

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division
DP Barcode D266605 Reg. No. or File Symbol 70871-RG
Manufacturing-Use [☒] or End-Use Product [☐] Case# _____

TO: Velma Noble/Tracy Lantz
PM Team No. 31

FROM: Anna Skapars, Chemist Anna Skapars 08-16-2000
Chemistry-Toxicology Team (CTT)
Efficacy and Science Support Branch (ESSB)

THRU: Karen P. Hicks, CT Team Leader
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Antimicrobials Division (7510C)

THRU: Michele E. Wingfield, Branch Chief
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Registrant is proposing to register new product for formulating disinfectants, sanitizers, antimicrobial agents, microbiostatic agents, fungistatic agents and deodorizers. Submission includes proposed label, CSF and product chemistry data in MRID Nos 451213-01 and 451213-02 and MSDS which include physical and chemical properties for the product.

Findings

Confidential Statement of Formula dated 5-8-2000 is in compliance with 40 CFR part 158.175 it agrees with the proposed label and CSF is acceptable. Certified limits for active and inert ingredients comply with 40 CFR part 158.175 and they are acceptable.

Provided product chemistry data in MRID Nos 451213-01 and 451213-02 provides data for Guideline Ref. Nos 830.1550, 830.1600, 830.1650, 830.1670, 830.1750, and 830.6317 and data matrix for physical and chemical properties in MSDS Sheet.

(See page 2)

(1)

Provided 12 month storage and stability data for Guideline Ref. No. 830.6317 (63-17) is in compliance with 40 CFR 158.190 and 40 CFR 160, in compliance with GLP. This data is adequate and satisfies 12 month storage and stability data for this product. All product chemistry data for this product is adequate.

In the proposed label pesticide disposal instructions should be

" Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. "

The net contents should be declared on the label or on the container.

PRODUCT CHEMISTRY REVIEW

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

Registration ☒

Reregistration ☐

Case No.: _____

DP Barcode/Chemist: D266605

- 1) _____ 3) _____
2) _____ 4) _____
1. Product Name: AM 3651 PI
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: 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 °C. 0.944 g/ml at 20°C
- 4f. pH (if dissolved or dispersed in water): 5-8
- 4g. Flash point and/or flame extension: 82.4°F
- 4h. NCs and CLs are acceptable: ☒ not acceptable ☐
- 4i. Active ingredient(s) NC LCL UCL
- | | | | |
|---|--------|--------|--------|
| A. 3(trimethoxysilyl)propyl dimethyloctadecyl ammonium chloride | 35.60% | 34.50% | 36.70% |
| B. Alkyl dimethyl benzyl ammonium chloride | 6.40 | 6.08 | 6.72 |
| C. Octyl decyl dimethyl ammonium chloride | 4.80 | 4.56 | 5.04 |
| D. Dioctyl dimethyl ammonium chloride | 1.92 | 1.82 | 2.02 |
| E. Didecyl dimethyl ammonium chloride | 2.88 | 2.70 | 3.02 |
- 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	CSF
61-2a Manufacturing Process ²	A	451213-01
61-2b Formulation Method ³	A	451213-01
61-3 Discussion of Impurities ⁴	A	451213-01
62-1 Analysis ⁵	N/A	
62-2 Certified Limits ⁶	A	CSF
62-3 Analytical Method for AIs ⁷	A	451213-02