

FILE COPY

Shaughnessy No.: 122804

Date Out of EFGWB: APR - 6 1989

To: Geo. LaRocca/A. Heywood
Product Manager # 15
Registration Division (TS-767)

From: Paul Mastradone, Ph.D., Acting Chief
Environmental Chemistry Review Section 1
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (TS-769-C)

THRU: Henry Jacoby, Acting Chief
Environmental Fate and Ground Water Branch/EFED (TS-769C)

Attached, please find the EAB review of...

Reg./File # : 618-OI

Chemical Name: Avermectin

Type Product : Miticide/Insecticide

Product Name : AGRI-MEK 0.15 EC

Company Name : MERCK

Purpose : Review request to register product on tomatoes.

Date Received: 11/15/88

Action Code: 181

Date Completed: _____

EFGWB#(s): 90143

Total Reviewing Time (decimal days): 2.0

Deferrals to:

_____ Ecological Effects Branch, EFED
_____ Science Integration & Policy Staff, EFED
_____ Non-Dietary Exposure Branch, HED
X _____ Dietary Exposure Branch, HED
_____ Toxicology Branch, HED

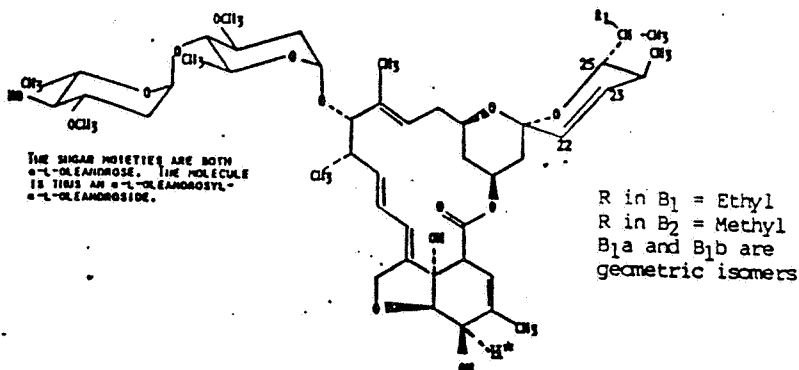
1. CHEMICAL:

Common Name— abamectin

Chemical Name— avermectin

Trade Name— AGRI-MEK 0.15 EC

Chemical Structure—



The active ingredient is composed of not less than 80% avermectin B_{1a} and not more than 20% avermectin B_{1b}.

2. TEST MATERIAL: Not applicable. Reference is to Abamectin 0.15 EC

3. STUDY/ACTION TYPE: The registrant is applying for registration of abamectin/avermectin B_{1a} and its delta 8, 9 isomer for use on tomatoes; a petition for permanent tolerances on tomatoes is also submitted.

4. STUDY IDENTIFICATION: Not applicable.

5. REVIEWED BY:

Herbert L. Manning, Ph.D.
Microbiologist, EFGWB/EFED

Signature: *Herbert L. Manning*

Date:

APR - 6

6. APPROVED BY:

Paul J. Mastradone, Ph.D.
Acting Chief, Section 1, EFGWB/EFED

Signature: *Paul J. Mastradone*

Date:

APR - 6

7. CONCLUSION:

Our files indicate two studies, Field Dissipation and Adsorption/Desorption, are required to support registration of abamectin/avermectin B_{1a} and its delta 8, 9 isomer on tomatoes. A

recent review (1/17/89, EFGWB # 90227, 90225) evaluated a field dissipation study and judged it unacceptable, since it was incomplete and amounted to an interim report. See Section 9A (Introduction to BACKGROUND) for a summary of the environmental fate data on abamectin.

8. RECOMMENDATION:

EFGWB (Environmental Fate & Ground Water Branch) recommends that the registrant send in for review the results of the analyses of the three remaining soil core replicates (study reviewed 1/17/89, Norton, J.A, 1988. Soil leaching/soil dissipation study for abamectin 0.15 EC miticide/insecticide, Acc. #409271-01), along with identification of residues, half-life calculations, and decline curves, in order to complete the soil dissipation study.

We also recommend an Adsorption/Desorption (batch equilibrium) leaching study be done, since abamectin/avermectin has been shown to give conflicting results in the soil TLC (immobile) and soil column (polar products leached) studies.

9. BACKGROUND:

A. Introduction- The data required for use of abamectin on tomatoes (terrestrial, food crop use), and the current status of the data in our files, is as follows:

<u>Studies Required</u>	<u>Current Status in Files</u>
o Hydrolysis	Stable to hydrolysis at pH 5,7, and 9 (review of 4/18/83, EAB #130). Acceptable study.
o Photodegradation- water/ soil	Rapid degradation; half-life of <12 hours in water and <one day on soil. Degradates were only characterized as polar, moderately polar, and nonpolar (review of 3/28/84, EAB #4170). Acceptable study.
o Aerobic/Anaerobic Soil Metabolism	Aerobic degradation depended on soil type; half-life varied from 2 weeks to 2 months. Fourteen degradates were detected, but not identified (review of 3/28/84). Acceptable study.

o Leaching (soil columns and
TLC)

Soil TLC indicated immobility
(Class I). Radioactivity
(mainly polar products) was
detected (<8%) in leachates of
all 4 columns in both aged and
unaged parent (review of
3/28/84). An Adsorption/
desorption study should be
done.

o Field Dissipation

Incomplete data from review of
1/17/89. Remainder of data will
be forthcoming.

o Rotational Crop

Presently under review.

o Fish Accumulation

Tested in bluegill sunfish,
bioconcentration factors were
69 for whole fish, 30 for
fillet, and 110 for viscera
(review of 3/28/84); study is
acceptable.

10. DISCUSSION OF INDIVIDUAL STUDIES:

Not applicable.

11. COMPLETION OF ONE-LINER:

Not applicable.

12. CBI APPENDIX:

There is no CBI in this review.

OFFICE OF PESTICIDE PROGRAMS DATA REVIEW RECORD

ATTACHMENT 1

Confidential Business Information-Does Not Contain National Security Information(E.O. 12065)
This form is to be used for individual studies and for submission of pesticide applications

1. PRODUCT NAME AGRI-MEK		CHEMICAL NAME IVERMECTIN	
2. IDENTIFYING NUMBER 618-01	3. RECORD NUMBER 234652	4. ACTION CODE 181	5. MRID/ACCESSION NUMBER N/A
		6. STUDY GUIDELINE OR NARRATIVE N/A	
7. REFERENCE NUMBER 2	8. DATE RECEIVED (EPA) OCT. 27, 1988	9. PRODUCT/REVIEW MANAGER/DCI LaRocca/Henward	10. PM/RM TEAM NUMBER PM-15
12. PROJECTED RETURN DATE Feb 15, 1989	13. DATE RETURNED TO (RD/SRRD) 4-6-89	11. DATE SENT TO (HED/EFED/RD/BEAD) Nov. 15, 1988	
INSTRUCTIONS: Refer to environmental fate data on file to support the proposed section 3 registration of ivermectin on tomatoes			

(THIS SECTION APPLIES TO REVIEW OF STUDIES ONLY)

14. CHECK APPLICABLE BOX:

15. NUMBER OF INDIVIDUAL STUDIES SUBMITTED

☐ ADVERSE 6(a)(2) DATA (405) ☐ GENERIC DATA (660) ☐ PRODUCT SPECIFIC DATA (655)
☐ SPECIAL REVIEW DATA (870) ☐ (REREGLSTRATION) ☐ (REREGLSTRATION)

16. HAVE ANY OF THE ABOVE STUDIES (in whole or in part) BEEN PREVIOUSLY SUBMITTED FOR REVIEW? (circle: yes or no) IF YES, PLEASE IDENTIFY THE STUDY(IES):

17. RELATED ACTIONS:

9F3703
9H5570

18. TO	TYPE OF REVIEW	19. REVIEWERS ALSO SENT TO	20. DATA REVIEW CRITERIA
HED	SCIENCE ANALYSIS & COORD.	— SAC — PC	A. Policy Note #31 ☐ 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
	TOXICOLOGY/HFA	— TOX/HFA — PL	
	TOXICOLOGY/IR	☒ TOX/IR	
	DIETARY EXPOSURE	☒ DEB — EA	
	NON-DIETARY EXPOSURE	☒ NDE — AC	
EF ED	ECOLOGICAL EFFECTS	— — BA	☒ 2 = data of particular concern from registration standard
SRRD	☒ ENVIRONMENTAL FATE & GROUND H2O	☒ EEB	
	SPECIAL REVIEW	— EFGWB	
	REREGLSTRATION	—	
RD	GENERIC CHEMICAL SUPPORT	— SR	
	INSECTICIDE-RODENTICIDE	— RER	
	FUNGICIDE-HERBICIDE	— GSC	
	ANTIMICROBIAL	—	
BEAD	PRODUCT CHEMISTRY	— IR	B. Section 18 ☐ 1 = data in support of section 3 in lieu of section 18
	PRECAUTIONARY LABELING	— FH	
	ECONOMIC ANALYSIS	— AM	
	ANALYTICAL CHEMISTRY	—	
	BIOLOGICAL ANALYSIS		C. Inert Ingredient ☐ 1 = data : contin List 1

☒ CONFIDENTIAL STATEMENT OF FORMULA (TRADE SECRETS)

☒ LABEL ATTACHED

White - Data Coordinator

Yellow - Data Review Section

Green - Return with completed review

Include original + two (2) copies with each submission

Pink -