

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



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

August 14, 2003

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF:  
SIS AM500**

**DP Barcode: 292204**  
**Manufacturing-use [ ] OR**  
**Action Code: 186**

**Reg. No.: 75174-E**  
**End-use Product [X]**  
**AD Due Date: 10/22/03**

**TO:** Velma Noble  
PM Team 31

**FROM:** Bipin C. Gandhi, Chemist  
Product Science Branch, CT Team  
Antimicrobials Division (7510C)

*B. C. Gandhi*  
8/16/03

**THRU:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
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8/21/03

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

**Product Formulation**

**Active Ingredient(s)** 3-(trimethoxysilyl) propyldimethyl octadecyl  
ammonium chloride 5.0% by wt.

**BACKGROUND:** This is an end-use new submission.

Manufacturing process information not included.

**FINDINGS:**

1. This product is an end-use product and it is formulated from 75174-R. Therefore, this product can not be reviewed until and unless all the deficiencies for 75174-R are cleared and it is registered.
2. Registrant has reported on CSF block 13a the amount of [REDACTED] and also for its alternate [REDACTED]. This is not correct, either remove one of the numbers or add parenthesis for one of them to correctly add to [REDACTED] for block 17 of CSF.
3. The pH range of 5-6 is reported under block 8 of CSF. However, under data matrix the pH is reported as 6.5 and 4.3 ( two different pH on two different data matrix sheets). Make all necessary corrections.
4. Please report the density in lbs/gal. in the column 8 of CSF.
5. The analysis of 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride under Table 1 and 2 for SiS AM 500 ( I assume SiS AM 500 is same as SiS AM 5001) is between 4.88 to 4.99. However, the label claim is 5.00. Make necessary adjustments in formulations.

**RECOMMENDATIONS:**

1. The Agency can not approve this submission until the technical product 75174-R is registered and all other discrepancies as reported under findings are corrected and submitted.

Reg. No 75174-G

MRID Reviewed: 460230-01, -02, and -03.