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

JUL 15 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride (Bioshield AM 500): Review of data requirements for residential use.

EPA Identification Numbers:

DP Barcode: D256888
Submission: S563593
MRID: N/A
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Action Requested: Request to review the proposed use sites of this product for human toxicological concerns.

Background

In a memorandum dated December 4, 1997 (D239858, from Timothy F. McMahon to Velma Noble), the available Toxicology data for the active ingredient, 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride, was listed in response to a request for waivers of acute toxicity studies with a related product, BST Mold and Mildew Remover. Of these data, it was noted that acute toxicity data existed for the product in question, but that several data gaps appeared to exist for a **non-food** use of the active ingredient. These were listed as: an acceptable dermal sensitization test; an acceptable subchronic toxicity test; an acceptable developmental toxicity test; and an acceptable mutagenicity battery (excepting the mouse micronucleus study, of which the Agency has an acceptable study).

The registrant apparently never responded to this memorandum, but now desires to market a formulation of the same active ingredient (BioShield AM 500) for use in residential settings (i.e. homeowner use). It appears that homeowner uses are extensive (sleeping bags, tents, apparel, shoes, carpeting, upholstery, sails, vinyl, toilets, fiberglass, and sheets) although specific uses are not described on the proposed label.

Conclusions

1)RASSB reiterates that several data gaps appear to exist for the use of this active ingredient, both for commercial use as well as homeowner use. In addition, based on the proposed residential uses for this active ingredient, additional studies to fully characterize risk to infants and children from residential exposure will be required, including a developmental toxicity study in a second species, and a 2-generation reproduction toxicity study in rats. Based on the potential exposure scenarios, chronic toxicity data (i.e. one year toxicity study in dogs) and / or carcinogenicity data (rat and mouse) may also be required. An acute neurotoxicity study and an immunotoxicity study will also be required under the present proposed use patterns.

2) The subchronic toxicity study should be conducted by the dermal route, as this route appears to be the major route of exposure to this active ingredient.