



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **BioShield AM 3651PI**

DP Barcode: **D297616**
Manufacturing-use []

Reg. No. or File Symbol: **75497-7**
End-use Product [**X**]

Active Ingredient Composition:

- 3-(Trimethoxysilyl) propyldimethyl octadecyl ammonium chloride.....35.60%**
- n-Alkyl (50%C₁₄ , 40%C₁₂ , 10%C₁₆) dimethyl benzyl ammonium chloride.....6.40%**
- Octyl decyl dimethyl ammonium chloride.....4.80%**
- Diocyl dimethyl ammonium chloride.....1.92%**
- Didecyl dimethyl ammonium chloride.....2.88%**

TO: Velma Noble PM 31

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

At 1/29/04

THRU: Karen P. Hicks, CT Team Leader
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K.P. Hicks
1/29/04

THRU: Michele E. Wingfield, Chief
Product Science Branch
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BACKGROUND:

This re-submission, for the subject disinfectant, was made by the registrant,

Nova BioGenetics, Inc.

The registrant, in this re-submission, has provided an explanation in support of declaring "trimethoxysilyl" as the chemical component of the active ingredient as the product is packaged and sold. The Agency letter dated 5/7/03 and September 3, 2003 suggested a "trihydroxysilyl" component in the active ingredient. According to the registrant, the "trihydroxysilyl" component is formed and present only when water is added to **BioShield AM 3651PI** for use as an end-use disinfectant, as per label instructions.

Therefore, no label changes were made to the active ingredient declaration. The only change to the new label, was the company transfer of registration from BioShield Technologies, Inc. (company # 70871) to Nova BioGenetics Inc. (company # 75497).

The following documents were submitted and examined in the chemistry review of this submission: registrant's cover letter dated December 8, 2003, pesticide application covering this re-submission dated 12/8/03, Agency letter dated September 3, 2003, Basic CSF dated 2/28/01 and 8/6/01 and new product label dated 12/19/03.

FINDINGS:

1. The use of the active ingredient name, 3-(trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride, is accepted based on the supporting justification provided by the registrant. No hydrolysis occurs to form, 3-(trihydroxysilyl), until water is mixed with **BioShield AM 3651PI**, per label directions, in the end-use of this product.

This chemical name is also an acceptable synonym for N-Octadecyldimethyl {3-(trimethoxysilyl) propyl} ammonium chloride and other acceptable chemical name variations of this active ingredient.

2. It is suggested the Basic CSF for this product be updated to reflect the company registration transfer and other possible changes.

RECOMMENDATIONS:

This re-submission, which provided an updated product label and a justification as to the chemical identity of the active ingredient, 3-(trimethoxysilyl)

propyl dimethyl octadecyl ammonium chloride, in **BioShield AM 3651PI**, is accepted with comment.

Registrant, should at the next convenient time updated this product's Basic CSF, as noted under item #2 of the Findings.

01/29/04 AT