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CASWELL FILE

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

MAR 23 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA File Symbol 618-OT - Avermectin B_1 (Also Called Abamectin) - Deferral from Exposure Assessment Branch Regarding Polar Degradates in Citrus and Cotton

Caswell No.: 63AB
Project No.: ~~8-1162~~
Record No.: 231,060

FROM: William Dykstra, Reviewer *William Dykstra 3/17/89*
Review Section I
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

TO: George T. LaRocca, PM 15
Insecticide-Rodenticide Branch
Registration Division (H7505C)

and

Akiva Abramovitch, Ph.D., Chemist
Review Section I
~~Non-Dietary Exposure Branch~~
~~Health Effects Division~~ (H7509C) EFED

THRU: Edwin R. Budd, Section Head *Budd 3/22/89*
Review Section I
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

Requested Action

Review Exposure Assessment Branch (EAB) deferral regarding the polar degradates of abamectin formed from use on citrus and cotton.

Review

In the memorandum of Dr. A. Abramovitch of August 18, 1988 (attached), EAB defers to Toxicology Branch (TB) and Residue Chemistry Branch regarding the need for field crop rotation studies. More specifically, EAB needed "to know the identity of the accumulated residues and their toxicity and what levels of detection are being used in setting tolerances."

Conclusion and Recommendation

In a telephone communication on March 1, 1989 with Dr. Abramovitch, it was learned that EAB is concerned about the photolytic polar degradates of abamectin formed from use on citrus and cotton. Based on a series of recent toxicity studies performed on the polar degradates (including acute oral toxicity and two teratology studies on CF-1 mice plus an Ames mutagenicity assay) and other pertinent information, TB has concluded that the photolytic polar degradates of abamectin are of very little toxicological concern as compared to the parent compound Avermectin B_1 and/or the delta-8,9-isomer.

Dr. Abramovitch stated that this conclusion resolves the EAB issue of field crop rotation.

Attachment

Shaughnessy Number: 122804

Date out of EAB: AUG 18 1988

TO: GEORGE LAROCCA
Product Manager 15
Registration Division (TS 767C)

FROM: Paul Mastradone, Ph.D.
Acting Chief, Review Section 1/EAB/HED (TS769-C)

THRU: Paul F. Schuda, Chief
Exposure Assessment Branch/HED (TS 769C)

Attached, please find the EAB review of...

Reg./File #: 618-CI

Chemical Name: Avermectin

Type Product: Insecticide

Company Name: Merck

Purpose: Field dissipation and crop rotation data requirements.

Date Received 6/27/88 Action Code: 181

Date Completed: EAB #(s): 80853

Monitoring Study Requested: Total Reviewing Time: 3 Days

Monitoring Study Volunteered:

Deferrals to: ___ Ecological Effects Branch

X Residue Chemistry Branch

X Toxicology Branch

3

1. CHEMICAL: AVERMECTIN

2. TEST MATERIAL: 0.15 EC Formulation.

3. STUDY/ACTION TYPE: Registration for use on citrus and cotton.

4. STUDY IDENTIFICATION: Accession 406650-01.
Response to EAB field dissipation and confined crop rotation data review.

5. REVIEWED BY:

Typed Name: A. ABRAMOVITCH, Ph.D.
Title: Chemist, Review Section 1
Organization: EAB/HED/OPP
Date: AUG 18 1988
Signature: Alan Abramovitch

6. APPROVED BY:

Typed Name: P. MASTRADONE, Ph.D.
Title: Acting Chief, Review Section 1
Organization: EAB/HED/OPP
Date: AUG 18 1988
Signature: Paul J. Mastradone

7. CONCLUSIONS:

Crop rotation:

EAB cannot accept the registrant's argument that a field crop rotation study is not warranted based on confined accumulation of 10 ppb. Also, the registrant should identify the accumulated residues in the confined rotated crops. Until these residues are identified, the confined crop rotation data requirement itself remains unsatisfied. Residues were not identified for RCB either as stated in their review of April 25, 1988, #3142,3143 and EAB cannot accept the registrant's claim that these residues are not avermectin, are non-toxic, etc., without scientific support. The need for field crop rotation issue is referred to both RCB and TS, since EAB needs to know the identity of the accumulated residues and their toxicity and what level of detection are being used in setting tolerances.

Field Dissipation and leaching data:

The field dissipation studies conducted by the registrant did not provide EAB with sufficient data to indicate that avermectin will not leach. Although EAB does not claim that avermectin is a leacher, the burden of proving that avermectin is not a leacher is the responsibility of the registrant. The studies conducted to depths of 4-6 inches were not conducted to sufficient depths to determine the extent of leaching. The registrant claims that avermectin dissipates rapidly in the top soil. This dissipation is due primarily to photodegradation. What would happen if it rained immediately after application? The studies did not simulate worse case leaching situation, since irrigation/rainfall were not applied immediately after application. EAB would like to be assured that neither avermectin nor its photoproducts will leach through the soil profile. EAB has to be concerned with the mobility of the photoproducts unless they will be notified by HED management to do otherwise.

The laboratory leaching data were inconclusive. Movement of residues through a silt loam soil column are now attributed by the registrant to channeling.

EAB cannot approve any registration of avermectin without being convinced that avermectin does not pose risks to ground water. EAB guidelines require that field dissipation studies be conducted under actual use conditions and simulating worse case situations for each registered use. The registrant conducted field studies to depths of 4 and 6 inches convinced by their laboratory studies that avermectin residues will not leach beyond 4 and 6 inches depths. Field studies protocols for registration on celery submitted to EAB (see EAB review of Jun. 23, 1988, EAB # 80078) plan to address leaching to depths of 0-6, 6-12, 12-24, and 24-26 inches. The choice of a sand or sandy loam soil with <1.5% organic material content is also good. The study will be conducted 0.15 lb ai/gal emulsifiable concentrate, 1.8% w/v at 0.02 lb ai/acre which is the maximum application rate.

EAB might be able to waive additional field studies on cotton and citrus when the field dissipation data on celery become available. Also, the registrant should be able to better convince EAB to do without field leaching data to 24 and 36 inches on cotton and citrus, by providing good, reliable soil column leaching data on avermectin and its photoproducts. Soil columns leaching data on sandy and silt loam soils are recommended.

8. RECOMMENDATIONS:

The request to waive additional field leaching studies for citrus and cotton registration will be considered when other field dissipation studies, such as on celery become available. Also, the registrant should support the argument to waive additional field leaching studies on citrus and cotton with additional soil column leaching data on radiolabeled avermectin and its photo products on sandy and silt loam soils.

EAB cannot concur with any registration of avermectin until it is fully convinced that avermectin and its degradates do not pose risks to ground water.

Normally, field crop rotation data are required by EAB whenever accumulation occurs in the confined crops. However, EAB would like to know what levels of residues of avermectin and its unidentified degradates would be considered significant before requesting the field crop rotation data. This issue should be referred to both RCB and TS. A decision should be made to whether an analytical method with a sensitivity level of 5 ppb for avermectin is adequate and whether field crop rotation are warranted based on the confined crop rotation accumulation of 10 ppb (see attached data). The registrant must identify the accumulated residues to satisfy the confined crop rotation data requirement.

9. BACKGROUND:

See EAB review of Sept 10, 1987 (EAB # 70392). A label was not enclosed with this submission.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: N/A.

11. COMPLETION OF ONE-LINER: No additional data from this review.

12. CBI APPENDIX: None.