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Shaughnessy #: 069003

Due date May 18, 1984

Init: CF for SMC

22 APR 1984
FBI - BOSTON

TO: George LaRocca
Product Manager #15
Registration Division (TS-767)

From: Joseph C. Reinert, Chief
Environmental Chemistry Review Section No. 2
Exposure Assessment Branch (TS-769C)
Hazard Evaluation Division (TS-769C)

Attached please find the EAB fate review of...

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

Chemical: Avermectin

Type Product: I

Product Name: AVIDTM

Company Name: MERCK

Submission Purpose: Exposure Assessment

ZBB Code: 3(c)(5)

ACTION CODE: 701

Date in: 2/28/84

EAB #: 4214

Date Completed: 4/20/84

TAIS (levels II) 63 Days 6

Deferrals To:

 Ecological Effects Branch

 Residue Chemistry Branch

 X Toxicology Branch

ADDENDUM

As an aid to registrants and others, the following background information describes how valid monitoring studies and quantitative exposure assessments are carried out:

1. Davis, James E. (1980). "Minimizing Occupational Exposure to Pesticides: Personnel Monitoring." Residue Reviews 75: 33.

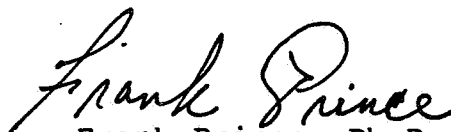
This review article describes state-of-the-art procedures for the actual field measurement of dermal and respiratory exposure.

2. Severn, David J. (1982). "Exposure Assessment for Agricultural Chemicals" in Genetic Toxicology - An Agricultural Perspective, R.D. Fleck and A. Hollaender, Eds. Plenum Press, New York, p. 235.

This paper presents an overview of how exposure assessments are carried out in EAB, including a discussion of the use of surrogate exposure studies for assessments when no data are available for a particular pesticide.

3. Severn, David J. (1980). "Use of Exposure Data for Risk Assessment." Presented at the "Symposium on Determination and Assessment of Pesticide Exposure." October 29. Hershey, PA.

This paper describes in greater detail what assumptions are made and how exposure assessments are performed in OPP.



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1.0 INTRODUCTION

Merck Sharp and Dohme has submitted a surrogate analysis of potential human exposure to AVID™, an Avermectin used for control of arthropod pests of ornamental plants

2.0 MK-936: Avermectin B₁: AVID

3.0 DISCUSSION

The investigators used data from a published Carbaryl exposure assessment study as a basis for estimating human exposure for an ornamental-use scenario with MK-936. They assumed that since Carbaryl was applied at a 3 lb. ai/acre level and MK-936 at a 0.025 lb. ai/acre level, that all dermal and inhalational exposure data previously collected for Carbaryl could be reduced by a factor of 120 and then be applicable to MK-936.

A. Summary of Carbaryl Study

The study which was used as a model for this surrogate analysis reported on the hourly dermal exposure(HDE) of agricultural workers to Carbaryl during both aerial and ground applications. The descending order of HDE by worker-type was found to be aerial flagger; mixer-loader; applicator ; bystander. The author found that the HDE varied with the type of formulation used(powder vs. aqueous suspension; i.e. 170 vs. 40 mg. respectively) and with the method of removing dry powder from the container.

Re-entry exposure assessments were made by measuring total extractable Carbaryl residues from apple leaves as a

function of time following an application.

A. Exposure Assessment

Carbaryl exposure assessment data for the mixer/loader in an agricultural scenario was used as a basis for comparison of indoor and outdoor ornamental-type applications with AVID. MERCK SHARP and Dohme Co. did not report on published exposure studies using Carbaryl in urban-type applications. These data would have provided a more valid comparison for surrogate analysis.

B. RE-Entry Exposure

Using several assumptions, the submitter calculated a theoretical maximum Dislodgeable Foliar Residues (DFR) for AVID applications. However no estimate of the transfer of DFR'S to human skin was given.

4.0 RECOMMENDATIONS

There is a need for submission of additional supporting data namely; 1) Actual or surrogate exposure assessment data for an ornamental-use scenario. 2) Re-entry exposure assessment data.