R. F

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

JUN 18 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6E3400 (RCB No. 894). Fenvalerate on Onions. Evaluation of Analytical Method and Residue Data (Accession No. 262394).

FROM: Nancy Dodd, Chemist Nancy Dodd
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

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

TO: Hoyt Jamerson, PM 43
Registration Support and Emergency Response Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

The petitioner, Interregional Research Project No. 4 (IR-4), on behalf of the IR-4 National Director, Dr. R.H. Kupelian and the Agricultural Experiment Station of Oklahoma, requests establishment of a tolerance for residues of the insecticide fenvalerate [cyano(3-phenoxyphenyl)methyl-4-chloro-alpha-(1-methylethyl)benzeneacetate] in or on the raw agricultural commodity onions at 3.0 parts per million (ppm).

Tolerances have been established for fenvalerate (40 CFR 180.379; 21 CFR 193.86, 193.97, and 561.97) on a variety of commodities at levels ranging from 0.02 ppm on corn grain, peanuts, and potatoes to 50 ppm on corn fodder and forage. PP#5F3222 for tolerances in meat and milk is in reject status (N. Dodd, May 16 and September 5, 1985).

A letter of authorization dated March 31, 1986 has been sent by E.L. Hobson, Ph.D. of Shell to Hoyt Jamerson, Registration Division, Office of Pesticide Programs to authorize use of Shell Oil Company file Nos. 201-401 (Pydrin Insecticide 2.4EC) and 201-402 (Technical Pydrin Insecticide) in support of the subject IR-4 petition for a fenvalerate tolerance on onions.

Trade names for fenvalerate (common name) are Pydrin, SD 43775, Ectrin, and DS 33459.

Conclusions

1. The metabolism of fenvalerate in onions is adequately understood. The residue of concern in onions at this time is fenvalerate per se.

2. Adequate analytical methods are available for enforcement of the proposed 3 ppm fenvalerate tolerance on onions.

3. Adequate storage stability data are available.

4. Available residue data are not adequate to support the proposed use on onions. The petitioner needs to address the following issues (see the Residue Data section of this review for further details):

   a. Provide the missing spray volumes for all of the TX studies.

   b. Resolve questions relating to the residues on onions where the minimum proposed spray volume of 20 gal/A is used.

   c. Provide residue data at a 7-day PHI for green onions grown in the TX study where residues ranged from 3.9 to 6.5 ppm at a 3-day PHI and also for green onions grown in OR and CA. If storage conditions do not allow the preceding requirements, then residue data from new studies will be required.

   d. Provide more residue data (reflecting the proposed use) on bulb onions harvested in MI, ID, and CO. The petitioner should refer to RCB's December 8, 1983 memorandum (Subject: IR-4 Crop Grouping Comments) for guidance.

5. No feed items are involved in this use on onions. No secondary residues are expected to occur in meat, milk, poultry, or eggs as a result of the proposed use. Therefore, this use falls in category 3 of §180.6(a) with respect to residues in meat, milk, poultry, and eggs.

6. An International Residue Limit Status sheet is attached. There are no Codex, Canadian, or Mexican tolerances for fenvalerate on onions. Therefore, no compatibility questions exist with respect to Codex.

Recommendations

At this time, RCB will not recommend for the establishment of a 3.0 ppm fenvalerate tolerance on onions (green and bulb) because of reasons given in Conclusion #4.

Detailed Considerations

Manufacture

RCB refers to a previous review of the manufacturing process for the technical product (PP#0F2013, E.L. Gunderson, April 21, 1978). No residue problems are expected from the impurities present in the technical product.

Formulation

The product is formulated as Pydrin® Insecticide 2.4 Emulsible Concentrate (EPA Registration No. 201-401). This formulation contains 30% active ingredient (2.4 lb ai/gal) and 70% inerts. The inerts in the formulation are cleared under 40 CFR 180.1001.

Proposed Use

Apply Pydrin® 2.4 EC to onions at the rate of 0.1-0.2 lb ai/A in a minimum of 20 gal/A by ground equipment only. Do not exceed 1.0 lb ai/A/season. Do not apply within 14 days of harvest of dry bulb onions and 7 days of green onions.

Nature of the Residue

No new plant metabolism studies were submitted with this petition.

Radiolabel metabolism studies have been conducted on cotton (PP#6G1755, E.L. Gunderson, May 14, 1978), apples and lettuce (PP#8E2024, E.L. Gunderson, June 21, 1978), tomatoes (PP#1F2367, K. Arne, January 7, 1981), and soybeans (PP#0F2375, K. Arne, December 23, 1980). Degradation is slow, with the major residue being parent compound. A photodegradation product, 4-chloro-beta-(1-methylethyl)-alpha-(3-phenoxyphenyl) benzenepropanenitrile, has been found in/on cottonseed, tomatoes, lettuce, apples, peas, pea vines, almond hulls, and celery. Pydrin does not readily translocate.

Toxicology Branch has previously concluded (memorandum of Albin Kocialski, July 19, 1984) that residues of the photodegradate were not significant (for then current uses) and that the photodegradate should not be included in the Pydrin tolerance expression.

RCB concludes that the metabolism of fenvalerate in onions is adequately understood. The residue of concern in onions at this time is fenvalerate per se.

Analytical Methods

Onions

In five of the seven submitted residue studies on onions, the analytical method used to determine residues was "Determination of SD 43775 Residues in Crops, Animal Tissues, Soil and Water - Electron Capture Gas Chromatographic Method," Shell Development Company, Biological Sciences Rsearch Center, CA, MMS-R-478-1. The sample is blended in hexane/isopropanol and filtered. The extract is partitioned with water to remove isopropanol. The hexane is then partitioned with CH_3CN. The residue in CH_3CN is then exchanged back to hexane. The residue is column chromatographed using Bondelut (Si) cleanup columns and hexane/ethyl acetate eluant. The minimum detectable concentration in onions is reported as 0.01 ppm. Recoveries on onions fortified at 0.05 to 1.0 ppm ranged from 93% to 125%.

In the other two studies, the analytical method was "Determination of SD 43775 Residues in Crops," Shell Development Company, Biological Sciences Research Center, CA, MMS-R-456-1, dated October 1976, with modifications dated March 1, 1984. The sample is blended with acetone and filtered through Na_2SO_4. The extract in a separatory funnel is shaken after the addition of 30 ml saturated Na_2SO_4, 100 ml hexane , and 200 ml distilled water. The top layer is filtered through Na_2SO_4. The sample is evaporated and redissolved in hexane . The sample is then cleaned up by eluting it through a Florisil sep-pak with 10 ml of 10 percent ethyl acetate in hexane.

The sample is analyzed by gas chromatography. The petitioner indicates that the sensitivity of the method on onions is < 0.04 ppm. Recoveries on onions fortified at 0.16 to 0.18 ppm were 100% to 110%.

A method for analysis of the metabolite 4-chloro-beta-(1-methylethyl)-alpha-(3-phenoxyphenyl)benzenepropanenitrile (SD 54597) is also submitted ("Determination of SD 54597 Residues in Crops - Electron-Capture Gas Chromatographic Method," Shell's Method No. MMS-R-527-1 dated May 1, 1982). This photodegradate is not included in the tolerance expression.

Method MMS-R-478-1 has been described in PAM II as an enforcement method and has undergone a successful method trial for Pydrin per se in cottonseed, meat, and milk (PP#7F2013, J.H. Onley, July 24, 1978).

RCB concludes that adequate analytical methods are available for enforcement of the proposed tolerance on onions.

Residue Data

Storage Stability

Storage stability of fenvalerate on okra and collards was previously discussed in connection with PP#5E3282 (M. Kovacs, August 30, 1985) and PP#4E2974 (M. Kovacs, March 19, 1984), respectively. Chopped collards stored at -10 °C indicated an average recovery of 79 percent for Pydrin following storage for up to 8 1/2 months. Pydrin on okra samples stored for 36 days at 0 °F degraded a maximum of 8 percent.

RCB concludes that adequate storage stability data are available.

Onions

Seven field studies were conducted in the states of OR (2), NY (1), TX (3), and CA (1) to determine residues on onions. (Four studies were conducted on green onions and three studies were conducted on dry bulb onions.) The application rate was 0.20 lb ai/A (1X), and in two studies also 0.40 lb ai/A (2X). Three or five applications were made. Preharvest intervals were primarily 3 to 14 days. The samples were stored frozen for 1 to 10 months. Residues ranged from nondetectable (ND) (87-day

PHI) to 6.5 ppm (on green onions 3 days after the fifth application at 0.20 lb ai/A). Residues are tabulated below:

State	Onion Type	Dosage (lb ai/A)	No. of Applic.	Spray Volume/A (gallons)	PHI	Fenvalerate Residues (ppm)
OR	Green	0.20	5	54	14	0.25-0.42
TX	Green	0.20	3	--	3	0.37-0.56*
					7	0.30-0.77*
					10	0.08-0.12
		0.40	3	--	3	0.43-0.72*
					7	0.62-0.91*
					10	< 0.04-0.06
CA	Green	0.20	5	56	3	2.9-3.0
NY	Dry bulb	0.20	5	65	14	0.03-0.07
OR	Dry bulb	0.20	5	54	14	0.18-0.21
TX	Dry bulb	0.20	3	--	87	ND (< 0.04)
		0.40	3	--	87	ND (< 0.04)
TX	Green	0.20	5	10	3	3.9-6.5

*Increase in maximum residues going from 3-day PHI to 7-day PHI.

The petitioner indicates that the high residues of 3.9 to 6.5 ppm in the TX study were due to lack of growth of the onions during the spraying period and application in a small spray volume of 10 gal/A.(The proposed use specifies application in a minimum of 20 gals/A). If the petitioner's analogy is correct, then it is essential that the petitioner provide the missing spray volumes for all of the TX studies. Further, the petitioner has submitted residue data (OR, CA, and NY) reflecting use of spray volumes ranging from 54 to 65 gal/A. If the spray volume is as critical as thought, then it follows that those residue values reported in the preceding chart could be higher if the recommended minimum spray volume of 20 gal/A was used. The petitioner must address the preceding issues.

Also, looking at the above chart, two of the green onion studies carried out in Texas show an increase in maximum residues going from 3-day PHI (0.56 and 0.72 ppm) to 7-day PHI (0.77 and 0.91 ppm) and then a decrease going from 7-day PHI to 10-day PHI (0.12 and 0.06 ppm). Thus, since the proposed PHI is 7 days, the petitioner must provide residue data at this PHI for green onions grown in the third TX study (which had residues ranging from 3.9 to 6.5 ppm at 3-day PHI) and also for green onion grown in OR and CA. If storage stability studies do not permit the preceding requirements, then new residue studies will be required.

Further, at the proposed 14-day PHI, the petitioner has only submitted residue data on bulb onions harvested at two locations (NY and OR). More residue data on bulb onions harvested in MI, ID, and CO are needed. The petitioner should refer to RCB's December 8, 1983 memorandum (Subject: IR-4 Crop Grouping Comments) for guidance.

Therefore, RCB concludes that the available residue data are not adequate to support the proposed use on onions.

Meat, Milk, Poultry, and Eggs

No feed items are involved in this use on onions. No secondary residues are expected to occur in meat, milk, poultry, or eggs as a result of the proposed use. Therefore, this use falls in category 3 of §180.6(a) with respect to residues in meat, milk, poultry, and eggs.

Other Considerations

An International Residue Limit Status sheet is attached. There are no Codex, Canadian, or Mexican tolerances for fenvalerate on onions. Therefore, no compatibility questions exist with respect to Codex.

Attachment 1: International Residue Limits Status sheet

cc with Attachment 1: Reviewer - N. Dodd, TOX, RF, PM#16, PP#6F3402, PMSD/ISB - Eldredge, Circu, EAB, EEB, FDA
RDI: J.H. Onley:6/4/86:RD Schmitt:6/4/86
TS-769:RCB:CM#2:RM810:557-1681:N. Dodd:Kendrick & Co.: 6/12/86

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Fenvalerate

PETITION NO GE 3400
M. Dodd
J. Hess 5/22/86

CCPR NO. _____

Codex Status

☐ No Codex Proposal Step 6 or above

Proposed U. S. Tolerances

Residue (if Step 9): _____

Residue: ~~fenvalerate~~ [cyano(3-phenoxyphenyl)methyl-4-chloro-alpha(1-methylethyl)benzeneacetate]

Crop(s)	Limit (mg/kg)
none (on onions)	

Crop(s)	Tol. (ppm)
onions	3.0

CANADIAN LIMIT

Residue: _____

Crop	Limit (ppm)
none (on onions)	

MEXICAN TOLERANCIA

Residue: _____

Crop	Tolerancia (ppm)
none	

Notes: