

US EPA ARCHIVE DOCUMENT

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



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

01/27/06

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: **SiShield Technologies Inc.**
DP Barcode: D324179
Reg. No. or File Symbol 75174-U

TGAI/Manufacturing-use Product **OR** **End-use Product**

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PM Team 31

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THRU:: Karen P. Hicks, CT Team Leader
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Antimicrobial Division (7510C) *2/1/06*

APPLICANT: SiShield Technologies, Inc.

Action code: A53
Due date: 02/21/06

Product Formulation
Active Ingredient(s)

3-(trimethoxysilyl) propyldimethyl octadecyl
ammonium chloride

% by wt.

72.0

BACKGROUND:

The registrant, SiShield Technologies, Inc., is submitting a new registration data package for review. The integrated manufacturing-use product, **SiShield Technologies Inc.**, 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 Statement of Formula, dated 10/31/05, for the basic formulation.
 - A letter, dated 10/31/05 MRID # 466829-00.
 - A label, undated.
 - Application for pesticide, dated 10/31/05. EPA Form 8570-1.
 - Self-certification statement for the physical/chemical properties (PR NOTICE 98-1), dated 10/31/05. EPA Form 8570-37.
 - Summary of the physical/chemical properties)PR Notice 98-1), dated 10/31/05. EPA Form 8570-36.
 - MSDS for SiShield SiS 7200, dated 10/07/05.
 - A Me-too label, BSTI 1860, dated 05/30/02.
 - A study title "SiS 7200: Product Identity and Disclosure of Ingredients Description of the Beginning Materials and Manufacturing Process, and Discussion of the formation of Impurities." Volume 2 of 4. MRID #466829-01.
 - A study title "Preliminary Analysis of Chemical Composition." MRID # 466829-02.
 - A study title "SiS 7200 Certified Limits." MRID # 466829-03.
2. The CSF, dated 10/31/05, for the basic formulation is revised.
3. The CSF and the label do not have the same nominal.
4. The CSF has a pre-reaction and a post-reaction. However, neither CSFs are identified as such.
- 5. The product contains an unregistered active ingredient (AI).
6. All inerts have clearance for inert use.
7. The percentage by weight and the certified limits need to be revised for all components. The certified limits do not harmonize with the EPA standard certified limits.
8. The CSF shows two inerts that are intentionally added as impurities. The impurities show values for the lower certified limit. One impurity shows a percentage by weight of [REDACTED] and the second impurity shows a percentage by weight of [REDACTED]

Manufacturing process information not included.

Manufacturing process information not included.

Inert ingredient information not included.

9. The registrant is using an alternate solvent, [REDACTED]. However, the solvent is not reflected in the CSF formulation. The solvent is cleared for inert use. See page 11 of 43 from MRID #466829-01.
10. The registrant does not indicate that the AI yields 100% after the chemical reaction. See page 12 of 43 from the MRID #466829-01. Furthermore, on page 7 of 20 from the MRID #466829-02, it is indicated that the AI concentration is found to be in a range of 71 – 73.6% from six lots. The assay does not indicate if it has been done for the pre-reaction or for the post-reaction.
11. The registrant indicates in the preliminary analysis that when using [REDACTED] as a solvent the AI yields 73.2% average. However, when using [REDACTED] as a solvent the AI yields 71.9% average. See MRID #466829-02, page 10 of 20.
12. The registrant has indicated (in MRID # 466829-01 & 03) that the information was not required under the GLP guidelines.
13. The phone number on the CSF is a voice mail for the registrant employees.

RECOMMENDATION:

1. The registrant should indicate on the CSFs the pre-reaction and the post-reaction.
2. The registrant should change the percentage by weight and the certified limits as follows:

Components	Percentage		Upper limit		Lower limit	
	by weight		%		%	
	from	to	from	to	from	to
AI	73.2	72.0	75.4	74.2	71.0	69.8

3. [REDACTED] should not be declared as impurities. These components are over 0.1% by weight in the formula.
4. The registrant should include the alternate solvent, [REDACTED] in the CSF formulation.
5. The registrant should indicate the purity of the AI in column 10 of the post-reaction CSF.
6. The registrant needs to submit a certificate of analysis of the final product.

7. The registrant needs to update the statement in MRID # 466829-01 & 03 documents, since the information provided indicated that both documents meets the GLP guideline. Furthermore, all 830 guidelines should be conducted under GLP.
8. The registrant should indicate in box 20 of the CSF the phone number that can be reached.

CONCLUSION:

The CSF, dated 10/31/05, for the basic formulation is not acceptable. The registrant must comply with the requirements, recommendations and findings listed above. Please see Product Chemistry Reviewer Table below for deficiencies found in the documents.

PRODUCT CHEMISTRY REVIEW

11. **CONFIDENTIAL STATEMENT OF FORMULA**

11a. Type of formulation and source registration

- Non-integrated formulation system
- Are all TGAI used registered? Yes No NA

- Integrated formulation system

- if "ME-TOO," specify EPA Reg. # of existing product: 70871-12 transfer to 75497-6.

11b. Clearance of inerts for non-food or food use:

Cleared for food use under 40 CFR §180.1001: Yes No NA

11c. Physical state of the product: semi solid.

11d. The chemical IDs and analytical information (including that for the TGAI), density, pH, and flammability are consistent with that given in 830.1000, Series A and 830.7300, .7000 and .6315 respectively: Yes No

11h. NCs and CLs are: acceptable Not acceptable

11i. Active ingredient (s) NC UCL LCL

A. 3-(trimethoxysilyl) propyldimethyl octadecyl ammonium chloride 73.2 75.4 71.0

These values do not harmonize with the following: the label, & the EPA standard certified limits.

11j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
Yes No Not applicable

- All impurities of $\geq 0.1\%$ in the product have been identified?
Yes No Not applicable

12. PRODUCT LABEL

12a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes No

12b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes No
- 1.0% or more of methyl alcohol: Yes No
- Sodium nitrite at any level: Yes No
- a toxic List 1 inert at any level: Yes No
- arsenic in any form: Yes No

12c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes No Not applicable

12d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes No Not applicable

12e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? PR Notice 84-1 Yes No Not applicable
PR Notice 83-3 Yes No Not applicable

12f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
Yes No Pending

13a.

PRODUCT CHEMISTRY (Series 830 Part A)

	Acceptance of Information	MRID No.
830.1550 Chemical ID (See Appendix)	U	466829-01
830.1600 Description of Materials	U	466829-01
830.1620 Description of Production Process ²	U	466829-01
830.1650 Description of Formulation Process	U	466829-01
830.1670 Discussion of Impurities	U	466829-01
830.1700 Analysis ⁵	A	466829-02
830.1750 Certified Limits	N	466829-03
830.1800 Analytical Method for AIs	G	

no GLP req.

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required,

G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLS recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR),

Physical and Chemical Characteristics (Series 830, Pair)

13b. Physical/Chemical Properties	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	Light brown	
830.6303 Physical State	A	Semi solid	
830.6304 Odor	A	Silane odor	
830.6313 Stability to normal & elevated temp., metals, & metal ions	NA		
830.6314 Oxidation/Reduction: chemical incompatibility.	A	No oxidizing agents	
830.6315 Flammability/Flash Pt	A	Flashpoint 44 °C	
830.6316 Explodability	A	Not explosive	
830.6317 Storage stability ¹	A	U	
830.6319 Miscibility	A	Not to be diluted with petroleum solvents	
830.6320 Corrosion characteristics ¹	A	U	
830.6321 Dielectric breakdown voltage	A	Not to be used around electrical equipment.	
830.7000 pH	A	4.7 (5% aqueous)	
830.7050 UV/Visible absorption	NA		
830.7100 Viscosity	A	11.2 cps @ 25°C	
830.7200 Melting point/melting range	NA		
830.7220 Boiling point/ boiling range	NA		
830.7300 Density/sp. gravity	A	8.03 WPG @ 25°C	
830.7370 Dissociation constants in water	NA		
830.7520 Particle size, fiber length, & diameter distribution	NA		
830.7550 Partition coefficient(n-octanol/water), shake flask method	NA		
830.7560 Partition coefficient(n-octanol/water), generator column method	NA		
830.7570 Partition coefficient(n-octanol/water),	NA		
830.7840 Water solubility: Column elution method; shake flask method	NA		
830.7860 Water solubility, generator column method	NA		
830.7950 Vapor pressure	NA		

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable. ¹= Registrant must perform one year study. U=requires upgrading.