

US EPA ARCHIVE DOCUMENT

(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 Walter 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                      than all three                      may be as alternate                      only one Confidential Formula.

Registrant should submit revised Confidential Statement of Formulae and list all three                      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 Subs 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.

(1)

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  $^{\circ}\text{C. } 0.9997 \text{ g/ml}$   
 at  $20^{\circ}\text{C}$
- 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:  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:
- All impurities of toxicological significance have an UCL:  yes  no  not applicable
  - All impurities  $\geq 0.1\%$  in the product have been identified:  yes  no  not applicable

## 5. PRODUCT LABEL

- 5a. The active ingredients statement (chemical IDs and NCs) is consistent with the CSF:  yes  no
- 5b. The formulation contains one of the following:
- 10% or more of a petroleum distillate:  yes  no
  - 1% 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
- 5c. If yes to any of the above, does the inert ingredients statement contain a footnote indicating this?  
 yes  no  not applicable
- 5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label:  
 yes  no  not applicable



<b>PRODUCT NAME:</b> BioShield AM 500 I		<b>EPA REG. NO. OR FILE SYMBOL:</b> 70871-E			<b>FORMULATOR EXEMPTION ASSERTED:</b> Yes								
<b>APPLICANT'S NAME AND ADDRESS:</b> BioShield Technologies, Inc. 4405 International Blvd., Suite B109, Norcross, GA 30093		<b>APPLICATION DATE:</b> May 14, 1997			<b>NAME OF ACTIVE INGREDIENT:</b> 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride								
<b>DATA REQUIREMENTS</b>		<b>SOURCE OF DATA SATISFYING REQUIREMENT</b>					<b>MRID NUMBER EPA ACCESSION NUMBER, OR OTHER EPA IDENTIFYING NUMBER</b>						
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 <sub>50</sub> - Rat	x	05/14/97				Waiver						
81-2	Dermal LD <sub>50</sub> -Rabbit	x	05/14/97				Waiver						
81-3	Inhalation LC <sub>50</sub> - Rat	x	05/14/97				Waiver						

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<b>Regulation Part 158/ Guideline Number</b>	<b>Name of Test</b>	<b>Submitted by Applicant</b>	<b>Date Submitted</b>	<b>Submitted by another person/firm (name)</b>	<b>Permission letter enclosed</b>	<b>Public literature</b>	<b>N.A. or waiver or other (explain)</b>						
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						