UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

February 28, 2003

SUBJECT: PRODUCT CHEMISTRY AND ACUTE TOXICITY REVIEW OF: AM-7 Antimicrobial

DP Barcode: D287377 and D287378 **Reg. No. Or File Symbol: 48737-R**
Manufacturing-use [] OR **End-use Product [X]**

TO: Velma Noble/Tracy Lantz
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THRU: Karen P. Hicks, CTT Team Leader
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3/4/03

THRU: Michele Wingfield, Branch Chief
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Manufacturing process information not included.

BACKGROUND:

The registrant has submitted separate packages for chemistry and acute toxicity in support of a new registration of an end-use product to be used as an industrial bacteriostat, fungistat, and preservative. The chemistry package contains Confidential Statement of Formulas for the manufacturing-use product and the end-use product, a label, and studies that have been submitted to and identified by the Agency as MRID's 45810101 and 45810102 which address Series 830 Group A and B data requirements. The acute toxicity package contains an acute eye irritation study and has been identified as MRID 45810103.

FINDINGS:

1. [redacted] However, the CSF for the end-use product states that the active ingredient is octadecylaminodimethyltrihydroxysilyl propyl ammonium chloride.

2. [redacted]

3. [redacted] The company needs to clarify the active ingredient.

4. [redacted]

5. The company has selected the cite-all method for support of the acute toxicity requirements. The company also has submitted an acute eye irritation study to fulfill the guideline 870.2400. The company cannot cite any data because this formulation contains a new active ingredient.

6. No further review of chemistry or acute toxicity will be conducted because the formulation may change.

CONCLUSIONS:

1. Product Science Branch has reviewed the submissions for chemistry and acute toxicity and concludes that the registrant has a formulation with a new active ingredient.