



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

9/2/97

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: BioShield AM 500 I, EPA File Symbol 70871-E
Data Package D236250

BioShield AM 500, EPA File Symbol 70871-R
Data Package D236249

From: Wallace Powell, Biologist *Wallace Powell*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510W)

Thru: *for* Laura E. Morris, Acting Team Leader *Allen W. Vaughan*
Risk Assessment and Science Support Branch *09/02/97*
Antimicrobials Division (7510W)

Norman Cook, Chief *mf Cook* *09/03/97*
Risk Assessment and Science Support Branch
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To: Velma Noble, Product Manager, Team 31
Barbara Pringle, Team Reviewer, Team 31
Registration Branch I
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BACKGROUND

The applicant, BioShield Technologies, Inc. (as represented by Jellinek, Schwartz & Connolly, Inc.), for registration of the two subject products has submitted a request for waivers of all product acute toxicity testing. These two products are identical in composition -- BioShield AM 500 (EPA File Symbol 70871-R) is a 100% repackaging of BioShield AM 500 I (EPA File Symbol 70871-E).



CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Product ingredient source information not included.
Inert ingredient information not included.

[REDACTED]

The applicant has cited several acute toxicity studies, submitted for the Dow Corning material during the years 1987 through 1994, claiming that EPA accepted these studies when it registered the Dow Corning product. (The studies with MRID Numbers 001285-46 through -49 appear to be the ones on which initial registration was based; the studies cited now by the applicant may or may not include re-submissions of those older studies.)

No Reregistration Eligibility Decision (RED) document has yet been issued for the active ingredient in these products, which is assigned to Reregistration Case 3148, Trimethoxysilyl Quats.

RECOMMENDATION

[REDACTED]

In BioShield AM 500 I is not expected to significantly alter the acute toxicity characteristics of the product.

[REDACTED]

However, it is recommended that this issue be attended to at the time of reregistration of the trimethoxysilyl quats, and that the precautionary statements proposed for the two BioShield products be accepted with the exception of the eye irritation human hazard statements mentioned above.

It is recommended that a primary eye irritation study (guidelines no. 81-4) be required for the BioShield material.

Inert ingredient information not included.

It is not clear that the BioShield material should be in Category I for eye irritation (note that the Material Safety Data Sheet for BioShield AM 500 I mentions that the material caused "slight" irritation in rabbits). No Toxicity Category for eye irritation can be assigned to these products since they represent a significant dilution of [REDACTED] To reflect the source material's Category I rating for eye irritation in the BioShield products may result in a significant overstatement of the hazard. It is recommended that the eye irritation study be required in the absence of any further information from the applicant.

Product ingredient source information not included.
