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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
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From: A. Najm Shamim, Chemist *A. Shamim*
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Thru: Laura Morris, Team Leader, Team-3 *Hand for 12/22/97*
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DP BARCODE No: D239763

SUBMISSION No: S531440

REG/FILE SYMBOL: 70871

CASE/TYPE: 061998/REGISTRATION

CAS No: 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 09/19/97 and 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 is adequate and support the registration requirements 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 satisfy 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.

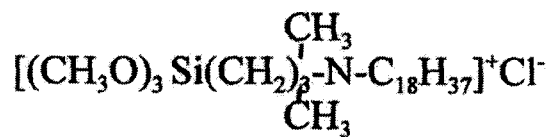
Group B: Series 830-Physical and Chemical Properties (40CFR § 158.190):MRID#:443762-03

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	Explosibility	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)
the Product:

Description of Materials Used to Produce

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 $\geq 0.10\%$ 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.