

(12-30-99)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **BioShield BSTI 1860**

(Formerly known as BioShield AMS 1860)

DP Barcode: **D261410**

Reg. No. or File Symbol: **70871-RE**

Manufacturing-use [**X**]

End-use Product []

Active Ingredient Composition:

3-(Trimethoxysilyl) propyldimethyl

octadecyl ammonium chloride.....71.2%

TO: Velma Noble PM 31

FROM: Alex Traska, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510C)

At 12/29/99

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

Karen P. Hicks
12/30/99

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510 C)

BACKGROUND:

This re-submission of a new product registration , for the subject manufacturing-use microbiocide, was submitted by SciReg, Inc. on behalf of the registrant, BioShield Technologies, Inc.

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In this submission, the registrant has responded to comments made in an Agency letter dated 10/28/99. More specifically, registrant addressed all chemistry related comments made in the 9/30/99 Chemistry Review and which were cited in the Agency letter.

The following documents were submitted and examined in the chemistry review of this submission: agent's cover letter dated November 18, 1999, Basic Formulation CSF dated 11/17/99, Product Chemistry Data for Guidelines 61, 62 and 63 (MRID # 449724-01) and revised product label dated 11/18/99. Also examined in completing this review was jacket file # 70871-RE.

FINDINGS:

1. All of the deficiencies noted in the prior review have been adequately addressed. More specifically:

a. the requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredient given in the Basic Formulation CSF agreed with the percentage declared on the label. The CSF and label declaration for the active ingredient was changed from 72% to 71.2%.

b. all active and inert ingredients utilized in the formulation have been appropriately identified as to their functionality.

c. Upper and lower certified limits for both the active and inert ingredients are acceptable.

2. Product Chemistry Data package has been updated to reflect all needed corrections.

3. All other elements of the CSF were acceptable.

RECOMMENDATIONS:

This re-submission of a new product registration, covering **BioShield BSTI 1860**, is accepted.

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