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

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dermal Toxicity and Label Recommendations for Fungal Cockroach Traps

TO: Michael Mendelsohn (PM-18)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: John L. Kough, Ph.D., Biologist
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THROUGH: Roy Sjoblad, Ph.D.
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BACKGROUND

After speaking about the registration status of Metarhizium anisopliae, we had concluded there were certain issues to be resolved about the acceptability of the dermal toxicity study and certain label claims about the safety for use in hospitals and nursing homes.

DERMAL TOXICITY

The company has apparently submitted a dermal toxicity study with the end product (which is the same composition as the technical grade active ingredient: TGAI) in rabbits utilizing a rate of 2 gm/animal rather than the acceptable rate of 2 gm/kg body weight. This error is based on a typographical error in the current version of Subdivision M Testing Guidelines and could result in a lower than desired dermal exposure for larger test animals like rabbits. The cogent points are that there were no indicated effects from the exposure at 2 gm/animal and that no toxicity rating higher than a tox category IV should result, if there are no effects, regardless of the dose. It may be valid to ask for a repetition of the study if the dosage is obviously too low.

However, in light of the current understanding of the Section 158 guidelines, the company has submitted a study that is not required as the end product is essentially the TGAI with inerts of no known or expected toxicity (growth media and container). This

finding is based on the assumption of no additional testing of the end product is required if the TGAI shows no toxicity in the acute studies and the end product and the TGAI are the same. In this instance, the TGAI/end product are assumed to have a toxicity category IV rating (memorandum from M. Mendelsohn to R. Sjoblad & O. Odiott, 7/10/92; and Subdivision M Guidelines, p. 194). Therefore, no precautionary statements are needed on the label with respect to dermal toxicity.

LABEL STATEMENTS

The company has made claims of safety for use of the product that to control cockroaches in hospitals and nursing homes. The toxicity testing guidelines in Subdivision M are meant to be a reasonable screen for mammalian toxicity and infectivity in most exposures for normal adult individuals. The current toxicity testing guidelines cannot address the safety of product use in situations where any microbial contamination, however benign, is unacceptable. It is beyond the scope of this document to address the possibility of designing tests to cover product use around less than fully immune competent individuals. However, common hygienic practices would require that microbial contamination as well as vermin be minimized in situations where weakened individuals are present or normal defense barriers (operating rooms) are compromised. However, it should be emphasized that no evidence from the submitted toxicity studies or the literature indicate that M. anisopliae would be infective or cause disease even in immunocompromised individuals.