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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Date Completed: Nov. 28, 1997

SUBJECT: PRODUCT CHEMISTRY REVIEW OF END-USE PRODUCT
BST PROTECTANT 50

To: Velma Noble, Product Manager, Team 31
Regulatory Management Branch I
Antimicrobials Division (7510W)

From: A. Najm Shamim, Chemist A Shamim
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Thru: Laura Morris, Team Leader, Team-3 for 12/22/97
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DP BARCODE No:	D239763
SUBMISSION No:	S531440
REG/FILE SYMBOL:	70871
CASE/TYPE:	061998/REGISTRATION
CASNo:	27668-52-6
EPA MRID Nos:	443762-01, 443762,02 443762-03

CHEMICAL NAME: 3-(TRIMETHOXYSILYL)PROPYL DIMETHYL OCTADECYL AMMONIUM CHLORIDE (0.500%)

CLASS OF COMPOUND: QUAT

DATA SUBMITTER:070871: BIOSHIELD TECHNOLOGIES, INC.

EPA RECEIVED DATE: 09/15/97

Please find the Product Chemistry Review of BST PROTECTANT 50

INTRODUCTION:

The submission by the applicant includes: product chemistry data, product 's CSF about the basic formulation dated 09/19/97and a label (EPA received date: 09/15/97).The applicant seeks registration for the end-use product (EP) under FIFRA Section 3.

FINDINGS:

1. The source AI is not registered; however, data on AI was submitted 5/14/97.

2. The CAS # of the AI was incorrectly reported as 27668-52-0; the correct CAS # is :27668-52-6.

3. The product is formed by a non-integrated formulation system: no chemical reaction was reported to have taken place, as claimed by the applicant.

✓4. The submitted product chemistry data ia adequate and support the registration requirments for this product.

5. Analytical Method for Enforcement of Limits of the AI (Springborn Laboratories Protocol # 102196/830:6317/Bioshield) were included with the submission; it was reviewed and found adequate. MRID#: 443762-02

6. The ingredient statement, the physical/chemical hazard statement and the storage and disposal statement cited on product label, EPA received 9/15/97, satisfy 40 CFR §156.10.

✓7. The submitted product's CSF's basic formulation dated 9/12/97 are adequate and satisy the requirement of PR-Nitice 91-2 on nominal concentrations.

8. Description of Formulation Process were included in the submission: MRID#: 443762-01

9. Product chemistry data were included in the submission and were found adequate in support of registration of this end-use product. MRID#: 443762-03

CONCLUSIONS:

1. Pending registration of the AI { 3-(trimethoxy silyl)propyl dimethyl octadecyl ammonium chloride}, we will have no objection to register this product.

✓2. The applicant has satisfied the product chemistry for a Section 3 FIFRA registration

DETAILED CONSIDERATIONS

REVIEW OF PRODUCT CHEMISTRY DATA:

Group A: Series 830-Product Identity, Composition and Analysis.

(40 CFR 155, 160, 162, 167, 175 and 180)

830-1550 (61-1). Product Identity & Disclosure of Ingredients: MRID#: 443762-01

This product was formulated using non-registered technical grade of active ingredient with no intended chemical reaction, a process also known as non-integrated formulation system.. No reaction or production of new ingredients was reported by the applicant. Data on the TGAI was recently submitted (5/15/97) and is under review.

830-1600 (61-2a) Description of Materials Used to Produce the Product:MRID#: 443762-01

Refer to Confidential Appendix A

830-1650 (61-2b) Description of Formulation Process:MRID#: 443762-01

Refer to Confidential Appendix A

830-1670 (61-3) Discussion of Formation of Impurities:MRID#: 443762-01
Refer to Confidential Appendix A

830-1700 (62-1) Preliminary Analysis:

Refer to Confidential Appendix A

830-1750 (62-2) Certified Limits:

Refer to Confidential Appendix A

830-1800 (62-3) Enforcement Analytical Method: MRID#: 443762-02

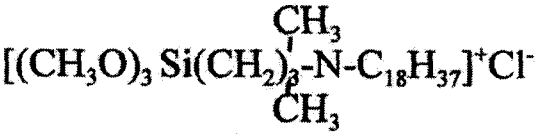
The enforcement method, developed at Springborn Laboratories: protocol #: 102196/830.6317/Bioshield, can be used to analyze Quaternary Ammonium Chloride(QUAT) for the TGAI in the technical or formulated product between 50 ppm to 100% concentrations without differentiation of chain length distribution.

Group B: Series 830-Physical and Chemical Properties (40CFR § 158.190):MRID#:443762-03

GUIDELINE REFERENCE #/TITLE		VALUE OR QUALITATIVE DESCRIPTION/ METHOD(s) USED WHERE APPLICABLE AND REFERENCES
-6302	Color	Colorless
-6303	Physical State	Liquid
-6304	Odor	Odorless
-6314	Oxidation/Reduction Incompatibility	No oxidizing or reducing potential exists

-6315	Flammability/Flame Extension	N/A
-6316	Explodibility	Does not contain explosive materials
-6317	Storage Stability	N/A
-6319	Miscibility	N/A
-6320	Corrosion Characteristics	Non-Corrosive to the containers
-6321	Dielectric Breakdown Voltage N/A	
-63-7000	pH	5.28
-63-7100	Viscosity	<85.5 mPa.s
-63-7300	Density/Rel. Density/ Bulk Density	0.984 g/ml

Structure:



~~CONFIDENTIAL APPENDIX A~~

830-1600(61-2a) Description of Materials Used to Produce the Product:

The raw materials are listed on Product's CSF

830-1600(62-2b) Description of Formulation Process:

The product is formulated by mixing the raw materials with no intended chemical reactions (it is a non-integrated system)

830-1670(61-3) Discussion of Formation of Impurities

The applicants claim that no impurities ≥ 0.10% by weight were known to form during formulation or storage as no chemical reaction takes place.

830-1700 (62-1) Preliminary Analysis:

Not applicable for non-integrated systems.

830-1750 (62-2) Certified Limits:

The applicant reported that certified limits of the active and the inert were established according to the standard limits required by 40 CFR § 158.175(b)(2). THE LIMITS ARE INDICATED ON PRODUCT'S CSF.

(NShamim:7510W:AD:RASSB:CS-1:Cubicle:3W71:12/02/97:703-308-9445:<70871-U)

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