122804

Shaughnessy #: 079402

Due Date: 02/25/85

Init: SMK

OUT DATE: FEB 15 1985

To: G. LaRocca
Product Manager #15
Registration Division (TS-767C)

From: Joseph C. Reinert, Ph.D., Chief
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

JCR

Attached please find the EAB review of...

Reg./File No.: 50658-EUP-R

Chemical: Avermectin

Type Product: Insecticide

Product Name: MK-936

Company Name: Merck & Co. Inc.

Submission Purpose: Exposure Assessment Protocol Review

ZBB Code: _____ ACTION CODE: 117

Date In: 1/25/85 EAB # 5256

Date Completed: 2/15/85 TAIS (level II) Days

2

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

1.0 INTRODUCTION

Merck Sharp and Dohme Research Laboratories has submitted an exposure assessment protocol prepared by Orius Associates, Inc. for review by EAB. The protocol is for accessing the exposure of workers who apply avermectin (MK-936 0.15 EC) by airblast to citrus.

2.0 EVALUATION AND RECOMMENDATIONS

A review of the protocol indicates that the Merck study will provide sufficient and adequate data to estimate worker exposure. EAB has several critiques and recommendations that Merck should consider.

The protocol is devised to measure both worker exposure and clothing efficacy. EAB strongly recommends that clothing efficacy not be evaluated as a concurrent part of the exposure study. EAB believes that established laboratory methods provide more reliable data on clothing efficacy and at lower cost to the registrant. An investigation of efficacy is encouraged and Merck should contact Dr. Alan Nielson of the Field Studies Section, Exposure Assessment Branch (703-557-0267) for further information on the subject.

The body sites selected for placement of the dosimeters are adequate; however, Merck should restrict the number of dosimeters to one per site. The placement of four or five dosimeters per site appears impractical and would be expected to restrict body movement. If Merck is interested in the percentage penetration of the avermectin spray through the protective clothing it is suggested that additional dosimeters be placed under the protective clothing required by the label. EAB requires that the workers wear whatever protective clothing is required by the label. The dosimeters can be placed on the back, chest, and thigh adjacent to but not under the dosimeter placed on the outside of the protective clothing.

The protocol calls for monitoring two workers for each task at each of four sites. This number of replicates is nominally acceptable. Because of differences in individual work habits, EAB recommends that field notes record unusual exposure incidents such as spills or the workers brushing against the spray tanks.

EAB suggests altering the methodology to determine respiratory exposure. Avermectin will be applied at extremely low levels which suggest that a personal air pump set to 1.0 l/min may not be capable of trapping detectable levels of residue. The respiratory volume for adult males during light activity is 29 l/min. A gauze pad procedure described by Durham and Wolfe (Measurement of the Exposure of Workers to Pesticides. Bull. WHO. 1962. 26:75-91) in which the worker's respiration produces the air flow may more reliably measure respiratory exposure.

Should the registrant have any questions regarding the protocol I can be reached at 703-557-3935.

Curt Lunchick

Curt Lunchick, Chemist
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

3 4 3