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

SEP 10 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#OF2389 (RCB No. 2162). Permethrin on Alfalfa.
Evaluation of Amendment dated February 6, 1987
(MRID No. 400724-01).

FROM: Nancy Dodd, Chemist *Nancy Dodd*
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: George LaRocca, Product Manager #15
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

The petitioner, FMC Corporation, has now submitted an amendment to PP#OF2389 concerning the proposed tolerances for residues of the combined cis and trans isomers of the insecticide permethrin, (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate, and its metabolites cis and trans 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylic acid, and 3-phenoxybenzyl alcohol, calculated as permethrin, in or on the following raw agricultural commodities:

<u>Commodity</u>	<u>ppm</u>
Alfalfa, Fresh	25.0
Alfalfa, Hay	55.0

and for residues of the combined cis and trans isomers of the insecticide permethrin, (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate, and its metabolites cis and trans 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylic acid, 3-phenoxybenzyl alcohol, and 3-phenoxybenzoic acid, calculated as permethrin, in or on the following commodities:

<u>Commodity</u>	<u>ppm</u>
Fat of cattle	2.5
Meat by-products of cattle	2.0
Meat of cattle	0.25
Milk fat, reflecting 0.25 ppm in whole milk	6.25

This amendment consists of a revised Section D containing residue data from three additional states (Kansas, New York, and Wisconsin). A summary section consists of summaries of metabolism, residue data, analytical methods, and storage stability data. Sections G, F, and B are also submitted. This amendment is submitted in response to RCB's reviews of PP#OF2389 dated March 14, 1985 and October 22, 1985.

Summary of Deficiencies Remaining to be Resolved

Note: All deficiencies are fully discussed in the Detailed Considerations Section that follows in this review.

Deficiency No. 5 concerning the omission of proposed tolerances in Section F for goats, horses, and sheep commodities remains outstanding; the petitioner needs to submit a revised Section F that includes these commodities.

Recommendations

RCB recommends against establishment of the proposed tolerances for permethrin and its metabolites on alfalfa, alfalfa hay, and animal commodities because of Deficiency No. 5.

Detailed Considerations

The deficiencies discussed in the March 14, 1985 review of the amendment dated December 13, 1984 and the October 22, 1985 review of the amendment dated July 24, 1985 are outlined below, followed by the petitioner's responses and RCB's discussions/conclusions.

RCB's Deficiency No. 2

The residue data are geographically inadequate. The petitioner should submit residue data on alfalfa grown in Wisconsin, New York, and Kansas which was stored for less than 1 1/2 years.

Petitioner's Response to Deficiency No. 2

The petitioner has submitted additional residue data on alfalfa and alfalfa hay from Wisconsin, New York, and Kansas which was stored for approximately 1 year.

RCB's Discussion #2

Five studies were conducted in New York (1), Wisconsin (3), and Kansas (1). Two to six ground applications of Pounce 3.2 EC Insecticide were made. Application rates were 0.1 or 0.2 lb ai/A. The preharvest intervals were 0 days when the 0.1 lb ai/A rate was applied and 14 days when the 0.2 lb ai/A rate was applied (except in Kansas where the PHI's for the 0.1 and 0.2 lb ai/A rates were 0 and 16 days, respectively). To obtain hay samples, green forage was dried 5 to 7 days. Samples at the lab were stored at -18 °C. Samples were analyzed approximately 1 year after collection.

Samples in all five studies were analyzed for permethrin per se. In the locations where parent residues were found to be the highest (i.e., New York and Wisconsin), samples were also analyzed for the metabolites dichlorovinyl acid (DCVA) and m-phenoxybenzyl alcohol (m-PBA). Maximum residues in green alfalfa and alfalfa hay are summarized below:

<u>Rate</u>	<u>Cutting</u>	<u>Permethrin (ppm)</u>	<u>Total DCVA (ppm)</u>	<u>m-PBA (ppm)</u>	<u>Total Residue (ppm)^a</u>
(Green Alfalfa)					
0.1	2nd	9.0	ND	0.125	9.12
0.1	3rd	15.2	0.162	0.424	15.8
0.2	2nd	6.3	0.374	1.43	8.10
0.2	3rd	12.6	0.588	1.69	14.9
(Alfalfa Hay)					
0.1	2nd	14.9	ND	0.347	15.2
0.1	3rd	31.5	0.332	0.759	32.6
0.2	2nd	10.6	0.442	1.39	12.4
0.2	3rd	11.4	1.16	2.11	14.7

^aSum of maximum residues found - permethrin + DCVA + m-PBA.

ND = < 0.2 ppm DCVA

= < 0.5 ppm m-PBA

= < 0.5 ppm permethrin

RCB's Conclusion #2

The petitioner has provided adequate additional residue data from Wisconsin, New York, and Kansas for samples which were stored for less than 1 1/2 years.

RCB concludes that the proposed tolerances for permethrin and its metabolites DCVA and 3-phenoxybenzyl alcohol of 25.0 ppm on fresh alfalfa and 55.0 ppm on alfalfa hay are adequate to cover residues resulting from the proposed use on alfalfa.

Deficiency No. 2 is resolved.

RCB's Deficiency #3

RCB cannot evaluate the proposed tolerances for residues of permethrin (parent plus metabolites) in animal commodities (meat, fat, meat by-products of cattle, horses, goats, and sheep; and milk) until questions concerning the residue data (see Conclusion 2 above) have been resolved.

Petitioner's Response to Deficiency #3

The petitioner has resolved the questions concerning the residue data (see Deficiency #2 above).

RCB's Discussion #3

Feed items used for dietary calculations from the proposed use on alfalfa are alfalfa forage and hay. (For alfalfa, the seed is considered to be a raw agricultural commodity only for alfalfa grown for seed, so alfalfa seed and meal are not considered separately in dietary calculations for this use.) There are no feed items for poultry and swine since forage and hay of alfalfa are not poultry or swine feed items.

Feeding studies on cattle and chickens were previously reviewed. Chicken and cattle feeding studies are summarized from RCB's review of PP#OF2389 dated April 10, 1981 (J. Onley) below:

"Feeding studies on cattle and chickens were reviewed previously in connection with PP#8F2034 and 9F2243. In the cattle feeding study, dairy cattle were fed permethrin at the levels of 0.2, 1.0, 10, and 50 ppm. At these feeding levels, the maximum permethrin (parent) residues found in milk were <0.01, <0.01, 0.06, and 0.2 ppm, respectively. Permethrin residues in tissues from the 0.2 and 1.0 ppm feeding levels were 0.04 ppm or less. At the 10 ppm feeding level, permethrin residues were found in most of the tissue; the highest amount, 0.25 ppm, was found in fat tissues. The 50 ppm feeding level gave a maximum residue value of 1.1 ppm in the fat samples. The feeding of alfalfa to cattle would result in the ingestion of more than 50 ppm in the cattle diet."

"In the chicken feeding study, laying hens were fed permethrin at levels of 0, 0.4, 3.4, and 33 ppm. Permethrin residues in the egg whites at all feeding levels were less than 0.02 ppm. At the 3.4 and 33 ppm feeding levels, residues in the yolk ranged up to 0.05 and 0.64 ppm, respectively. Permethrin residues in all liver samples at all feeding levels were less than 0.01 ppm. Residues in muscle samples were less than 0.01 ppm at the 0.4 and 3.4 ppm feeding levels. However, muscle samples from the 33 ppm feeding level had residues ranging up to 0.08 ppm."

The petitioner also analyzed the above cattle samples for metabolites, and those results are summarized in RCB's (J. Onley) July 22, 1981 review of an April 2, 1981 amendment to PP#8F2099/8H5190 as follows:

"No metabolite residue data were reported on any of the fat samples from the 0.2-50 ppm feeding studies. DCVA, 3-PBalcohol and 3-PBAcid residues in liver, kidney, and muscle samples from the 1.0 ppm feeding level were all <0.01 ppm; these animals received the treated diet for 28-31 days and were then slaughtered. At the 10 ppm feeding level, liver samples contained <0.01 ppm DCVA, 0.01-0.03 ppm 3-PBalcohol and 0.01-0.02 ppm 3-PBAcid; kidney samples contained <0.01-0.02 ppm DCVA, <0.01 ppm 3-PBalcohol and <0.01-0.02 ppm 3-PBAcid; and muscle samples contained <0.01 ppm DCVA, 3-PBalcohol or 3-PBAcid. At the 50 ppm feeding level, liver samples contained 0.01-0.04 ppm DCVA, 0.05-0.1 ppm 3-PBalcohol and 0.1 ppm 3-PBAcid; kidney samples contained 0.07-0.09 ppm DCVA, 0.01-0.09 ppm 3-PBalcohol and 0.03-0.04 ppm 3-PBAcid; and muscle tissues contained <0.01-0.02 ppm DCVA, <0.01 ppm 3-PBalcohol and <0.01 ppm 3-PBAcid."

In another feeding study on cows receiving 150 ppm permethrin in the diet (see RCB's July 22, 1981 review of an April 2, 1981 amendment to PP#8F2099/8H5190), the data were summarized in part as follows:

"Milk samples taken at Day-1 contained <0.06 ppm permethrin and <0.01 ppm of each DCVA, 3-PBalcohol and 3-PBAcid metabolites. Milk samples taken from Day-3 to Day-26 contained 0.1 to 0.6 ppm permethrin, 0.02 to 0.03 ppm DCVA, 0.01 to 0.03 ppm 3-PBalcohol and 0.01 to 0.02 ppm 3-PBAcid. Within four days after cessation of the permethrin diet, the milk contained <0.01 ppm of each residue, permethrin, DCVA, 3-PBalcohol and 3-PBAcid."

"Residues of permethrin and three metabolites in tissues of cows receiving 150 ppm permethrin in the diet are summarized below:

Tissue	Permethrin	DCVA	Residue (ppm)	
			3-PBalcohol	3-PBAcid
Muscle	0.1-0.3	0.04-0.1	0.01-0.1	< 0.01-0.05
Subcutaneous fat	3-4	0.1-0.3	0.08-0.2	0.04-0.06
Peritoneal fat	5-6	0.2-0.3	0.02-0.3	0.02-0.05
Liver	0.01-0.03	0.2-0.3	0.7-1.0	0.4-0.6
Kidney	0.2-0.4	0.4-0.5	0.7-0.9	0.2-0.4

"The muscle, liver, and kidney tissues from the cow sacrificed after an 8-day recovery period contained <0.1 ppm of each residue, permethrin, DCVA, 3-PBalcohol and 3-PBAcid. The maximal level of permethrin in subcutaneous fat was 1.2 ppm, and the residue values for the metabolites did not exceed 0.05 ppm. The maximal level of permethrin

in peritoneal fat was 3.1 ppm, and the residue values for the metabolites did not exceed 0.1 ppm."

Sample dietary intakes for beef and dairy cattle as a result of this proposed use and registered uses are calculated below:

Beef Cattle

<u>Commodity</u>	<u>% in Diet</u>		<u>Tolerance (ppm)</u>		
Sweet corn forage	25	x	60	=	15.00
Alfalfa hay	25	x	55	=	13.75
Almond hulls	25	x	20	=	5.00
Cottonseeds	25	x	0.5	=	1.25
	<u>100</u>				<u>35.00</u> ppm

Dairy Cattle

<u>Commodity</u>	<u>% in Diet</u>		<u>Tolerance (ppm)</u>		
Sweet corn forage	10	x	60	=	6.00
Alfalfa hay	80	x	55	=	44.00
Almond hulls	10	x	20	=	2.00
	<u>100</u>				<u>52.00</u> ppm

RCB's Comments/Conclusions #3

After correlating those results obtained in the cattle feeding studies to possible dietary intakes resulting from this proposed use on alfalfa and registered uses, RCB concludes that the proposed permethrin tolerances of 2.5 ppm on fat of cattle, 2.0 ppm on meat by-products, 0.25 ppm on meat, and 6.25 ppm on milk fat (reflecting 0.25 ppm in whole milk) are adequate.

Deficiency #3 has been resolved.

RCB's Deficiency #5

The revised Section F no longer contains proposed tolerances for goats, horses, and sheep commodities (meat, fat, and meat by-products). Since alfalfa forage and hay are feed items for these animals (i.e. 100% of the horse diet; 50% of the sheep diet; 25 to 80% of the goat diet), the petitioner should submit a revised Section F including tolerances for goats, horses, and sheep.

Petitioner's Response to Deficiency #5

None.

RCB's Conclusion #5

Deficiency No. 5 remains outstanding.

Other Considerations

An International Residue Limits (IRL) Status sheet is attached to this review. RCB repeats its comments regarding compatibility of Codex, U.S., Mexican and Canadian limits/tolerances (see J. Onley memorandum, February 2, 1984):

"No Mexican tolerances for permethrin have been established on alfalfa forage and hay. Canada has established a 'negligible residue type tolerance' of 0.1 ppm on beef cattle (presumably meat, fat, meat by-products)."

"Codex has established a permethrin (parent compound only) tolerance of 100 ppm on alfalfa fodder (dry wt.); the petitioner is asking for the establishment of a U.S. permethrin (parent plus metabolites) tolerance (of 55 ppm) on alfalfa hay [alfalfa hay may be equivalent to (Codex) alfalfa fodder]. The Codex and U.S. tolerances on dry alfalfa are incompatible, and it would be impossible to match them since the Codex's 100 ppm tolerance on alfalfa fodder/hay would allow too much permethrin residues (a contribution of 0.35 ppm permethrin residues, calculated from U.S. cattle feeding studies) to enter into the whole milk of cows. In one of the March 15, 1982 conferences on permethrin, TOX expressed an opinion/guideline wherein no more than 0.25 ppm permethrin residues should be allowed in whole milk. Further, in view of the above correlation between the U.S. cattle feeding studies and the Codex tolerance of 100 ppm on alfalfa fodder, RCB finds that the Codex's tolerances of 0.1 ppm permethrin in milk is too low."

"The Step 5 (established) Codex and proposed U.S. tolerances on meat are 1 and 0.25 ppm, respectively; the higher Codex tolerance of 1 ppm permethrin on meat is in better agreement with the Codex 100 ppm permethrin tolerance established on alfalfa fodder."

"Finally, RCB also finds that the Codex and U.S. tolerances (0.1 and 0.25 ppm, respectively) on cattle meat by-products are incompatible and that a calculated correlation between the U.S. cattle feeding studies and the Codex tolerance of 100 ppm on alfalfa fodder illustrates that the Codex tolerance of 0.1 ppm permethrin on meat by-products of cattle and sheep is too low."

Attachment 1: International Residue Limit Status Sheet

cc: RF, Circu, Reviewer - N. Dodd, PP#OF2389, PMSD/ISB -
Eldredge, PM #15, TOX

RDI:J.H. Onley:8/31/87:R.D. Schmitt:8/31/87

TS-769:RCB:CM #2:RM 800D:X1681:N. Dodd:Kendrick & Company:9/8/87

INTERNATIONAL RESIDUE LIMIT STATUS

J. Jones
9/28/87

CHEMICAL permethrin

CODEX NO. 120

CODEX STATUS:

No Codex Proposal
Step 6 or above

Residue(if Step 8): _____

permethrin (sum of isomers)

PROPOSED U.S. TOLERANCES:

Petition No. OF2389

RCB Reviewer N. Dodd

Residue: permethrin and its
metabolites*

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
alfalfa fodder (dry wt.)	100
Meat of cattle, pigs & sheep	1 (fat basis)
Edible offal of cattle	0.1
Edible offal of pig	
Milks	0.1 ^{1/}

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
alfalfa, fresh	25.0
alfalfa, hay	55.0
cattle fat	2.5
cattle meat by-products	2.0
cattle meat	0.25
milk fat (reflecting 0.25 ppm in whole milk)	6.25

CANADIAN LIMITS:

No Canadian limit

Residue: _____

permethrin

MEXICAN LIMITS:

No Mexican limit

Residue: _____

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
Cattle	0.1 ^{2/}

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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^{1/} whole basis

NOTES:

* DCVA and 3-phenoxybenzyl alcohol for alfalfa;
DCVA, 3-phenoxybenzyl alcohol and
3-phenoxybenzoic acid for animal commodities.
^{2/} Negligible residue type limit.