5/13/87

Shaughnessy No. 102001

Date Out of EAB: MAY - 1 1987

To: Lois Rossi
Product Manager #21
Registration Division (TS-767C)

From: Emil Regelman, Supervisory Chemist
Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached, please find the EAB review of...

Reg./File # : 4581-280

Chemical Name: Thiophanate methyl

Type Product : Insecticide

Product Name : TOPSIN M 4.5 Flowable

Company Name : PENNWALT

Purpose : Review of protocols for field rotational crop studies.

ACTION CODE: 177

EAB #(s) : 70319

Date Received: 3/10/87

TAIS Code: 46

Date Completed: MAY - 1 1987

Total Reviewing Time 2.0 day

Monitoring study requested: _____

Monitoring study voluntarily: _____

Deferrals to: _____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

1. CHEMICAL: Thiophanate-methyl

   Chemical Name: Dimethyl[1,2-phenylenebis(iminocarbonothioyl)]bis [carbamate]

2. TEST MATERIAL: 4.5 pound per gallon flowable formulation.

3. STUDY ACTION TYPE: Review of protocols for field rotational crop studies.

4. STUDY INDENTIFICATION: Protocols for field rotational crop studies (165-2): Field accumulation study for lettuce, carrots, spinach and red beets grown in rotation with celery which was treated with thiophanate methyl. (Project No. WT-86-C-28). Field accumulation study for corn and peppers grown in rotation with dry beans which were treated with thiophanate methyl. (Project No. WT-86-c-29). Pennwalt letter of January 20, 1987.

5. REVIEWED BY:

   Arthur Schlosser
   Chemist, Review Section #3
   EAB/HED/OPP

   Signature: Arthur C Schlosser
   Date: May 1, 1987

6. APPROVED BY:

   Emil Regelman
   Supervisory Chemist
   Review Section #3
   EAB/HED/OPP

   Signature E Regelman
   Date: MAY - 1 1987

7. CONCLUSION: See DISCUSSIONS Section 10 for comments on the proposed protocols.

8. RECOMMENDATIONS: The proposed protocols on field rotational crop studies cannot be fully evaluated until acceptable confined rotational crop studies carried out with radiolabled active ingredient have been submitted. See Section 10, DISCUSSION, for general comments and recommendation for use of Data Reporting Guidelines.

9. BACKGROUND: Registrant is submitting protocols for the development of field rotational crop data in response to requirements of the registration standard for thiophanate methyl. There are no acceptable confined rotational crop data for this chemical in EAB files at this time.

10. DISCUSSION: It is not appropriate to comment specifically and in detail on protocols for field rotational crop studies before reviewing the results of adequate, acceptable confined studies carried out with radiolabeled active ingredient. Confined studies are needed for the proper identification of plant residues and metabolites and the development and evaluation of suitable analytical methodology. The confined radiolabeled study can also provide useful estimations of the amount of residue uptake by rotated crops and the safe treatment to planting interval. All of this information is needed for the design of meaningfull field rotational crop studies. In addition,if the confined study indicates that no significant residues are taken up by rotated crops under maximum treatment conditions, a field study may not be required.

The following general comments are made on the protocols submitted:

(1) The studies should be conducted according to the Pesticide Assessment Guidelines, Subdivision N, (165-2).

(2) Studies should include data to support all applicable crop uses, and major geographical areas of use.

(3) Data on small grains should be included unless it is certain that they will never be rotated in areas treated with thiophanate methyl.

(4) Applications should be made according to label recommendations. Some of the data should reflect maximum application rates and the maximun number of applications for each crop, or application options that may be expected to result in maximum soil residues.

(3) Soil samples should be taken so as to fairly represent actual residues and include areas of maximum expected residues.

(4) Plant samples should be analyzed for the residues and metabolites identified in the confined rotational crop study.

(5) Analytical methodology should be developed to detect residues to the 0.01 PPM level if feasible; recovery data should be included.

(6) All corrections made for recovery, sample storage stability or backbground should be reported.

(7) Studies should be designed to support a specific application to planting interval(s) after which no significant thiophanate methyl related residues will be found in rotated crops.

(8) The following publication is recommended as a guide for the reporting of data on rotational crop field studies.

Field Accumulation Studies On Rotational Crops
Subdivision N, Addendum 1
NTIS Document #PB86-247848
EPA Document #540/9-86-149

See attached instructions for ordering these guidelines.

11. COMPLETION OF ONE-LINER: Not applicable.

12. CBI APPENDIX: The information submitted is claimed to be CBI and should be treated as such.