (Density/Relative Density/Bulk Density).

| **Product Formulation** | |
|---|---|
| **Active Ingredients:** | **% by wt.:** |
| 3-(trimethyoxysilyl)propyl dimethyl octadecyl ammonium chloride | 0.84% |

**BACKGROUND:**

On behalf of Aegis Environmental Management, Inc., ChemReg International, LLC is submitting an application for registration of Aegis 444-02 RTU Antimicrobial, a new end-use product. The product is a ready-to-use dilution of the currently registered Aegis Antimicrobial, EPA Reg. No. 64881-3.

**RECOMMENDATIONS:**

We are not providing recommendations or acceptability statements.

## 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, Group B:
Yes [X] No [ ]

4e. NCs and CLs are acceptable: Yes [ ] No [X]

4f. Active ingredient(s)

| | NC (%) | LCL (%) | UCL (%) |
|---|---|---|---|
| A. 3-(trimethyoxysilyl)propyl dimethyl octadecyl ammonium chloride | 0.84 | 0.80 | 0.88 |

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

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

**Product Chemistry (830 Series, Group A)**

| 6a. Data Requirements | Acceptance of Information | MRID No. |
|---|---|---|
| 830.1550[1] Product Identity | | 466938-01 |
| 830.1600 Description of Materials | | 466938-01 |
| 830.1620 Production Method[2] | | |
| 830.1650 Formulation process[3] | | 466938-01 |
| 830.1670 Formation of impurities[4] | | 466938-01 |
| 830.1700 Preliminary Analysis[5] | | 466938-01 NA |
| 830.1750 Certified Limits[6] | | 466938-01 |
| 830.1800 Analytical Method[7] *Titrometric determination* | | 466938-01 |

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

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

| 6b. Physical/Chemical Properties* | Acceptance of data | Value or qualitative description | MRID No. |
|---|---|---|---|
| 830.7220 Boiling Point/Boiling Range | | | |
| 830.7300 Density/Relative Density/Bulk Density | | 0.998 at 21 °C. (Ref. CCL SOP 10.16 based on ASTM D891-89). | 466938-02 |
| 830.7370 Dissociation Constants in Water | | | |
| 830.7550/830.7560/830.7570 Partition Coefficient | | | |
| 830.7840/830.7860 Water Solubility | | | |
| 830.7950 Vapor Pressure | | | |

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.

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