

(2-5-98)

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobial Division
DP Barcode D240665 Reg. No. or File Symbol 70871-R
Manufacturing-Use ☒ OR End-Use Product ☐

TO: Velma Noble / Barbara Pringle
PM Team No. 31

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 a new product for manufacturing use as an antimicrobial agent and protectant.

Confidential Statement of Formula dated 10-15-97, which was registered source for the active ingredient, this CSF is in compliance with PR Notice 91-2, it agrees with the label and is acceptable.

The other Confidential Statement of Formula dated 8-15-97, which was an unregistered source for the active ingredient, is not acceptable.

Using unregistered source complete chemical identity must be listed in the CSF including chemical name and the amount of each ingredient in unregistered source.

Provided product chemistry data in MRID Nos 442794-01, 442794-02, 442794-03 and 442794-04 provides data for Guideline Serial Nos 61, 62 and 63 and it satisfies product chemistry data for this product except for
Guideline Ref No. 63-3 - analytical method to verify certified limits for active ingredient and
63-20 - corrosion characteristics.

Note to PM:

Is claim "Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning,"

is this claim acceptable

Also: "Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde"

"Product performance with little degradation up to 37.5°F."

Anna Skapars
2-5-98

PRODUCT CHEMISTRY REVIEW

END-USE PRODUCT ☐ **MANUFACTURING-USE PRODUCT** ☒
EPA Reg. No. (or File Symbol No.) 10871-R

Registration ☒

Reregistration ☐
Case No.: _____

D240665

DP Barcode/Chemist: Anna Skapars

1)

3)

2)

4)

1. Product Name: Bio Shield AM 500

2. Company: BioShield Technologies, Inc.

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 ☐

- 3
- 4e. Density (or bulk density for solids): at °C.
- 4f. pH (if dissolved or dispersed in water): 0.9997 g/ml at 20°C
- 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) propyldimethyloctadecyl
- B. Ammonium chloride 5.0% 4.6% 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 ≥ 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 contains 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 ☐

- 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	N/A	
62-2 Certified Limits ⁶	A	CSF
62-3 Analytical Method for AIs ⁷		

6b. Physical/Chemical Properties	Accept of Data	Value or quality descrip	MRID No.
63-3 Physical State	A	viscous liquid	442794-04
63-7 Density/Bulk Density (g/cc)	A	0.9997 g/ml at 20°C	-
63-12 pH of product ⁹	A	5 ppm free H ₂ O/V 4.8 at 20°C	-
63-14 Oxid/Red Action			
67-15a Flash Point (°C) ¹⁰	A	167.5°C (CC)	
63-15b Flame Extension			
63-16 Explodability			
63-17 Storage Stability (% degradation of AIs at 20-30°C for ≥ 1 year)			
63-18 Viscosity	A	393 mPa.s 20°C 246 mPa.s 40°C	
63-19 Miscibility (with hydrocarbon solvents) ¹¹			
63-20 Corrosivity (specify metals/conditions)			
63-21 Dielectric Breakdown Voltage ¹²			

Explanations: A = Acceptable; N = not acceptable; NA = technically not applicable; G = data gap; U = requires upgrading; W = waived; E = EPA estimate.

Footnotes: ¹ See Confidential appendix A for additional information; ² For NP/EP products produced by an integrated formulation system; ³ For products produced from a TGA1 or NP; ⁴ May be waived unless actual/possible impurities are of tox concern; ⁵ Five batch analysis required for products produced by an integrated formulation system; ⁶ If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A; ⁷ Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc. ⁸ Provide brief description, e.g., color - yellow or property value, e.g. density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C; ⁹ If product is a water solution or dispersion; ¹⁰ Not required for aerosols; ¹¹ Emulsifiable liquids only; ¹² For end-use products used near electrical equipment.

Attachment: Confidential Appendix A (page 3).

cc: Reviewer's Name and Control File (Reg. No. or Boreg Case No.)

E7505V:ED:ESB:PCRS:CS-

1:XXXXX:Reviewer's Name:Typist Initials:XX/XX/94:703-308-XXXX:Code (Reg or Boreg No.)

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