#63AB

Shaughnessy #: 079402

Due Date: 11/3/84

Init: 10 SEP 1984

To: George LAROCCA
Product Manager #15
Registration Division (TS-767)

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

Attached please find the EAB review of...

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

Chemical: Avermectin B_1

Type Product: I

Product Name:

Company Name:

Submission Purpose: Appl exposure assessment crop destruct EUP on citrus

ZBB Code: ?

ACTION CODE: 701

Date In: 8/15/84

EAB # 4515

Date Completed: 9/10/84

TAIS (level II)	Days
63	11/2

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

MEMORANDUM 10 SEP 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Toxicology Branch Request for Exposure Assessment of Avermectin B_1; 50658-EUP-R; Accession #252431

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

and

William Dykstra, Ph.D.
Toxicology Branch
Hazard Evaluation Division (TS-769)

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

JCR

The Toxicology Branch requested on 9 July 1984 that an exposure assessment for ground boom and aerial application of Avid™ be conducted for mixer/loader, applicator, and re-entry activities by 60 kg pregnant women. The requested exposure assessment was to be based on a surrogate carbaryl study submitted by Merck Sharp & Dohme Research Laboratories (Avid™ 0.15 EC Miticide/Insecticide Used on Ornamentals: Risk Assessments for Ground Boom Application and Reentry Based on Surrogate Studies. Submitted on 21 February 1984.).

The surrogate study was evaluated by Frank Prince, Ph.D. of EAB on 20 April 1984. Dr. Prince determined that the Merck study was inadequate because the study was based on a field crop (potato) scenario rather than an ornamental scenario (or citrus) and because actual reentry exposure was not determined. Dr. Prince recommended that "additional supporting data ...actual or surrogate exposure assessment data for an ornamental use scenario (and) reentry exposure assessment data" be submitted.

A memorandum of 26 July 1984 from David Severn, Chief of EAB, to William Burnam, Chief of the Toxicology Branch, further addressed the question of an exposure assessment for avermectin on ornamentals. The memo stated that EAB could not comply with the Toxicology Branch request for an exposure assessment because of the difficulty of extrapolating the application rates from our surrogate data to the extemely low application rate (0.02 lbs a.i./acre) used with Avid™. A copy of that memorandum is attached.

On 20 August 1984 Merck Sharp & Dohme Research Laboratories submitted additional data in support of their EUP application. The submission, Experimental Use Permit Application for Avermectin B_1 0.15 Pound/Gallon Emulsifiable Concentrate on Citrus (50658-EUP-R) Supplemental Information-Accession #254459, consisted of three attachments. The three attachments concerned fate, residues, and metabolism of Avermectin B_1 and therefore are not of assistance in assessing mixer/loader and applicator exposure.

The Exposure Assessment Branch would require field exposure studies in citrus orchards and on ornamentals for mixer/loaders, applicators, and field workers from the registrant in order to proceed with the Toxicology Branch request.

Curt Lunchick

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

Dykstra, William

JUL 26 1984

MEMORANDUM

SUBJECT: Exposure Assessment for the Use of Avermectrin on Ornamentals (Sec. 18)

FROM: David J. Severn, Chief
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

TO: William L. Burnam, Chief
Toxicology Branch
Hazard Evaluation Division (TS-769C)

EAB has looked into the possibility of preparing an exposure assessment for the section 18 request for avermectrin on ornamentals, as you requested. The difficulty is that the application rate is extremely low (0.02 lbs ai/acre). Our surrogate data base for pesticide exposure during application to ornamentals is very scanty, and we have absolutely no useful data on field worker exposure. Such applicator data as we possess are for much higher application rates, and we would have little confidence in extrapolation to the proposed avermectrin use rate.

EAB received from the registrant (submitted in conjunction with the recent citrus action) an exposure assessment (not an actual field study) such as you requested. We rejected it because the surrogate study utilized was inappropriate for estimating exposure during application to ornamentals.

EAB thus cannot comply with your request for an exposure assessment for this section 18 action. If the registrant requests a registration for avermectrin on ornamentals, then we would most likely require field exposure studies for applicators and field workers.

(TS-769)REINERT:Rm#709:557-0699:7/26/84

cc: D. Stubbs