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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

11/23/99

MEMORANDUM

Subject: BST Protectant 75
EPA File Symbol 70871-L
Data Package D254692

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To: Velma Noble, Product Manager, Team 31
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BACKGROUND

The applicant, BioShield Technologies, Inc., as represented by an agent, has cited studies for acute inhalation toxicity, primary eye irritation, and primary dermal irritation, in response to the Agency's 01/13/98 letter. The studies were cited as part of a re-submission of the application for registration of BST Protectant 75. This product is a microbiostatic agent and protectant for use in or on surfaces, furnishings, laundry, and a variety of consumer goods. The active ingredient in the product is 3-(trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride (EPA chemical code 107401), at 0.75% of the formulation by weight.

DISCUSSION AND RECOMMENDATION

Acute oral and acute dermal toxicity:

Toxicity Categories IV and III, respectively, were recommended in the Product Science Branch (PSB) review dated 01/13/98.

Acute inhalation toxicity:

The applicant has cited MRID 411578-03. This study was rejected in a PSB memorandum dated 01-13-98 (Data Package D239768, regarding EPA File Symbol 70871-G) based on a cursory review. However, a previous Health Effects Division (HED) review of the study was located which indicated that, once the purity of the test material was provided, the study's status was upgraded to Acceptable (Core Minimum). The study has been 'bridged' to support the Registration No. 70871-2 product (formerly File Symbol 70871-E) based on the similarity of, but more diluted state of, the 70871-2 product in comparison with the test material. Category III was assigned to the 70871-2 product. The subject product 70871-L represents a [redacted] dilution of the 70871-2 formulation, and so the study can support the subject product as well.

The study results indicated LC_{50} > 0.45 mg/L, because no animals died at the 0.45 mg/L dose nor at the study's other dose of 0.35 mg/L. The above-mentioned HED review of the study placed the test material in the Toxicity Category II range. Because this is very close to the Category III limit dose of 0.5 mg/L, the 'actual' LC_{50} would most likely be in the Category III range since all animals survived the 0.45 mg/L dose. This in addition to the diluted state of the 70871-2 product or the 70871-L product in comparison with the test material would arguably make Category III a better choice than Category II.

Primary Eye Irritation:

The applicant has cited (descriptively, no MRID number provided) a study previously submitted for EPA File Symbol 70871-G. PSB assumes that this is the MRID 447899-01 study, which was reviewed and accepted by PSB on 07/13/99. The subject product (70871-L) represents a [redacted] dilution of the 70871-G product and is therefore not expected to be any more irritating. Since eye irritation Category III was assigned to the 70871-G product, it is also being assigned to the subject product.

Primary Dermal Irritation:

The applicant has cited MRID 403852-01. This study was mentioned in PSB's 07/13/99 review (Data Package D255210) for BST Protectant Concentrate C15, EPA File Symbol 70871-G:

Inert ingredient information not included.

> As pointed out in the 1/13/98 ESSB review, the subject product 70871-G would appear similar to the product for which the cited study [MRID 403852-01] was submitted in the past (EPA Reg. No. 64881-2), except that the subject product is far less concentrated in terms of the active ingredient. Because the cited study indicates Category III, the subject product can also be assigned to Category III.

Inert ingredient information not included.

Because the present subject product, File Symbol 70871-L, represents a [redacted] dilution of the 70871-G product, Category III can be assigned to the subject product as well, based on the cited MRID 403852-01.

Dermal Sensitization:

A study previously cited by the applicant, MRID No. 421974-01, was accepted in the 01/13/98 PSB review on a tentative basis and indicated that the test material was not a sensitizer. The study appeared acceptable upon cursory review, but it was not formally reviewed at that time because a review was pending for it in the reregistration program. It will suffice here simply to quote PSB's 07/13/99 review (Data Package D255210) for BST Protectant Concentrate C15, EPA File Symbol 70871-G:

> The cited study, MRID No. 421974-01, was cited in the applicant's previous submission. (It appears that the study was initially submitted for EPA Reg. No. 64881-1 or -2; purity of active ingredient was 72%.) The study had been submitted as 'generic' data in the reregistration process. In the 1/13/98 ESSB review for the subject product (70871-G), based on a cursory review, the study was said to appear acceptable and could be bridged to support the subject product on a tentative basis. A formal review was (and still is) pending in the reregistration process. Since that time, a 2/7/92 Agency review was found which calls the study acceptable with a non-sensitizing response. In the unlikely event that the pending reregistration review disagrees with the 2/7/92 review, a resulting requirement will be given under the reregistration program.

Because the present subject product (File Symbol 70871-L) is similar to the products mentioned above except for being less concentrated, the negative result for sensitization in the MRID 421974-01 study can be accepted in support of the subject product as well.

Summary:

The acute toxicity regulatory profile for the subject product is indicated in the following table.

Table: Acute toxicity regulatory profile

Data Requirement	Means of Support	Tox. Category
Acute Oral Toxicity	Previously cited study, MRID 424565-11	IV
Acute Dermal Toxicity	Previously cited study, MRID 403852-01	III
Acute Inhalation Toxicity	Cited study, MRID 411578-03	III
Primary Eye Irritation	Cited study, MRID 447899-01	III
Primary Dermal Irritation	Cited study, MRID 403852-01	III
Dermal Sensitization	Previously cited study, MRID 421974-01	Non-sensitizer

PRODUCT LABELING

The human-hazard precautionary statements on the proposed product label (EPA Received date 03/19/99) appear acceptable and conform reasonably well to the *Label Review Manual*. Although the proposed label omits the phrase "or clothing" (from the required instruction, "Avoid contact with skin, eyes, or clothing") and the statement, "Remove contaminated clothing and wash clothing before reuse," these label instructions might be confusing if placed on the label of a product meant for laundry treatment. Although the instruction to avoid contact with clothing could be made more tenable by changing it to refer explicitly to the "concentrate" (the product 'as sold'), this arguably is unnecessary. An instruction to avoid skin contact (which the proposed label does have) can be considered to *imply* that significant contact with clothing that a person is wearing should be avoided. In addition, because of the low concentration of this product relative to the test materials of the cited studies, the Category III ratings for dermal toxicity and dermal irritation are not considered 'strong' Category III's. Category IV would arguably be a more likely representation of the 'actual' hazard. For these reasons, the omissions of the references to "clothing" appear to be acceptable.

The practical-treatment statements on the proposed label are acceptable.