10-6-99

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **BioSchield AMS 1860**

DP Barcode: **D258500** Reg. No. or File Symbol : **70871-RE**
Manufacturing-use [**X**] End-use Product [ ]

Active Ingredient Composition:
3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride.....72%

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9/30/99

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BACKGROUND:

This application for a new product registration, for the subject manufacturing use antimicrobial, was submitted by SciReg, Inc. on behalf of the registrant BioShield Technologies, Inc.

A "me too" registration was initiated by the registrant, since the proposed

product is substantially similar to Aegis Environmental Management Inc. product. The product referred to is: AEM 5772 Antimicrobial MUP, EPA Reg # 64881-5.

The Bio-Schield product, **AMS 1860**, is made by non-integrated process. The process utilizes a non-registered source of the active ingredient [redacted] which currently is not in active use per EPA's REFS database.

With this application, registrant's own product chemistry data was provided. Registrant will, however, rely on the cite-all method to meet other data requirements. Letters of compensation to companies listed for the active ingredient 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride (TPOA) have been issued.

In the course of this review, the following documents were examined: SciReg, Inc. cover letter dated July 19, 1999, Basic Formulation CSF dated July 19, 1999, **AMS 1860** product label dated 07/20/99, Product Chemistry Guidelines: Product Identity and Composition 61-1, 61-2, 61-3; Analysis and Certification of Ingredients 62-1, 62-2; Physical and Chemical Chracteristics 63-2, 63-3, 63-4, 63-7, 63-12, 63-15, 63-18, Boiling Point/ Boiling Range 63-6 (OPPTS GRN 830.7220) and Stability to Normal and Elevated Temperatures, Metals, and Metal Ions 63-13 (OPPTS GRN 830.6313). Also referred to were file jackets # 64881-5 for AEM 5772 Antimicrobial MUP and # 70871-RE for BioSchield's pending **AMS 1860** file.

FINDINGS:

1. In review of the Basic Formulation CSF and the Product Chemistry addressing product identity and composition, the following questions and clarifications are needed:

a.In the CSF and manufacturing description, [redacted]

Manufacturing process information not included.

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b. In CSF and SciReg Product Chemistry Study, the" [redacted] is interchangeably referred to as [redacted]

c. Similarly in the CSF, [redacted] is identified as a starting material and in the finished product as an impurity. More accurately, it is excess or unreacted starting material which should be termed as an intentionally added impurity.

e. Manufacturing process description only peripherally discusses the starting materials and the chemistry of the reaction in forming the active ingredient, TPOA. Detail is also lacking to better understand the kinetics of the reaction in forming TPOA and the impurities formed as a result of the reaction. Impurities introduced via the starting materials will also need to be identified and quantified. All impurities present at a 0.1% or greater must be disclosed.

2. Data presented in the Product Chemistry Data Package does support a 72% nominal concentration for TPOA shown in the CSF and declared on the product label. Per analytical data provided, the expected concentration or nominal concentration of the active ingredient, 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride or TPOA, is 70.8% or 71%.

3. Registrant's certified limits for the active ingredient and impurities (other ingredients) are significantly wider than those suggested in the EPA guidelines for Certified Limits, CFR 40 158.175. Registrant should provide an explanation and data in support of the upper and lower limits given in the Basic Formulation CSF.

4. Review of the following Study Titles showed them to be satisfactory and complete, adhering to GLP's and OPPTS Test Guidelines: Stability to Normal and Elevated Temperatures, Metals, and Metal Ions; Boiling Point/Boiling Range; Preliminary Analysis and Physical and Chemical Properties for Color, Physical State, Odor, Flammability, Density, Viscosity, pH were also acceptable .

RECOMMENDATIONS:

This application for a new product registration is not acceptable. Registrant must provide supplemental information detailing the chemistry in the formation of the active ingredient and all impurities present in the finished product. An explanation and supporting data as to the use of a 72% nominal concentration for TPOA in the CSF is also requested. Additionally, registrant should provide basis for the upper and lower limits utilized.

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