

US EPA ARCHIVE DOCUMENT

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



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

04/13/06

DP BARCODE: D327271

MRID : N/A

SUBJECT: SIS 7200

REG. NO. OR FILE SYMBOL: 75174-U

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use OR End-use Product

INGREDIENTS (PC Codes): 107401 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride

CAS Number: 27668-52-6

TEST LAB: N/A

SUBMITTER: SiShield Technologies, Inc.

GUIDELINE: 830.6317, 830.6320, & 830.1800

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón ORGANIZATION: AD

APPROVER: Karen P. Hicks APPROVED DATE: 4/17/06

COMMENT: See Product Chemistry Review, dated 04/13/06.

TO: Velma Noble / Tracy Lantz
PM Team 31

FROM: Juan F. Negrón, Chemist *JFN*
Product Science Branch, CT Team
Antimicrobial Division (7510C)

THRU:: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobial Division (7510C) *KPH*

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

4/17/06

APPLICANT: SiShield Technologies, Inc.

Action code: A53
Due date: 06/02/06

Product Formulation
Active Ingredient(s)

	% by wt.
3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride	72.0

BACKGROUND:

The registrant, SiShield Technologies, Inc., is submitting a new registration data package for review. The integrated manufacturing-use product, **SIS 7200**, can be used as a preservative to control growth of odor causing bacteria, mold, mildew, and algae.

FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
 - Confidential Statements of Formula, dated 10/31/05, 02/15/06, & 03/01/06, for the basic formulation.
 - Letters, dated 02/15/06, & 02/21/06.
 - A label, undated.
 - Application for pesticide, dated 10/31/05. EPA Form 8570-1.
 - Certificate of analysis, dated 05/11/04.
 - Storage Stability and Corrosion Characteristic studies. (Via email, dated 03/10/06).
2. The CSF, dated 10/31/05, & 02/15/06, for the basic formulation is obsolete.
3. The CSF, dated 03/01/06, for the basic formulation is revised.
4. The CSF and the label have the same nominal.
5. The pre-reaction CSF, dated 02/15/06 is acceptable. However, the post-reaction CSF, dated 02/15/06 is obsolete.
6. The product contains an unregistered active ingredient (AI).
7. All inerts have clearance for inert use. *Inert ingredient information not included.*
8. The registrant submitted a certificate of analysis for the raw material active ingredient (AI). The results are based on amine since the method that the laboratory used was designed for amine.
9. The registrant did not include an alternate solvent, [REDACTED] due to the toxicity profile. This means that the registrant cannot use the [REDACTED] in this product.
10. The 830.6317 Corrosion Characteristics study conducted from 05/13/04 to 03/09/06 shows no evidence of deterioration or any signs of corrosion to a five-gallon pails and 55-gallon drums. The product is packaged and marketed in 5-gallon pails and a 55-gallon drum that consists of a heavy-duty type-high density plastic 40BH with tubular rubber gaskets (type 40CR or 40CT). For more information, see study mentioned above.
11. The storage stability shows that the certified limits for the AI meets the EPA standard certified limits.
12. The registrant indicates that the preliminary analysis study in volume 3 of 75174-U submission can be used as the 830.1800 Enforcement Analytical Method. See statement, dated 03/08/06 email.

CONCLUSION:

The pre-reaction CSF, dated 02/15/06, for the basic formulation is acceptable. The post-reaction CSF, dated 03/01/06, for the basic formulation is acceptable. The certificate of analysis is acceptable. The Storage Stability and Corrosion Characteristic studies are acceptable.