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

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Memorandum

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: 86-LA-12. Proposed Section 18 for Fenvalerate (Pydrin® 2.4EC, EPA Reg. No. 201-401) on Grain Sorghum.
RCB #1224

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To: Emergency Response and Minor Use Section
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

The Louisiana Department of Agriculture requests a section 18 specific exemption for the use of fenvalerate (Pydrin® 2.4EC, 2.4 lbs.a.i./gallon emulsifiable concentrate) on approximately 350,000 acres of grain sorghum to control sorghum midge. Section 18 exemptions were issued to Texas in 1984 (M. Loftus, 10/15/84) and 1985 (L. Cheng, 6/6/85) for applications of fenvalerate to sorghum.

Tolerances are established for residues of fenvalerate [cyano(3-phenoxyphenyl)methyl-4-chloro-alpha-(1-methylethyl)benzene acetate] ranging from 0.02 ppm in corn grain, peanuts and potatoes to 50 ppm in corn forage and fodder; and include 0.3 ppm in milk, 7 ppm in milk fat, and 1.5 ppm in the meat, fat and meat by-products of cattle, goats, hogs, horses and sheep. Tolerances are not established for poultry and eggs. Numerous tolerances are pending including the following:

| | |
|---|---|
| Sorghum fodder | 50 ppm |
| Sorghum forage | 50 ppm |
| Sorghum milling fractions | 50 ppm |
| Sorghum grain | 10 ppm |

A Registration Standard has not been completed for fenvalerate nor is one scheduled within the next year.

The proposed use calls for applications of Pydrin® 2.4EC at rates of 0.025-0.05 lbs.a.i./A/application as necessary to a maximum total application of 0.6 lbs.a.i./A/season. Virtually all applications would be made by aerial equipment, and a 21-day PHI would be imposed. Sorghum forage would not be used as animal feed within 21 days of treatment.

A metabolism study utilizing applications of Pydrin® to wheat was reviewed by E.T. Haeberer (5/3/85). No evidence was found of translocation of Pydrin® to new growth or to other plant parts. The major residue found was Pydrin per se with minor amounts of other components. The metabolism of pydrin in small grains is considered adequately understood. The residue of concern includes only the parent compound.

The metabolism of pydrin in ruminants is also considered adequately understood (R. Perfetti, 5/1/84; 9/13/84). The residue of concern consists only of pydrin.

The metabolism of pydrin in poultry is not adequately understood at this time pending further identification of uncharacterized residues in poultry liver (E.T. Haeberer, 2/26/86). However, for the limited purposes of this section only, we consider the poultry metabolism of fenvalerate adequately delineated.

The analytical methods used to determine residues of pydrin in animal and plant commodities are MMS-R-478-1 (most studies) and MMS-R-456-1 which is similar. The former method has undergone successful method try-out for cottonseed, meat and milk (PP#7F2013). Briefly, the raw agricultural commodity is extracted with hexane/isopropanol (3/1), filtered, and the isopropanol is extracted into water. The remaining hexane is either partitioned with acetonitrile followed by florisil column clean-up (for oily crops), or cleaned-up on florisil without prior partitioning. Analysis is accomplished by GLC using an electron capture detector. Recoveries ranged from 68-137% at fortification levels of 0.05-5.0 ppm for various sorghum commodities.

Residue data for sorghum were submitted with PP#4F3003/FAP#4H5419 (Acc. No. 072171). Pydrin® 2.4EC was applied at rates of 0.05-0.4 lbs.a.i./A for 5-9 applications (1 study utilized aerial applications). Residues are summarized in the following table.

| Commodity | PHI (days) | Residue (ppm) |
|---|---|---|
| Sorghum grain | 22 - 29 | 1.13 - 7.89 |
| | 30 - 32 | 0.32 - 5.51 |
| Sorghum Forage | 22 - 29 | 7.35 - 15.06 |
| | 30 - 32 | 0.09 - 6.63 |
| Sorghum stover | 22 - 29 | 2.30 - 16.97 |
| Sorghum fodder | 30 - 32 | 2.10 - 4.17 |

A sorghum processing study using sorghum grain containing 1.7-2.6 ppm (replicate) fenvalerate residues indicated the following concentration factors in processed sorghum commodities.

| | |
|---|---|
| Bran | 5.0 X |
| Germ | 5.2 X |
| Grit, meal, flour | No concentration |

Utilizing the above data as well as residue data translated from corn forage and fodder to sorghum (see R.B. Perfetti, 9/13/84), we conclude that residues of fenvalerate will not exceed the following values as a result of the proposed use:

| Commodity | Maximum Likely Residue (ppm) |
|---|---|
| Sorghum grain | 10 |
| " forage | 50 |
| " fodder | 50 |
| " milling fractions | 50 |
| " flour | 10 |

Meat, Milk, Poultry and Eggs

The diets of cattle and poultry could contain residues of fenvalerate as shown in the table below.

| | | Percentage of Diets (and resulting ppm) | | | |
|---|---|---|---|---|---|
| | | Cattle | | Poultry | |
| Commodity | Tolerance | Beef | Dairy | Turkeys/ Broilers | Laying Hens |
| Apple pomace | 20 | 50 (10) | 10 (2) | 5 (1) | |
| Corn fodder | 50 | 30 (15) | 50 (25) | | |
| Corn grain | 0.02 | | | 5 (0.001) | |
| Peas | 0.25 | | | 10 (0.025) | 40 (0.1) |
| Soybeans | 0.05 | | | 20 (0.01) | |
| Sorghum grain | 10 | 20 (2) | 40 (4) | 60 (6) | 60 (6) |
| Residues in diet from water, resulting from space use | | | | (11.5) | (11.5) |
| Residues in diet (other sources) from space use | | | | (4.0) | (4.0) |
| Total residues in diet | | 27 ppm | 31 ppm | 22.5 ppm | 22.5 ppm |

Dermal use of fenvalerate could add 0.05 ppm residues to poultry tissues and eggs. It should be noted that many tolerances are currently pending which could significantly increase the dietary exposure of animals to fenvalerate.

A cattle feeding study was reviewed previously in conjunction with a proposed tolerance for Pydrin® on apples and tomatoes (K. Arne, 1/5/82). Five lactating cows were administered $^{14}C$-labelled fenvalerate (labelled at either the p-chlorophenyl or phenoxyphenyl moiety) at a level of approximately 80 ppm for 21 days. Three animals were sacrificed 12 hours after the last dose, and the remaining 2 were given untreated feed and sacrificed at 10 and 20 days following the last dose. Maximum residues found 12 hours after sacrifice are summarized in the table below. In cows sacrificed 10 and 20 days after the last dose of pydrin, residues decreased considerably for all tissues except liver and kidney where residues remained the same or increased slightly.

| Tissue | Maximum Residue (ppm) |
|---|---|
| Cattle, muscle | 0.3 |
| , kidney | 1.59 |
| , liver | 2.21 |
| , fat | 3.36 |

Milk samples were also obtained from these cattle and analyzed for residues of pydrin. Residues were found to plateau between days 3 and 7 with a maximum residue of 0.76 ppm found.

A poultry feeding study was submitted in conjunction with PP#2F2657/2H5340 (memo K. Arne, 2/21/84). Poultry were fed $^{14}C$-labeled fenvalerate in their feed at 9, 29 and 86 ppm for periods of 50, 23 and 23 days respectively. Maximum activity in tissue and eggs, expressed as pydrin equivalents, are summarized in the table below. Most of the residue found in meat, fat and egg yolk was parent pydrin. 47-60% of the residue in liver was not extractable, and of that which was extractable, none was parent.

| ppm in Feed | Maximum Residue (ppm) | | | |
|---|---|---|---|---|
| | Liver | Fat | Meat | Egg Yolk |
| 9 | 0.60 | 0.08 | <0.02 | 0.14 |
| 29 | 0.94 | 0.33 | <0.06 | 0.41 |
| 86 | 3.4 | 0.36 | <0.2 | 1.2 |

Based on these data, we conclude that the established tolerances of 0.3 ppm for milk (7 ppm in milk fat), and 1.5 ppm in the meat, fat and meat by-products of cattle, goats, hogs, horses and sheep are not likely to be exceeded as a result of the proposed use. Residues are not likely to exceed 1.2 ppm in the meat, fat and meat by-products of poultry, and 0.5 ppm in eggs.

Conclusions

(1) The metabolism of fenvalerate in plants and animals is adequately understood for the purposes of this section 18. The residue of concern includes the parent compound only.

(2) Analytical methods are available for enforcement (PAM II, Methods I and II).

(3) Fenvalerate residues are not likely to exceed the following values as a result of the proposed use on sorghum: 10 ppm on sorghum grain; 50 ppm in sorghum forage and fodder; 50 ppm in the milling fractions of sorghum; 10 ppm in sorghum flour; 1.5 ppm (established tolerance) in the meat, fat and meat by-products of cattle, goats, hogs, horses and sheep; 0.3 ppm in milk and 7 ppm in milk fat (established tolerances); 1.2 ppm in the meat, fat and meat by-products of poultry; and 0.5 ppm in eggs.

(4) Analytical reference standards are available from the Pesticides and Industrial Chemicals Repository.

Recommendations

TOX considerations permitting, RCB has no objections to this section 18. An agreement should be made with the FDA regarding the legal status of the treated commodities in commerce.

cc: Fenvalerate (Pydrin®) S.F., R.F., Section 18 S.F., Circu, M. Metzger, PMSD/ISB
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