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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN 13 1998

MEMORANDUM

Subject: BST Protectant Concentrate C15
EPA File Symbol 70871-G
Data Package D239768

BST Protectant 50
EPA File Symbol 70871-U
Data Package D239765

BST Protectant 75
EPA File Symbol 70871-L
Data Package D239760

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To: Velma Noble, Product Manager, Team 31
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BACKGROUND

The applicant, BioShield Technologies, Inc. (as represented by Jellinek, Schwartz & Connolly, Inc.), has applied for registration of BST Protectant Concentrate C15, BST Protectant 50, and BST Protectant 75, three manufacturing-use products proposed for incorporation into anti-microbial products that are

used in cleaning products, textile and building treatment products, and a variety of manufactured items. The applicant has submitted a request for waivers of all product acute toxicity testing, and has cited several studies to show that existing data are sufficient to support registration.

DISCUSSION

According to a December 4, 1997 EPA memorandum from Timothy McMahon to Velma Noble, the following data is available for the active ingredient contained in these products. The memorandum notes that these tests were conducted on a 50% formulation.

Study Type	MRID No.	Tox. Category
Acute Oral Toxicity	403852-01	IV
Acute Dermal Toxicity	403852-01	III
Primary Eye Irritation	403852-01	I
Primary Dermal Irritation	403852-01	III

The subject products are water dilutions of a product resembling the product for which the studies cited in this memorandum were submitted. The dilution factors are rather large.

In support of registration of the subject products, the applicant has cited the above MRID 403852-01 and several additional studies also: 424565-11 (acute oral toxicity), 432199-01 (acute dermal toxicity), 411578-03 (acute inhalation toxicity), 932180-47 and 424565-13 (primary dermal irritation), and 421974-01 (dermal sensitization). Of these, according to our records, the acute oral toxicity study, MRID 424565-11, has been reviewed previously with a Toxicity Category IV result (LD_{50} = 12.27 g/kg), which is in agreement with the result in the list above. Because this is the Category of lowest toxicity, Category IV can be assigned to the subject products.

The acute dermal toxicity study with MRID No. 432199-01 is also not being reviewed for this memorandum. The study listed above with MRID No. 403852-01 was assigned Category III for acute dermal toxicity, and this Category can be assigned to the subject products for labeling purposes.

Based on a cursory review of the acute inhalation study, MRID No. 411578-03, the number and spacing of the dose concentrations were not appropriate for the calculation of an LC_{50}. Two dose concentrations were used (both within the Toxicity Category II

range). There was no third concentration, and there was no mortality which could be used for calculating an LC_{50}. The study is therefore not acceptable. An acceptable acute inhalation study is required, as conducted on the subject product formulations, as represented by BST Protectant Concentrate C15 (since its concentration is the highest of the three products).

As for primary eye irritation, Toxicity Category I is listed above for the concentrated material, but it is not known what Toxicity Category would result from the dilution represented by the subject products. Therefore an acceptable eye irritation study is required, as conducted on the subject product formulation. To reflect the source [redacted] material's Category I rating for eye irritation in the BioShield products may result in a significant overstatement of the hazard.

As for the primary dermal irritation studies with MRID Nos. 932180-47 and 424565-13, based on a cursory review of the studies it was noticed that individual animal data was not included, and observations ended at 72 hours in spite of the presence of significant irritation. The two studies suggest a Toxicity Category of I or II for primary dermal irritation. This is not in agreement with the Category III indicated for the MRID 403852-01 study listed above. Thus, the dermal irritation assessment is inconclusive, and a study is required for the diluted material.

The cited dermal sensitization study, MRID No. 421974-01, appears acceptable based on cursory review, indicating no sensitization response for the concentrated material. Therefore, the study is applicable to the subject product as well, acceptable on a tentative basis, until a complete review is conducted in the reregistration process. (It is this reviewer's intention to provide a review report well prior to that time.)

CONCLUSION

As per the foregoing discussion, the following Toxicity Categories can be assigned to the subject product for purposes of determining appropriate precautionary labeling.

Note that if the outcomes of the evaluations as a part of the Reregistration process (which are not yet completed) differ from these Toxicity Categories listed below, new data will be required.

Acute Effect	Category
Acute Oral Toxicity	IV
Acute Dermal Toxicity	III (assigned)
Acute Inhalation Toxicity	Study is required
Primary Eye Irritation	Study is required
Primary Dermal Irritation	Study is required
Dermal Sensitization	Non-sensitizer (tentative)

The precautionary labeling requirements for the subject product will be determined once the acute toxicity data requirements have been fulfilled.