

(6-11-97)

SUBJECT: **PRODUCT CHEMISTRY REVIEW - Antimicrobial Division**
DP Barcode 7236247 **Reg. No. or File Symbol** 70871-E
Manufacturing-Use [☒] **OR End-Use Product** []

TO: 31 Walker Francis
PM Team No. Barbara Pringle

FROM: Anna Skapars, Chemist
Risk Assessment and Science Support Branch

THRU: Norman Cook, Chief
Risk Assessment and Science Support Branch

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

This application is for registration of new manufacturing use product.
Submitted are three Confidential Statements of Formulae one basic and two alternate Formulations.

Registrant should note that for manufacturing use products alternate formulations are not acceptable. Manufacturing use products may have alternate sources of supply for inert ingredients. Since the only change in each product is different [redacted] than all three [redacted] may be as alternate [redacted] only one Confidential Formula.

Registrant should submit revised Confidential Statement of Formulae and list all three [redacted] as an alternate sources.

In block 7 enter the pounds per gallon or bulk density

Provided product chemistry data in MRID Nos 442794-01, 442794-02, 442794-03 and 442794-04 provides data for Guideline Suris 61, 62 and 63. This data is in compliance with 40 CFR part 158.155-158.190 and it satisfies product chemistry data requirement except for Guideline Ref No. 62-1 - preliminary analysis

- 62-2 - certification of the ingredient limits
- 62-3 - analytical methods to verify certified limits
- 63-17 - storage and stability data

These data will be submitted when complete.
Anna Skapars
6-11-97

Inert ingredient information not included.

PRODUCT CHEMISTRY REVIEW

END-USE PRODUCT ☐ MANUFACTURING-USE PRODUCT ☒
EPA Reg. No. (or File Symbol No.) 70871-E

Registration ☒

Reregistration ☐
Case No.: _____

DP Barcode/Chemist: *Anna Skapars*

1) _____ 3) _____

2) _____ 4) _____

1. Product Name: *BioShield AM 500 I*

2. Company: _____

3. Type of Submission: New ☒ Resubmission ☐ Amendment ☐
"ME-TOO" ☐ Alternate Formulation ☐ REPACK ☐
Expt Use Permit ☐ Other (Specify) _____

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system
• Are all TGAIs used registered • yes ☒ • no ☒
- Integrated formulation system ☐
- If "ME-TOO", specify EPA Reg. No. of existing product: _____

4b. Clearance of inerts for non-food or food use:

Cleared for food use under 40CFR§180.1001:

- yes ☐ • no ☐ If yes: • c ☐ • d ☐ • e ☐
Cleared for non-food use: • yes ☒ • no ☐

4c. Physical state of product: *viscous liquid*

4d. The chemical IDs, analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in GRN 61, 62, and 63-7, 63-12, and 63-15, respectively. • yes ☒ • no ☐

- 4e. Density (or bulk density for solids): at $\cdot$ C. 0.9997 g/ml
at 20°C
- 4f. pH (if dissolved or dispersed in water): 4.8 (5 part/100 (w/w) in water)
- 4g. Flash point and/or flame extension: N/A
- 4h. NCs and CLs are acceptable: $\cdot$ [✓] $\cdot$ not acceptable []
- 4i. Active ingredient(s) NC- LCL UCL
- A. 3-(trimethoxysilyl) propyl dimethyl
- B. Octadecyl ammonium chloride 5.0% 4.75% 5.25%
- C.
- D.
- 4j. For products produced by an integrated formulation system:
- $\cdot$ All impurities of toxicological significance have an UCL: $\cdot$ yes [] $\cdot$ no [] $\cdot$ not applicable [✓]
 - $\cdot$ All impurities $\geq 0.1\%$ in the product have been identified: $\cdot$ yes [] $\cdot$ no [] $\cdot$ not applicable [✓]

5. PRODUCT LABEL

- 5a. The active ingredients statement (chemical IDs and NCs) is consistent with the CSF: $\cdot$ yes [✓] $\cdot$ no []
- 5b. The formulation contains one of the following:
- $\cdot$ 10% or more of a petroleum distillate: $\cdot$ yes [] $\cdot$ no [✓]
 - $\cdot$ 1% or more of methyl alcohol: $\cdot$ yes [] $\cdot$ no [✓]
 - $\cdot$ sodium nitrite at any level: $\cdot$ yes [] $\cdot$ no [✓]
 - $\cdot$ a toxic List 1 inert at any level: $\cdot$ yes [] $\cdot$ no [✓]
 - $\cdot$ arsenic in any form: $\cdot$ yes [] $\cdot$ no [✓]
- 5c. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this?
 $\cdot$ yes [] $\cdot$ no [] $\cdot$ not applicable [✓]
- 5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label:
 $\cdot$ yes [✓] $\cdot$ no [] $\cdot$ not applicable []

5e. 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: • yes [☒] • no []

6f. 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 [☒]

6. PRODUCT CHEMISTRY (GRN 61, 62, 63)

6a. <u>Chemical IDs/Manufacture/Analytical Information</u>	<u>Accept of Information</u>	<u>MRID No.</u>
61-1 Chemical ID (see Appendix) ¹	A	442794-02
61-2a Manufacturing Process ²	A	442794-02
61-2b Formulation Method ³	A	442794-02
61-3 Discussion of Impurities ⁴	A	442794-03
62-1 Analysis ⁵	will be submitted	
62-2 Certified Limits ⁶	A	CSF
62-3 Analytical Method for AIs ⁷	will be submitted	

PRODUCT NAME: BioShield AM 500 I		EPA REG. NO. OR FILE SYMBOL: 7 0871-E		FORMULATOR EXEMPTION ASSERTED: Yes													
APPLICANT'S NAME AND ADDRESS: BioShield Technologies, Inc. 4405 International Blvd., Suite B109, Norcross, GA 30093		APPLICATION DATE: May 14, 1997		NAME OF ACTIVE INGREDIENT: 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride													
DATA REQUIREMENTS		SOURCE OF DATA SATISFYING REQUIREMENT						MRID NUMBER EPA ACCESSION NUMBER, OR OTHER EPA IDENTIFYING NUMBER									
Regulation Part 158/ Guideline Number	Name of Test	Submitted by Applicant	Date Submitted	Submitted by another person/firm (name)	Permission letter enclosed	Public literature	N.A. or waiver or other (explain)										
63-11	Octanol/Water Partition Coefficient						n/a										
63-12	pH	x	05/14/97														
63-13	Stability						n/a										
63-14	Oxidizing or Reducing Action						n/a										
63-15	Flammability						n/a										
63-16	Explosibility						n/a										
63-17	Storage Stability						being conducted										
63-18	Viscosity	x	05/14/97														
63-19	Miscibility						n/a										
63-20	Corrosion Characteristics						n/a										
63-21	Dielectric Breakdown Voltage						n/a										
81-1	Oral LD ₅₀ - Rat	x	05/14/97				Waiver										
81-2	Dermal LD ₅₀ -Rabbit	x	05/14/97				Waiver										
81-3	Inhalation LC ₅₀ - Rat	x	05/14/97				Waiver										

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Regulation Part 158/ Guideline Number	Name of Test	Submitted by Applicant	Date Submitted	Submitted by another person/firm (name)	Permission letter enclosed	Public literature	N.A. or waiver or other (explain)									
81-4	Primary Eye Irritation - Rabbit	x	05/14/97				Waiver									
81-5	Primary Dermal Irritation - Rabbit	x	05/14/97				Waiver									
81-6	Dermal Sensitization - Guinea Pig	x	05/14/97				Waiver									