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

JUN 5 1986

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: 86-MT-09 Section 18 request for use of Sethoxydim (Poast) on Safflower in Montana
[No Accession No., RCB No. 1012]

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The State of Montana Department of Agriculture requests a Section 18 Specific Exemption for the use of Poast (EPA Reg. No. 7966-58) to control wild oats and volunteer cereal grains on safflower. Poast contains 18% sethoxydim [2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one], or 1.5 lb ai/gal.

Tolerances have been established for residues of 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety in or on cottonseed, soybeans, sugarbeet tops and roots, milk, and meat, fat, and meat byproduts of cattle, goats, hogs, horses, poultry, and sheep at levels ranging from 0.05(N) to 10 ppm. (40 CFR 180.412). A Feed Additive tolerance has been established for residues in cottonseed soapstock at 15 ppm (21 CFR 561.430). Tolerances for residues of sethoxydim in alfalfa, fruiting vegetables, peanut, tomato and sunflower commodities are pending.

Proposed Use

Poast (EPA Reg. No. 7969-58), containing 1.5 lb ai/gal is to be applied at the rate of 1-1/2 pt formulation (0.28 lb ai) per acre along with 2 pt oil concentrate in a minimum of 5 gallons per acre. Ground or aerial application can be used. To control volunteer cereal grains, Poast can be applied before tillering when the weeds are up to 6" and prior to wintering. To control wild oats, Poast can be applied when weeds are up to 4". A 70 day PHI is imposed. One application per season is allowed.

The label should be changed to indicate that the oil concentrate should be EPA approved.

Nature of the Residue

a. Plants

The metabolism of sethoxydim in sugarbeets and soybeans and alfalfa has been previously discussed (PP#3F2904, K. Arne, 6/26/85). The metabolism of sethoxydim is very complex, although the majority of the terminal residue consists of compounds containing the 2-cyclohexen-1-one moiety. This moiety is detected in the analytical methodology.

The nature of the residue is considered adequately understood for the purposes of this Section 18 request. The residue of concern in safflower is sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety.

b. Animals

The metabolism of sethoxydim in lactating goats and laying hens has been discussed in connection with PP#3F2904 (K. Arne, 6/26/85).

In goats, metabolism of sethoxydim involves oxidation of the sulfur atom to the sulfoxide and the sulfone, demethylation to form a "nor" series of metabolites, hydroxylation of the ring in the 5-position, de-ethoxylation of the imino group, and formation of an oxazole via Beckman rearrangement. The majority of these residues are determined by the analytical methodology, however, additional validation data were requested. For the purposes of this Section 18 request, we will consider the metabolism in ruminants to be adequately understood.

The laying hen metabolism study submitted in connection with PP#3F2904 was considered inadequate for determining the nature of the residue in poultry because characterization was attempted only for liver, and since the proposed methodology is capable of determining only 44% of the liver 14C activity, 43% of the fat activity, and 64% of the muscle

activity. The residue in eggs was considered adequately understood. Additional attempts at characterization in liver, fat, and muscle were requested (PP#3F2904, K. Arne, 6/28/85). For the purposes of this Section 18 request, the residue of concern in poultry will be considered to be sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety, determined by the available analytical method.

Analytical Method

An analytical method is available for the determination of sethoxydim residues in sunflower commodities, "Determination of BAS 9052H and its metabolite residues in Sunflower Seed and sunflower Seed Process Fraction Samples (Sunflower Seed, Hull, Meal, Crude Oil, Soapstock, and Refined Oil)." This method was submitted with this Section 18 request and had previously been submitted in connection with PP#3F2950. It has been reviewed in connection with PP#3F2950/FAP#3H5413 and PP#5F3234/5H5464 (M.P. Firestone, 7/17/85).

The method involves extraction with methanol/water and various cleanups depending on the commodity. The residue is oxidized with hydrogen peroxide to the substituted pentanedioic esters. The residues are cleaned up by solvent partitioning and column chromatography. Analysis is by GC using a column packed with 3% OV-17 on Chromosorb W-HP 100/120 mesh. A Flame Photometric Detector (FPD) was used in the sulfur mode. This method is similar to BWC Method 30, "Gas Liquid Chromatographic Determintion of Residues of Poast and its Metabolites in Soybean Seed, Soybean Seed Process Fractions, Chicken Tissues, Beef Tissues, Milk, and Eggs," which has undergone a successful method trial on soybeans, milk, and liver. This method is considered adequate for enforcement purposes, and is designated PAM II Method I.

An analytical reference standard of sethoxydim is available from the EPA Pesticide and Industrial Chemical Repository in RTP (code 6068).

Residue Data

No residue data on safflower were submitted with this Section 18 request. Residue data on sunflower commodities, which were originally submitted in connection with PP#3F2904 were resubmitted with this request.

Sunflower field trials were conducted in the states of MN, ND, TX, KS, and OK. A single application at the rate of 0.5 lb ai/A was made. PHI's ranged from 53 to 118 days. The method of application (ground or air) was unclear. Total sethoxydim residues ranged from 0.08 to 5.8 ppm in or on sunflower seeds. A tolerance of 7 ppm was recommended. In the absence of evidence that the data reflected aerial application, a prohibition against aerial application was recommended (PP#3F2904, K. Arne, 6/28/85).

The proposed rate of application on safflowers is 0.3 lb ai/A. Based on this application rate, we estimate that residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety are not likely to exceed 5 ppm.

Sunflower seed processing studies were resubmitted with this Section 18 request, and were submitted earlier with PP#3F2904. Maximum concentration factors in sunflower commodities were 0.5 in hulls, 2.6 in meal, 0.35 in crude oil, 0.1 in refined oil, and 1.9 in soapstock. Only residues in sunflower meal and soapstock concentrated on processing. Sunflower meal is an animal feed item. A food additive tolerance of 20 ppm was recommended (PP#3F2904, K. Arne, 6/28/85).

Safflower meal is also an animal feed item. Based on a concentration factor of 3, we estimate that residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety will not exceed 15 ppm. Residues would not be expected to exceed 2 ppm in crude oil and 0.5 ppm in refined safflower oil.

Meat, Milk, Poultry, and Eggs

Safflower seed and safflower meal are animal feed items. Tolerances have been established for residues of sethoxydim and metabolites in/on the cottonseed at 5 ppm, soybeans at 10 ppm, sugarbeet tops at 0.1 ppm, sugar beet roots at 0.2 ppm, and a feed additive tolerance has been established for residues of sethoxydim and metabolites in cottonseed soapstock at 15 ppm.

Considering all possible feed items associated with this Section 18 request and existing tolerances, the maximum dietary burden would be 10.25 ppm for poultry and 10.75 ppm for cattle. The results of cattle and poultry feeding studies are discussed in our review of PP#2F2748 (J. Onley, 12/15/82). When poultry were fed 10 ppm sethoxydim, maximum secondary residues were <0.05, 0.17, and 0.34 ppm in the muscle, liver, and eggs, respectively. When cattle were fed 50 ppm sethoxydim, maximum residues were <0.05, 0.10, 0.15, and <0.05 ppm in the muscle, kidney, liver, and milk, respectively.

The established tolerances of 0.05 ppm for milk, 0.5 ppm for eggs, and 0.2 ppm for meat, fat, and meat byproducts will be adequate to cover secondary residues resulting form the use of sethoxydim on safflower and from other registered uses of sethoxydim.

Conclusions

1. The directions for use should be revised to require use of an EPA approved oil concentrate.

2. For the purposes of this Section 18 request, the nature of the residue in safflower, ruminants, and poultry is considered adequately understood. The residue of concern is sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety.

3. Adequate analytical methodology is available for enforcement purposes (PAM II, Method I). A sethoxydim analytical reference standard is available from the EPA Pesticide and Industrial Chemical Repository in RTP, NC.

4. Residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety in or on safflower seed are not likely to exceed 5 ppm as a result of the proposed use.

5. Residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety in or on safflower meal are not likely to exceed 15 ppm. Residues would not be expected to exceed 2 ppm in crude oil and 0.5 ppm in refined safflower oil.

6. Secondary residues in meat, milk, poultry, and eggs will be covered by the existing tolerances for these commodities.

Recommendation

Provided that the label is amended to require use of an EPA approved oil concentrate, and TOX considerations permitting, we have no objections to the issuance of this Section 18 exenption. An agreement should be made with FDA regarding the legal status of the treated commodities in commerce.

cc: R.F., circu, sethoxydim S.F., sethoxydim Sec. 18 File, S. Hummel, PMSD/ISB
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