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

MAY 10 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#5F3171 Pydrin® in/on Carrots. Evaluation of Analytical Method and Residue Data. (Accession No. 073025)

FROM: V. F. Boyd, Chemist
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and

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Shell Oil Company proposes a tolerance of 0.5 ppm for the residue of the insecticide, cyano (3-phenoxyphenyl) methyl-4-chloro-alpha-(1-methylethyl) benzeneacetate (generically known as fenvalerate) in or on carrots.

Pydrin (fenvalerate) tolerances are established for several commodities ranging from 0.02 ppm on potatoes to 50 ppm on corn fodder and forage (40 CFR 180.379). Tolerances have also been proposed for Red beets at 0.5 ppm, with beet tops at 20 ppm (PP#4E3104, Haeberer, 9/4/84) and at 0.5 ppm on sugarbeets with 10 ppm proposed on sugarbeet tops (PP#4F3120, Firestone, 8/24/84),

Conclusions:

(1a) The nature of the residue has been determined in metabolism studies on apples, cotton, lettuce, tomatoes and soybeans. There are no metabolism studies in a root crop. Fenvalerate tolerances are based on the parent compound.

Since some of the pyrethroids have tolerances based on parent plus metabolites and metabolism of the various pyrethroids is very similar, RCB is currently evaluating data on all pyrethroids to develop a more consistent tolerance expression for this class of compound.

The nature of the residue in plants is adequately understood for purposes of this petition and the residue of concern is fenvalerate, per se.

(1b) The nature of the residue in cattle, goats, horses, sheep and swine is adequately understood. The residue of concern is fenvalerate.

Carrots are not a significant poultry feed item, therefore transfer of secondary residues to poultry tissues and eggs is not of concern in the current petition.

(2) Adequate analytical methodology exists for the determination of fenvalerate, per se, in carrots, meat and milk, and is considered adequate for enforcement of the proposed tolerance.

(3a) The residue data submitted are limited in number, but present a geographical distribution representative of 80% of the carrot growing area. These data plus beet and sugarbeet data, previously presented, allow the conclusion that residues of fenvalerate, as parent compound, will not exceed the proposed tolerance for carrots when Pydrin is applied, by ground, according to the proposed use.

(3b) Since there are no residue data reflecting aerial application of Pydrin on carrots, the proposed use will need to be corrected to restrict Pydrin on carrots to ground application, only. A revised Section B should be submitted.

(4) Culled carrots (approximately 30% of total production) are used as livestock feed. The established tolerances for fenvalerate in meat and milk (CFR. 180.379) will not be exceeded due to feeding of carrots containing fenvalerate at the proposed tolerance level of 0.5 ppm.

(5) The International Residue Limit Status Sheet is attached. There are no established tolerances for Pydrin in/or on carrots, however, fenvalerate has a Codex tolerance of 0.05 ppm in root and tuber vegetables. It is presumed that the International use must differ considerably from the presently proposed use pattern. We cannot recommend harmonizing the requested tolerance of 0.5 ppm to 0.05 ppm.

Recommendations:

Providing a revised Section B is submitted per conclusion 3b above and Toxicology considerations permitting, we could recommend for the establishment of the proposed tolerance of 0.5 ppm for residues of fenvalerate in/on carrots.

Detailed Considerations

Manufacturing Process:

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Technical Pydrin is produced by the [redacted] 92% pure. The chief impurities are [redacted] impurities. RCB anticipates no residues from these impurities.

Formulation:

Technical fenvalerate is formulated as Pydrin, 2.4 EC (EPA Reg. No. 201-401), which contains 2.4 lbs ai/gal. (30% by weight) of technical fenvalerate in an emulsifiable liquid formulation. The inert ingredients are all cleared for use in pesticide formulation under 40 CFR 180.1001 (see review of PP#7E2013).

Proposed Use:

For control of Aster Leafhopper Cutworms apply Pydrin 2.4 EC (according to label directions) at a rate of 0.1-0.2 lbs ai/A (5 1/3-10 2/3 Fl. oz/A of formulation) in 12-24 gal./A, but do not exceed 2.0 lbs. ai/A per season.

The restriction concerning the rotation of root crops is included on label, as previously requested by EAB for other root crops.

Nature of the Residue:

No new metabolism studies were submitted in conjunction with this petition. Radiolabeled metabolism studies have been presented on cotton (PP#6G1755, E.L. Gunderson 5/14/78), apple and lettuce (PP#8E2024, E.L. Gunderson, 6/21/78), tomatoes (PP#1F2367, K. Arne, 1/7/81) and soybeans (PP#OF2375, K. Arne, 12/23/80).

All of the plant metabolism studies have shown fenvalerate to be a long lasting chemical that degrades very slowely. Most of the residues are surface deposits indicating limited penetration past the waxy plant surface. Fenvalerate does not translocate in the plant; leaf deposits stay on the leaves. As much as 10% of residue may be found as a photodegradate, 4-chloro-beta-(1-methylethyl)-alpha-(3-phenoxyphenyl) benzene. Less than 10% may be found as any of five different benzeneacetates or phenoxybenzoates, usually conjugated and water solsuble. The predominant residue of Pydrin (80-90%) is the parent compound. All of the metabolism studies have been performed with appropriate mixtures of C^{14}-ring labeled (benzyl or chlorophenyl) compound.

It is concluded that fenvalerate (parent compound) is the terminal residue of significance resuting from application of Pydrin. TOX has recommended that the photodegradate found in plant tissues not be included in the tolerance expression since it is not considered a significant residue (Accession Nos. 072144, 07245, A. Koclalski memo, 7/19/84). Although a metabolism study has not been performed in a root crop, sufficient metabolic work has been reviewed showing that fenvalerate does not translocate in plant tissues to conclude that the nature of the residue in carrots is sufficiently clear. Fenvalerate is the terminal residue which requires regulation.

No new animal metabolism studies were submitted in this petition. Studies of fenvalerate metabolism in cattle have been previously reviewed (PP#7F2013, E. Gunderson, 6/15/78) and PP#OF2367, K. Arne, 1/5/82). In lactating cows fed 10.9 ppm fenvalerate (C^{14}-benzyl labeled) for 28 days, fenvalerate equivalents were analyzed as: 0.13 ppm in milk and 1 ppm in milkfat; 0.34 ppm in liver; 0.18 ppm in kidney; 0.06 ppm in muscle; 0.8 ppm in mesenteric fat. Most of the residue in fat (90%) and milk (80-90%) was parent compound. Identification of residues in liver and kidney indicated that the major degradative pathway was by ester cleavage to form 4-chloro-alpha-(1-methyethyl) benzeneacetic acid, or its hydroxylate, and 3-phenoxybenzoic acid.

TOX has concluded that these terminal metabolites in liver and kidney are not of toxicological concern (PP#OF2367, A. Kocialski, 2/8/82).

Metabolism in rats and cattle have been shown to follow the same degradative pathway with parent compound being the significant residue, and rapidly being excreted as the same water soluble benzeneacetic and phenoxybenzoic acids as described above in cattle liver and kidney. The parent compound is the regulable residue in livestock products and sufficient data is available to estimate residue in meat and milk.

Analytical Method

The analytical methodology used to generate the Pydrin (parent compound only) residue data submitted in this petition is entitled. "Determination of SD 43775 Residues in Crops, Animal Tissue, Soil and Water - Electron-Capture Gas Chromatographic Method," MMS-R-478-1. This method is described in the Pesticide Analytical Manual - Volume II (Pesticide Reg. Section 180.379).

The procedure involves blending of a representative sample in the presence of hexane/IPA using a high-speed Waring Blendor. The filtered extract is partitioned with water to remove isopropanol. The hexane fraction is then partitioned with acetonitrile. Discard the hexane fraction and exchange acetonitrile back to hexane for column cleanup on Bondelut (Si), eluting with hexane/ethyl acetate. Quantitate by capillary GC/EC using SE-20 on WCOT.

The minimum detectable level in carrots is 0.01 ppm. All check samples were reported as <0.01 ppm.

Recovery values in carrots averaged: 109% (86-127% Range) at 0.05 ppm fortification; 99% at 1.00 ppm fortification, and 115.5% (106-125% Range) at 0.1 ppm fortification.

Another method is available for the enforcement of meat and milk tolerance (Shell method MMS-R-447-3). This procedure has undergone a successful method trial in conjunction with PP#7F2013 (J. Onley memo of 7/24/78).

Adequate methodology is available for enforcement purposes for analysis of fenvalerate as a residue in carrots, meat or milk,

Residue Data

Residue studies are reported from 6 trials in 6 states, MI, CA, TX, OR, NY and OH, across the U.S. Although the number of trials is minimal the geographic locations represent 77% of the carrot growing acreage in the U.S. (Agr. stat. 1982). All of the residue trials are samplings of carrots after the maximum application (0.2 lbs. ai/A and 10 applications or 2.0 lbs a.i./A total), and were harvested seven days following last application. Therefore all carrot data reflect the proposed use pattern.

Since all applications were made with ground equipment, there is no indication of residue levels resulting from application by air. Until some comparatire data on residues resulting from aerial application is available, it will be necessary to limit the proposed use to application by ground equipment, only. A new Section B reflecting this change in labeling will be needed.

The samples were analyzed using the MMS-R-478-1 methiod from PAM II which has been validated for enforcement purposes, samples were stored at -10°C from harvest to analysis. Storage periods were from a few days up to 4 months in 5 studies, and for a period of 10 months in the Ohio study. Storage stability in beet roots for 11 months resulted in 89% recovery (PP#4E3104); in cottonseed for 23 month (PP#6G1755) and in apples, alfalfa and sorghum grain for 21 months (PP# 2023) there was no apparent loss of fenvalerate residues during storage. Therefore, there is no reason to question residues reported in this petition in regard to storage stability.

Residue data presented for carrots ranged from 0.06 ppm to 0.27 ppm, with control values, in all trials, of <0.01 ppm. The two analytical determinations for each trial are as follows, according to State location:

State	Residues (ppm)
Michigan	0.06, 0.09
California	0.27, 0.27
Texas	0.07, 0.08
Oregon	0.08, 0.11
New York	0.13, 0.13
Ohio	0.12, 0.20

Data can also be translated from residue data reported in PP#4E3104 for red beet roots at a 7-day PHI. Residues reported according to State location were:

State	Application lb. a.i./A (Total)	Residue (ppm)
New Hampshire	0.8	0.06 - 0.20
	1.6	0.20 - 0.40
Michigan	1.2	0.13 - 0.24
	2.4	0.41 - 0.53
Oklahoma	1.4	0.05 - 0.11

All residues in beets were within the proposed 0.5 tolerance for carrots except the 0.53 ppm value which resulted from 2.4 lbs a.i./A. The maximum rate, according to the proposed use for carrots, is 2.0 lbs. a.i./A.

The residue data presented in this petition compare closely with the results previously reported for red beets. The geographical distribution of carrot data is good (77% of acerage within the 6 states represented). There are no aberrant values within the carrot and beet data and the range of values (0.06 - 0.4 ppm) is rather compact. It is concluded that these data are adequate to estimate a tolerance level for the proposed use in carrots - 0.5 ppm for fenvalerate residues in carrots is appropriate, as proposed.

Meat, Milk, Poultry and Eggs:

Tolerances are established for cattle (fat, meat and meat byproducts) at 0.5 ppm, for milk at 0.3 ppm and for milk fat at 7.0 ppm. Because of expense and availability carrots are used as cattle feed (culled carrots - Ca. 30% of total crops) are sold for cattle feed, but are not fed to poultry and other livestock.

A cattle diet intended to include the highest concentration of fenvalerate residues, could be:

	Tolerance (ppm)	X	% in diet	=	ppm in diet
Apple pomace	20.0	X	50		10.0
Soybean	0.05	X	25		1.25
Carrots	0.5	X	25		12.5
					23.75

From a feeding study reviewed previously (PP#OF2367, K. Arne, 1/5/82) 80 ppm of C^{14}-benzyl labeled fenvalerate resulted in concentrations in meat and milk as folows:

Commodity	80 ppm in Diet	23.75 ppm in Diet	Tolerance Established
Milk	0.76	0.24	0.3
Milk fat	16.47	4.89	7.0
Meat	0.3	0.09	1.5
Fat	3.36	1.00	1.5

These tabulations show that fenvalerate residue values in meat, meat byproducts, milk and milk fat, extrapolated from the referenced feeding study results, indicate that the presently established tolerances would not be exceeded by secondary residues derived from carrots containing 0.5 ppm of fenvalerate. It is concluded that the established tolerances for meat and milk are adequate to allow for a tolerance of 0.5 ppm fenvalerate in carrots, as proposed by this petition.

Other Considerations:

The International Residue Status sheet is attached. There are no tolerances, internationally, for fenvalerate on carrots. There is a Codex tolerance for root and tuber vegetables at 0.05 ppm. Since the basis of tolerance, fenvalerate per se, is the same in U.S. and Codex, it is assumed that the use as proposed for carrots differs greatly from the international registered use.

RCB:TS-769:F.Boyd:vg:CM#2:Rm810:X77377:5/3/85
cc: R.F., Circu., Reviewer, TOX, EEB, EAB, FDA, Thompson, PP#5F3171
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