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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT PP#0F2389 [RCB #1482]. Permethrin on Alfalfa.  
Evaluation of Amendment Dated July 24, 1985,  
(No Accession Number).

FROM: Michael P. Firestone, Ph.D., Chemist  
Tolerance Petition Section II  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769C)

TO: George LaRocca, Product Manager No. 15  
Registration Division (TS-767C)

and

Toxicology Branch  
Hazard Evaluation Division (TS-769C)

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

FMC Corporation has submitted this amendment, consisting solely of a cover letter from R. Stewart of FMC to G. LaRocca of EPA, in response to several deficiencies cited in RCB's previous review of the subject petition (see M. Firestone memo of March 14, 1985).

These deficiencies will be restated below, followed by the petitioner's response and RCB's comments/conclusions.

Deficiency 2:

As per RCB's request, additional residue data representing the Midwest and Eastern U.S. have been submitted. However, treated samples from three States (NY, PA, KS) of the four fields trials were stored for periods of time between 5 1/2 and 6 years. Since available storage stability data reflect only 1 1/2 years storage for parent compound and only 2 3/4 years storage for metabolites (26% breakdown of DCVA in lettuce),

additional storage stability data for permethrin, DCVA, and 3-PBA1c reflecting very long storage periods (i.e., 6 years) will be required to support the NY, PA, and KS field trial data. In lieu of submitting supporting storage stability data, the petitioner could generate additional residue data generated on permethrin-treated alfalfa samples grown in NY and/or PA and KS and stored for less than 1 1/2 years. At this time, the proposed tolerances for residues of permethrin (parent plus metabolites) in/on alfalfa forage and hay cannot be evaluated.

Petitioner's Response:

"It is FMC's contention that the data collected from Eastern U.S. is an accurate assessment of residues expected from the proposed use pattern, i.e., one application per cutting of 0.1 lb. ai/a 0 day PHI or 0.2 lb. ai/a 14 day PHI. The attached (Table 1) compares residue data collected from Western U.S. stored less than 18 months at -18 °C to that collected from Eastern U.S. and stored 5-1/2 and 6 years at -18 °C.

It should be noted that western data shown for the proposed rates and PHI's (0.1 lb., 0 day and 0.2 lb., 14 day) was (sic) collected from 12 different locations. From 8 of the 12 locations 3 subsequent cuttings were treated and analyzed at each time interval for each rate. From the remaining 4 locations a single cutting was sampled at each time interval. Duplicate samples were analyzed for each sampling time. Consequently, each average value presented in Table 1 is represented by 56 analyses for green alfalfa and 56 analyses for alfalfa hay.

Eastern data shown for the proposed rates and PHI's were collected from 4 locations. From 3 of the 4 locations 3 subsequent cuttings were treated and analyzed at each time interval for each rate. From the remaining location one cutting was sampled for each time interval. Duplicate samples were analyzed for each sampling time. Consequently, each average value presented is represented by 20 analyses for green alfalfa and 20 analyses for alfalfa hay.

With the overwhelming number of samplings and analyses and the very good comparisons for data for samples stored less than 18 months to that for samples stored for 5-1/2 to 6 years, the proposed tolerances for residues of permethrin (parent plus metabolites) in/on alfalfa forage and hay can be evaluated. This is reinforced by the fact that storage stability studies for permethrin and metabolites (DCVA and

MPBA) in alfalfa (green and hay) although not carried out for 5-1/2 to 6 years, showed absolutely no sign of instability during the 1-1/2 and 2-3/4 years storage periods."

RCB's Comments/Conclusions re: Deficiency 2:

RCB is unable to analyze the equivalency (or lack thereof) of the Eastern and Western U.S. residue data since the residue levels can depend on many variables including the following:

- a. Storage stability (length of time sample is stored) [note: Western U.S. samples were stored less than 18 months while Eastern U.S. samples were stored between 5 1/2 and 6 years];
- b. Rainfall, temperature, and other meteorological variables;
- c. Soil types;
- d. Method of application (ground vs. aerial, spray volume, type of equipment, weather conditions during treatment, etc.).

RCB is concerned with the integrity of the Eastern U.S. residue data, not the quantity. Thus, without storage stability data for residues of permethrin, DCVA and 3-PBA1c reflecting 6 years of frozen storage, RCB continues to be unable to reach any conclusion regarding the adequacy of the alfalfa residue data generated in NY, PA, and KS.

RCB reiterates its previous conclusion that without storage stability data reflecting six (6) years frozen storage, additional residue field trials must be conducted in NY and/or PA and KS, reflecting minimal frozen storage prior to analysis.

At this time, Deficiency 2 remains outstanding.

Deficiency 3:

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

Petitioner's Response:

None.

RCB's Comments/Conclusions re: Deficiency 3:

Deficiency 3 remains unresolved at this time pending resolution of Deficiency 2.

Deficiency 5:

The revised Section F no longer contains previously proposed amended tolerances (see Amendment November 7, 1983, to PP#0F2389) for goat, horse, and sheep commodities (meat, fat, meat byproducts). Since alfalfa forage and hay are feed items for these animals (i.e., 100% of horse diet; 50% of sheep diet; 25 to 80% of goat diet), amended tolerances may need to be repropose in a future revised Section F.

Petitioner's Response:

None.

RCB's Comments/Conclusions re: Deficiency 5:

Deficiency 5 remains unresolved pending resolution of Deficiencies 2 and 3.

Other Considerations:

An International Residue Limit Status sheet is included with this review as Attachment 1. RCB reiterates its previous comments regarding the compatibility of U.S. proposed tolerances with established Codex, Mexican, and Canadian limits/tolerances (see J. Onley memo of 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) tolerances 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 (a contribution of 0.35 ppm permethrin residues, calculated from U.S. cattle feeding studies) residues, 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."

Recommendation:

At this time, RCB recommends against establishment of the permethrin tolerances proposed in this amendment because of the reasons cited in Conclusions 2, 3, and 5 of this review. RCB suggests that the Product Manager send an unabridged version of this review to the petitioner.

Attachment 1: International Residue Limit Status Sheet

cc: R.F., Circu, MPFirestone, EAB, EEB, PMSD/ISB, FDA, PP#0F2389  
RDI:JHOnley-10/16/85:RDSchmitt:10/16/85  
RCB:TS-769:MPFirestone:CM#2:Rm800b:557-7484  
typed by Kendrick:10/18/85:edited by MPF:10/22/85

A. Jones 10/14/85

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: permethrin

PETITION NO.: OF 2389

CCPR NO.: 120

REVIEWER: Michael P. Firestone

Amendment of July 24, 1985

Codex Status

No Codex Proposal Step 6 or above

Residue (if Step 9): \_\_\_\_\_

Permethrin (sum of isomers)

Proposed U.S. Tolerances

Residue: permethrin plus its metabolites DCVA and 3-phenoxybenzyl alcohol.

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
<u>alfalfa fodder</u>	<u>100</u> <u>(dry wt. basis)</u>
<u>carcass meat of cattle</u>	<u>1 (in the fat)</u>
<u>cattle meat byproducts</u>	<u>0.1</u>
<u>milk</u>	<u>0.1</u>

<u>Crop(s)</u>	<u>Tol. (ppm)</u>
<u>alfalfa, fresh</u>	<u>25</u>
<u>alfalfa, hay</u>	<u>55</u>
<u>cattle meat</u>	<u>0.25</u>
<u>cattle meat by-products</u>	<u>2.0</u>
<u>cattle fat</u>	<u>2.5</u>
<u>milk fat</u>	<u>6.25</u>
<u>(reflecting in whole milk)</u>	<u>0.25</u>

CANADIAN LIMIT

Residue: permethrin

MEXICAN TOLERANCIA

Residue: \_\_\_\_\_

<u>Crop(s)</u>	<u>Limit (ppm)</u>
<u>"cattle"</u>	<u>0.1</u>

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

Notes:

" Negligible residue type limit