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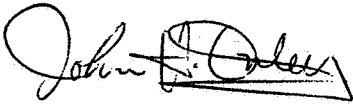
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460


MAR 31 1982

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: PP#2F2624/FAP#2H5335. Permethrin in or on
Field Corn. Evaluation of Analytical Methods
and Residue Data.

From: John H. Onley, Ph.D., Chemist 
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Thru: Charles L. Trichilo, Chief 
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

To: Franklin D. R. Gee, Product Manager No. 17
Insecticide-Rodenticide Branch
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

ICI Americas, Inc. proposes that a 0.1 ppm tolerance for the residues of the insecticide permethrin [(3-phenoxyphenyl) methyl(+)-cis,trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate] and its metabolites (+)-cis,trans-3-(2,2-dichloro ethenyl)-2,2-dimethylcyclopropanecarboxylic acid and (3-phenoxyphenyl)methanol be established in or on corn grain.

ICI has also proposed the establishment of food additive tolerances for residues of permethrin and its metabolites (+)-cis,trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylic acid and (3-phenoxyphenyl)methanol in or on the following commodities:

1 ppm in corn oil

1 ppm in corn soapstock

No tolerance is proposed for corn forage and fodder. The petitioner states in this petition that this is because corn forage and fodder tolerances were proposed in PP#9F2207. In a recent conference, the petitioner indicated that the corn tolerance proposals in that petition would be withdrawn.

Conclusions

- 1.) We conclude that the nature of the residue in plants and animals is adequately understood.
- 2.) We conclude that adequate analytical methodology is available for the regulation of permethrin and its metabolites.
- 3.) The petitioner's label contains a PHI of 14 days. A revised Section B should be submitted in which a PHI of 30 days is proposed.
- 4.) The petitioner will need to submit a revised Section F wherein a tolerance of 12 ppm is proposed on corn forage and fodder.
- 5.) If the petitioner revises Sections B as requested in conclusion 3 above, the proposed permethrin tolerances/food additive tolerances of 0.1 ppm on corn kernels, 1 ppm in corn oil and 1 ppm in corn soapstock will not be exceeded.
- 6.) With regards to meat, milk, poultry and eggs commodities, we place the proposed use under Category 1 of Section 180.6(a) of CFR 40.

The petitioner stated in the conference of 3/16/82 that appropriate meat, milk, poultry and egg tolerances would be proposed which would cover secondary residues in these commodities resulting from the uses proposed in this petition as well as all other pending permethrin petitions.

Recommendations

If TOX and EFB considerations permit, RCB recommends that permethrin (parent + metabolites) tolerances/food additive tolerances of 0.1 ppm on corn kernels, 1 ppm in corn oil and 1 ppm in corn soapstock be established, provided that the petitioner satisfies the deficiencies cited in conclusions 3 and 6 above. The petitioner should also propose a tolerance for corn forage and fodder as requested in conclusion 4. Registration Division is coordinating the resolution of these questions.

Detailed Considerations

Manufacture and Formulation

Our review of PP#8F2034 (memo of 3/3/78 - A. Rathman) contains a detailed discussion on the manufacturing process and impurities in the prepared material. The purity of the technical permethrin is about 92% [REDACTED]

technical material. However, at the given percentages, these impurities should not present any residue problems.

The insecticide to be used on field corn is formulated as Ambush. This formulation contains 2 lb. active ingredient (technical permethrin)/gallon. Inerts in the formulation have been cleared under Section 180.1001.

Proposed Uses

The proposed use is given below:

Crop	Target	Dosage (lb ai/A)	Remarks
Field corn	Black cutworm	0.05 - 0.1	Apply as needed using not less than 15 gpa (ground). For aerial applications, apply as needed using not less than 3 gpa. Do not apply more than 6 applications.
	Western corn rootworm		
	European corn borer	0.1 - 0.2	
	Southwestern corn borer		
	Corn earworm		
	Western bean cutworm		

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

The label of Section B contains a PHI of 14 days. The Petitioner should submit a revised Section B that contains a PHI of 30 days; this would adequately cover permethrin residues resulting from the proposed use (see also Residue Data Section of this petition).

Nature of the Residue

Plants. The Nature of the Residue has been discussed in our reviews of PP#8F2099/FAP#8H5190 (R. Perfetti - 5/3/79) and subsequent amendments; also, the Nature of the Residue has been discussed in several related PP's and FAP's.

The nature of the residue in plants is adequately understood. The terminal residues of concern in plants are the parent compound permethrin, cis- and trans- (3-phenoxyphenyl) methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate and the metabolites, cis- and trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylic acid (DCVA) and 3-phenoxybenzyl alcohol (MPBA).

Animals. Metabolic studies on chickens, cows, goats and rats have been reviewed previously. For each species, the various types of tissue samples contained residues of permethrin, cis- and trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid and 3-phenoxybenzyl alcohol. In addition to the preceding residues, the liver and kidney also contained the metabolites, 3-phenoxybenzoic acid and 4'-hydroxy-3-phenoxybenzoic acid. All metabolic products were found in free and/or conjugated form. The isomeric residue patterns (¹⁴C and cold studies) for the parent compound, permethrin, were in agreement; that is, the cis isomer became more predominant with time.

We consider the nature of the residue in animals to be adequately understood. Future tolerance regulations should include permethrin and the metabolites, c-, t-DCVA, 3-PBA and 3-phenoxybenzoic acid (calculated as parent).

Analytical Methodology

Permethrin (parent compound)

Analytical methodology for the parent compound has been discussed in our reviews of PP#8F2099/FAP#8H5190 (5/3/79) and subsequent amendments and related permethrin petitions. Recoveries for permethrin on corn kernels, cobs and stover are given below:

	<u>Fortification, ppm</u>	<u>Recoveries, %</u>
Corn kernels	0.05 - 2.0	93 - 142
Corn cobs	0.1 - 0.2	72 - 82
Corn stover	0.5 - 5.0	82 - 101

We conclude that adequate analytical methodology for the determination of permethrin (parent compound) in pop and field corn commodities is available for regulatory purposes.

Cis-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA) and 3-phenoxybenzyl alcohol (3-PBA)---
[metabolites]

Analytical methodology for the metabolites of permethrin has been discussed in our review of PP#9F2207/FAP#9H5219 (4/3/80). In the present petition, the following recoveries were observed on corn commodities:

DCVA

<u>Commodity</u>	<u>Fortification, ppm</u>	<u>Recovery, %</u>
Corn kernels	0.1 - 0.2	100 - 103
Corn cob	0.1 - 0.2	101 - 108
Corn stover	0.1 - 0.2	100 - 120

3-PB alcohol

Corn kernels	0.1 - 0.2	40 - 50
Corn cob	0.1 - 0.2	72 - 86
Corn stover	0.1 - 0.2	65 - 147

On March 5, 1982 RCB received a favorable oral report on the metabolites methodology from R. F. Thomas (Method Trial Unit) of BFSD. In view of this and other pertinent considerations, we conclude that adequate metabolites methodology is available for regulatory purposes.

Residue Data

Permethrin and Metabolites. Field corn grown in the states of Texas, Colorado, Georgia, Nebraska, South Dakota and New Mexico was analyzed for residues of permethrin. The formulation was applied at (1x) 0.1 to 0.2 lb. a.i./A in 1-6 application spray programs (aerial and ground). The Petitioner is recommending a 14-day PHI on the label specimen.

The residue data for the parent compound, permethrin and its metabolites, DCVA and MPBA, are summarized below:

Stover

ppm

<u>PHI</u>	<u>Permethrin</u>	<u>DCVA</u>	<u>MPA</u>
0 - 13	1.7 - 4	ND	0.2
14	1.0 - 1.7	1	1
16	8.5	1.5	ND - 0.8
28 - 89	tr - 3	0.3 - 0.6	ND - 0.4

tr = trace

Cobs

ppm

<u>PHI</u>	<u>Permethrin</u>	<u>DCVA</u>	<u>MPA</u>
0 - 13	0.1	ND	ND
14	-	-	-
16	ND	ND	ND
28 - 29	ND - 0.2	tr	ND

Grain

<u>PHI</u>	<u>Permethrin</u>	<u>DCVA</u>	<u>MPA</u>
0 - 89	ND - tr	ND	ND

In addition to the above residue data, one trial on field corn fodder and one trial on pop corn fodder were carried out in the state of Nebraska and two trials on sweet corn fodder were carried out in the state of Wisconsin. The trials involved 3 to 7 (0.2 lb. a.i./A) applications and PHI's of 30-43 days. Residues observed were 0.6-1.5 ppm permethrin, ND-0.24 ppm DCVA and none detected amounts of 3-PBA.

Fodder control samples carried through the methodology had permethrin backgrounds of none detected to 1.93 ppm, DCVA backgrounds of ND to 0.24 ppm and no 3-PBA backgrounds. None detected to trace backgrounds were report for DCVA and 3-PBA on kernels and cob samples.

Also, a corn fractionation study was submitted and these results are given below:

	<u>Residue, ppm</u>							
	<u>Control</u>				<u>Treated</u>			
	<u>Per</u>	<u>DCVA</u>	<u>3-PBA</u>	<u>Total</u>	<u>Per</u>	<u>DCVA</u>	<u>3-PBA</u>	<u>Total</u>
Whole corn	Tr	ND	ND	Tr	0.016	ND	ND	0.016
Meal	Tr	ND	ND	Tr	0.037	ND	ND	0.037
Crude oil	0.12	ND	0.040	0.16	0.19	0.017	0.037	0.24
Refined oil	0.099	0.003	0.037	0.14	0.14	0.004	0.027	0.17
Soapstock	0.073	0.019	0.027	0.12	0.11	0.013	0.080	0.20

Comments/Conclusions

The data submitted in this petition support the proposed grain tolerance at a 14 day PHI.

There is no tolerance proposal for forage and fodder. There is a 30 ppm tolerance pending in PP#9F2207. However, the petitioner has indicated that this will be withdrawn. There is a tolerance proposal for corn forage and fodder at 12 ppm in the copending petition from FMC Corporation (PP#IF2476). That tolerance proposal for the same general use as is proposed in this petition has a 30 day PHI. While the data in the subject petition would support a shorter 14 day PHI, we conclude that the PHI for corn forage and fodder from both petitioners should be the same. This PHI should be 30 days. The petitioner in this petition (ICI) should propose a 12 ppm corn forage and fodder tolerance with a 30 day PHI.

The petitioner has also proposed food additive tolerances of 1 ppm in corn oil and 1 ppm in corn soapstock; these proposed tolerances are based on residue data for grain and the processed products reflecting a PHI of only 14-days. Residue data for corn grain at a 30 day PHI show undetectable amounts of permethrin residue on corn kernels. Thus, the data would support a conclusion that there would not likely be any concentration of permethrin residues in corn oil and corn soapstock. Nevertheless, these proposed food additive tolerances will adequately cover any possible permethrin residues concentrating in the subject commodities. In conclusion, the Petitioner should submit a revised Section B that contains a PHI of 30-days. Also the Petitioner will need to submit a revised Section F wherein a tolerance is proposed on corn forage and fodder; residue data will support a tolerance of 12 ppm on each of the preceding commodities.

Meat, Milk, Poultry and Eggs

The feed items involved in this petition are corn grain, forage, fodder, silage and cobs. Depending upon the particular animal, these feed items may be fed at dietary levels ranging from no use to 85%. Cows and poultry feeding studies have previously been reviewed (see our reviews of PP#s 8F2034, 9F2196 and Amendment 4/2/81 to PP#8F2099/8H5190). Proposed tolerances that will adequately cover secondary residues resulting from feed items were critiqued at a March 16, 1982 meeting between representatives of FMC, ICI, TOX, RD and RCB/HED. The establishment of the new permethrin (parent + metabolites) tolerances will adequately cover secondary residues in meat, milk, poultry and eggs commodities; with regards to these commodities, we place the proposed use under Category 1 of Section 180.6(a). Revised Section F's on these commodities are to be submitted by the Petitioners (FMC and ICI).

TS-769:RCB:J.H.Onley:MCH:CM#2:RM810:X77377:3/29/82
cc: RF, Circu., J. Onley, Thompson, TOX, EEB, EFB, FDA,
PP#2F2624/FAP#2H5335
RDI: Quick, 3/19/82; Schmitt 3/22/82

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Permethrin

PETITION NO 2F2624

CCPR NO. 120

Reviewer: J. Onley

Codex Status

Proposed U. S. Tolerances

No Codex Proposal
Step 6 or above

Residue (if Step 9): Permethrin
(sum of isomers); metabolites excluded ^{1/}

Residue: Permethrin plus
its metabolites

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
cereal grains	2 ^{1/}
maize fodder & straw	100 (dry weight basis) ^{1/}

<u>Crop(s)</u>	<u>Tol. (ppm)</u>
Corn grain	0.1
Corn oil	1.0
Corn soapstock	1.0

CANADIAN LIMIT

MEXICAN TOLERANCIA

Residue: permethrin
(cis & trans isomers)

Residue: _____

<u>Crop</u>	<u>Limit (ppm)</u>
corn	0.1 ^{2/}

<u>Crop</u>	<u>Tolerancia (ppm)</u>
none	

Notes: ^{1/} Step 3 temporary MRLs, pending receipt of carcinogenicity studies.
^{2/} "Negligible residue" type tolerances.