R.F.

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

APR 12 1989

MEMORANDUM

SUBJECT: 89-MT-05. Section 18 Exemption for the use of Esfenvalerate (Asana® XL 0.66 EC) on Small Grains to Control Russian Wheat Aphid(RWA).
EPA Reg. No. 352-515.
(No MRID #, DEB # 5145).

From: Freshteh Toghrol Ph.D., Chemist F. Toghrol
Special Registration Section II
Dietary Exposure Branch
Health Effect Division (H7509C)

THRU: Francis B. Suhre, Acting Section Head Francis B Suhre
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To: D. Stubbs/Jim Tompkins, PM 41
Emergency Response Section
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and
Toxicology Branch
Health Effect Division(H7509C)

The Montana Department of Agriculture requests a Section 18 exemption for the use of esfenvalerate to control Russian wheat aphid (Diuraphis noxia) in or on small grains.

Asana® XL 0.66 EC (EPA Reg. No. 352-515) is a registered pesticide (insecticide) of E.I. DuPont DeNemours & Co.; the product contains 8.4% s-fenvalerate (0.66 lb/gal) as its active ingredient .

A maximum of 250,000 acres of wheat and 100,000 acres of barley will be treated with 0.03 to 0.05 lbs of active ingredient per acre in a total of 26,250 gallons of Asana XL insecticide.

Tolerances are established (40 CFR 180.379) for fenvalerate [cyano(3-phenoxyphenyl)methyl-4-chloro-alpha-(methyl-ethyl) benzeneacetate] in or on numerous commodities, ranging 0.02 ppm for peanuts to 50.0 ppm for corn forage and fodder; to include (but not limited to): meat, fat and meat by-product of cattle, goats, hogs, horses and sheep at 1.5 ppm; and milk at 0.3 ppm.

Tolerance petitions (PP# 6E3404, F. Griffith, 6/23/86; and PP#5F3172, M. Bradley, 1/30/85; and PP#4F3021, E.T. Haeberer, 5/3/85) for fenvalerate on mustard green, spinach, and small grain are in rejection status (for data gap in plant and animal metabolism). Pending tolerances include those for barley grain at 5 ppm, barley straw, forage and hay at 40 ppm, wheat grain at 1 ppm, wheat straw, forage and hay at 25 ppm.

Feed tolerances are established (21 CFR 561.97) for residues of fenvalerate in or on dried apples pomace at 20 ppm,dried tomato pomace at 10 ppm, soybean hulls at 1.0 ppm, sugarcane bagasse at 20 ppm, and sunflower hull at 2.0 ppm.

No plant or animal metabolism studies were submitted with this request. However metabolism data were previously submitted in connection with PP#4F3003/FAP#4H5419 and PP#4F3021. For the purpose of this Section 18, we consider the metabolism of fenvalerate in small grains to be adequately understood. The residue of concern is fenvalerate, per se (all isomers).

89-MT-05 calls for a single aerial or ground application of Asana XL Insecticide at 0.03 to 0.05 lb ai/A and a 21 day PHI.

The analytical method for fenvalerate described in PAM II is adequate for enforcement purposes. Fenvalerate standards are available from the EPA Repository.

Residue data reflecting 2 applications of pydrin (EPA Reg. No. 201-401; 0.72 lb S, and R-fenvalerate ai/gallon) to small grains at 0.2 or 0.4 lb ai/A (ca 10X the proposed rate for 89-MT-05) were submitted in conjunction with PP#4F3021/4H5423 (E.T. Haeberer, 5/3/85). These data are summarized below:

States (ppm)	Commodity	lb ai/A(total)	PHI	Maximum Residue
ND	Wheat grain	0.4	21	0.15
WA		0.4	21	0.65
OK		0.4	21	<0.01
NY		0.4	21	0.1
TX		0.4	7	0.3
ND	Wheat Straw	0.4	21	19.3
WA		0.4	21	20.6
OK		0.4	21	0.98
NY		0.4	21	15.0
TX		0.4	7	44.0
CA	Barley grain	0.4	21	0.03
ND		0.4	21	3.39
WY		0.4	21	0.93
OK		0.4	21	0.31
NY		0.4	21	2.5
CO		0.4	7	1.5
ND	Barley straw	0.2	21	32.9
WY		0.2	21	4.2
OK		0.2	21	1.7
NY		0.2	21	15.0

Based on these data we estimated that residues of s-Fenvalerate will not exceed 5.0 ppm in or on wheat and barley grain; and 40 ppm in or on wheat and barley forage and fodder as a result of this Section 18 request.

Meat, Milk, Poultry and Eggs:

Wheat and barley (grain, forage and hay, straw and milled products) are important animal feed items. Wheat and barley grains may account for up to 50 and 80% of the daily diet of beef and dairy cattle, and up to 70% of the daily diet of poultry. Furthermore, the forage, fodder and straw of small grain crops may account for up to 25 and 70% of the daily diet of beef and dairy cattle.

Based on estimated fenvalerate residues of 5.0 ppm in or on wheat and barley grains, and 40 ppm in or on the forage and fodder of these grains; we estimate a maximum fenvalerate dietary burden of 30 ppm for cattle, and 4.0 ppm for poultry may result from this Section 18 request.

In support of PP#0F2367/PP#H5266, (K. Arne memo, 6/5/82, a lactating cow was fed 80 ppm ^{14}C fenvalerate for 21 days and was sacrificed 12 hours after the last dose; fevalerate residues were found as follows:

Tissue	Fenvalerate ppm
muscle	0.3
kidney	1.5
liver	2.21
fat	3.36
milk	0.76(7 days)

Since the anticipated dietary burden to cattle from this proposed section 18 is 0.4X the dose used in this study, we conclude that residues resulting from this Section 18 use will not exceed 0.3 ppm in milk, and 1.5 ppm in meat, fat, and mbyp.

Residues of fenvalerate in poultry (PP#2F2657, memo of k. Arne, 2/21/84) fed 9 ppm ^{14}C fenvalerate for 50 days were 0.6 ppm in liver, 0.08 ppm in fat, <0.02 ppm in meat, and 0.14 ppm in egg yolk. Based on these data, we estimate that residues of fenvalerate are not likely to exceed 0.1 ppm in poultry meat, (except for liver, 0.5 in liver), and 0.5 ppm in eggs as a result of this Section 18 request.

Conclusions:

1. The metabolism of s-fenvalerate in plants and animals is adequately understood for the purpose of this Section 18. The residue of concern is fenvalerate.

2. Analytical method I for fenvalerate or esfenvalerate as described in PAM II, is adequate for enforcement purposes. Analytical reference standards of fenvalerate are available from the EPA Repository.

3. Residues of fenvalerate per se (all isomers) are not expected to exceed 5.0 ppm in or on wheat and barley grain, and 40.0 ppm in or on wheat and barley forage and fodder, as a result of this section 18 request.

4. Fenvalerate residues are not expected to exceed the established tolerances of 1.5 ppm in meat, fat, milk, and meat by-products of cattle, goats, hogs, horses, and sheep; and 0.3 ppm in milk, as a result of this Section 18 request.

5. Fenvalerate (esfenvalerate) residues are not expected to exceed 0.1 ppm in poultry meat, and 0.5 ppm in eggs as a result

of this Section 18 request.

Recommendations:

TOX considerations permitting, DEB 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 S.F., R.F., Section 18 S.F., Circ., F. Toghrol, PMSD/ISB, TAS (S. Stanton), Schmitt.
RDI: F. B. Suhre Acting Section Head (4/6/89): E. Zager: Acting Deputy Chief (4/11/89):
TS-H7509C:DEB:F.Toghrol:F.T.:RM:802:CM#2:4/11/89