

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
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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.