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

OCT 15 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 84-TX-40 Proposed Section 18 exemption for the use of fenvalerate, trade name: Pydrin 2.4 EC, on grain sorghum for the control of sorghum head worm in Texas.

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On September 4, 1984, the Texas Department of Agricultrure issued a crisis exemption for the use of fenvalerate (cyano (3-phenoxyphenyl)methyl-4-chloro-alpha-(1-methylethyl) benzene acetate), trade name: Pydrin 2.4 EC, on grain sorghum for the control of sorghum headworn. They now request a specific exemption for this use.

No metabolism studies of fenvalerate on a grain crop are available. However, metabolism studies on cotton, apples, lettuce and tomatoes have been submitted and reviewed in connection with PP#'s 6G1755, 8G2024, 0E2367 and 0F2375. These studies show that fenvalerate does not readily translocate and that the major residue is the parent compound (10/29/81 review of PP#1F2430 by K. Arne). A photodegradation product of fenvalerate, 4-chloro-beta-(1-methylethyl)-alpha-(3-phenoxyphenyl) benzenepropanenitrile, has been observed

on a variety of raw agricultural commodities and may comprise up to 34% of the total residue. TOX has now concluded, though, that the photodegradate is not of concern (7/19/84 memorandum of A.B. Kociakski). For the purposes of this §18 exemption, we consider the nature of the residue to be adequately understood. The residue of concern in plants is the parent, fenvalerate.

Tolerances for are established for the parent fenvalerate on a variety of raw agricultural commodities and animal feeds, and range from 0.02 ppm in/on corn grain to 50 ppm in/on corn forage and fodder. (CFR 40 §180.379 and CFR 21 §561.97).

The proposed use calls for multiple treatments with Pydrin 2.4 EC at an application rate of 0.05-0.1 lb ai/A. The total dosage per season is not to exceed 0.6 lb ai/A and a 21 day PHI will be observed. This use is the same as that proposed for grain sorghum in PP#4F3003 (currently in reject status).

The analytical method used to determine residues of fenvalerate per se is Method I in PAM II. This method has undergone a successful method trial for cottonseed, meat and milk. The method was used for sorghum grain, forage, fodder, and processed commodities in connection with PP#4F3003 (5/1/84 review of R. Perfetti). It will be adequate for enforcement of this §18 exemption. Method sensitivity is 0.01 ppm.

Residue data for grain sorghum (PP#4F3003/Acc#0F072171) reflect 13 field studies in TE, MO, AR, KS, CA, SD and OK in which Pydrin 2.4 EC was applied 5-9 times, either by aircraft (1) or ground equipment, at a total dosage for all treatments of 0.55-2.0 lbs ai/A (0.9 - 3.3 X total proposed dose).

Following a dosage 0.55-0.6 lbs ai/A (0.9-1X from 5-9 applications at the rate of 0.05-0.2 lbs ai/A), sorghum grain sampled 30-32 days after the last treatment showed residue ranging from 0.33 ppm to 2.6 ppm Pydrin. Following a dosage of 0.65 lbs ai/A (1.1X from 9 applications at the rate of 0.05-0.2 lbs ai/A), residue in sorghum grain was 0.32-5.51 ppm at 30-32 day PHI's. Following a dosage of 1.0 lb ai/A (1.7X from 5 applications at the rate of 0.2 lb ai/A) sorghum grain sampled 21 days following the last treatment showed residues ranging from 1.13 to 7.89 ppm. Following a dosage of 2.0 lbs ai/A (from 5 applications at the rate of 0.4 lb a.i./A), sorghum grain sampled 21-22 days following the last treatment showed residues ranging from 3.85 to 4.11 ppm. On the basis of these data, we conclude that residues of fenvalerate per se in/on sorghum grain will not exceed 5 ppm as a result of the proposed use.

Following a total dosage of 1.0 lb ai/A (1.67X from 5 applications at the rate of 0.2 lb ai/A), residue of fenvalerate per se in/on sorghum forage and fodder ranged

from 2.30-16.97 ppm when sampled 21 days following the last treatment. Following a total dosage of 0.55-0.65 lbs ai/A (0.9-1.2x from 5-9 applications at the rate of 0.05-0.1 lbs ai/A), residue ranged from 0.09-6.63 ppm in/on sorghum forage and fodder sampled 30-32 days following the last treatment.

Residue data are also available for field corn forage and fodder reflecting the use proposed for sorghum. (PP#2F2598/ Acc#070452; 3/11/82 review by K. Arne). For corn forage and fodder following a total dosage of 1 lb ai/A (1.67x from 5 applications at the rate of 0.2 lb ai/A), residue of fenvalerate per se did not exceed 12.1 ppm at a 21 day PHI. At twice this dosage and 21-23 day PHI's, residue did not exceed 30.9 ppm.

On the basis of the above residue data for the forage and fodder of both grain sorghum and field corn, we conclude that residues of fenvalerate per se in/on sorghum forage and sorghum fodder will not exceed 10 ppm from the proposed use provided that a restriction against foraging treated sorghum for 21 days after treatment is added to the label.

In a milling study (PP#4F3003/Acc#072171), sorghum grain containing up to 1.7 to 2.6 ppm (replicates) of fenvalerate showed concentration of residues in bran (8.5 ppm) and germ rich feed (8.8 ppm). No apparent concentration of residues was observed in grit, meal or flour. The maximum concentration factors for bran and germ rich feed were 5X and 5.2X, respectively.

On the basis of these data , we conclude that residues of fenvalerate per se in/on sorghum flour will not exceed the actionable level set for sorghum grain (i.e., 5 ppm).

On the basis of these data, we conclude that residues of fenvalerate per se in/on sorghum milling fractions (except flour) will not exceed 30 ppm.

Meat, Milk, Poultry and Eggs

The nature of the residue in ruminants is adequately understood. The residue of concern in ruminants consists of the parent. (9/13/84 review of PP#4F3003 and PP#4F3004 by R. Perfetti).

The nature of the residue in poultry is not considered to be adequately understood because 46-60% of the radioactivity in poultry liver was unextractable (2/21/84 review of PP#2F2657/ Acc#072242 by K. Arne). However, for the limited purpose of this §18 use, we consider the nature of the residue in poultry to be adequately understood. The residue of concern in poultry consists of the parent.

The maximum dietary burden of fenvalerate for beef cattle will not change as a result of the proposed use because the maximum intake of Pydrin would result from a diet of 50% corn forage and fodder and 50% dried apple pomace. Thus, we conclude that secondary residues of fenvalerate per se in the meat, fat, and meat byproducts of cattle will not exceed the established tolerance of 1.5 ppm.

The potential for residues of Pydrin in the feed of other food animals is less than that for cattle. We therefore also conclude that the 1.5 ppm tolerances would be adequate for the meat, fat, and meat byproducts of sheep, hogs, horses, and goats.

For dairy cows, a diet that would result in a maximum potential for secondary residues in milk is as follows:

	Tolerance (ppm) or action level	%of Diet	PPM in Diet
Sweet corn cannery waste	50	50	25
Apple pomace	20	25	5
Sorghum grain	5	25	1.25
			31.25

When lactating cows were fed ^{14}C Pydrin at 80 ppm in the feed, the milk produced contained residues of up to 0.76 ppm, the milk fat up to 16.5 ppm (in Pydrin equivalents). An eariler feeding study at 10.9 ppm produced residues of up to 0.1 ppm in milk and 1.92 ppm in milk fat. (3/3/82 review of PP#1F2430 by K. Arne).

The 80 ppm feeding study indicates that the above diet would produce Pydrin levels of 0.30 and 6.5 ppm in milk and milkfat, respectively. The 10.9 ppm feeding study indicates that the above diet would produce Pydrin levels of 0.29 and 5.5 ppm in milk and milkfat, respectively. We conclude that the tolerance of 7 ppm in milkfat and 0.3 ppm in whole milk will not be exceeded as a result of the proposed use.

For poultry, a diet containing the maximum residues of Pydrin would consist of the following:

	Tolerance or action level	%of Diet	PPM in Diet
Apple pomace	20	5	1.0
Sorghum grain	5	60	3.0
Corn grain	0.02	35	<0.01
			4.0

Below are the maximum ^{14}C activities found in poultry tissues and eggs, expressed as Pydrin, following several feeding levels:

Feeding level (ppm)	Maximum residue (ppm)				
	skin	liver	fat	meat	yolk
9	0.04	0.6	0.08	<0.02	0.14
29	0.06	0.94	0.33	<0.06	0.41
86	<0.2	3.4	0.36	<0.2	1.2

The above feeding studies indicate that the aforementioned diet containing the maximum residues of Pydrin (4 ppm) would result in secondary residues of 0.06 ppm in eggs. Since no available feeding studies reflect a feeding level of ≤4 ppm and since a higher proportion of secondary residues in eggs may occur at lower feeding levels, we conclude that an actionable level of 0.1 ppm is necessary for secondary residues in eggs.

Below are maximum secondary residues expected in poultry liver and meat as a result of 4 ppm Pydrin in the diet of poultry:

Expected residue in	Expected secondary residues (ppm)		
	Based on 9 ppm feeding study	Based on 29 ppm feeding study	Based on 86 ppm feeding study
liver	0.27	0.13	0.16
meat	<0.008	<0.008	<0.009

On the basis of the available feeding studies, we conclude that secondary residues of Pydrin in the meat, fat, and meat byproducts of poultry will not exceed 0.5 ppm. In arriving at this actionable level, we have taken into consideration that the actionable level must accomodate residues that may occur in all meat products and that no available feeding studies reflect feeding levels ≤4 ppm. Therefore, the 0.5 ppm actionable level is needed.

Conclusions

1. The residue of concern is the parent fenvalerate (cyano (3-phenoxyphenyl) methyl-4-chloro-alpha-(1-methylethyl) benzene acetate).

2a. The analytical method for determination of residue of the parent is Method I in PAM II. Method Sensitivity is 0.01 ppm.

2b. Reference standards of fenvalerate are available in the U.S. EPA Pesticides and Industrial Chemicals Repository.

3a. Residue of fenvalerate per se will not exceed 5 ppm in/on sorghum grain and flour as a result of the proposed use.

3b. Residue of fenvalerate per se will not exceed 30 ppm in/on sorghum milling fractions (except flour) as a result of the proposed use.

3c. Residue of fenvalerate per se will not exceed 10 ppm in/on sorghum forage and fodder as a result of the proposed use at a 21 day PHI. A restriction against foraging treated sorghum for 21 days after treatment should be added to the label.

4a. Residues of fenvalerate per se in the meat, fat, and meat byproducts of cattle, goats, horses, hogs and sheep will not exceed the established tolerances of 1.5 ppm as a result of the proposed use.

4b. Residue of fenvalerate per se in milk and milkfat will not exceed the established tolerances of 0.3 ppm and 7 ppm, respectively, as a result of the proposed use.

4c. Residue of fenvalerate per se in the meat, fat, and meat byproducts of poultry will not exceed 0.5 ppm as a result of the proposed use.

4d. Residue of fenvalerate per se in eggs will not exceed 0.1 ppm as a result of the proposed use.

Recommendation

TOX considerations permitting and provided the restriction specified in conclusion 3c is added to the label, we have no objections to the issuance of this Section 18 exemption. An agreement should be made with FDA regarding the legal status of the treated commodities.

TS-769:RCB:M.Loftus:vg:CM#2:Rm810:X77484:10/12/84
cc: RF, Circu., Reviewer, Fenvalerate or Pydrin S.F., §18 S.F.
RDI: Zager, 10/10/84; Schmitt, 10/10/84