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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 85-WA-06 Vinclozolin: Section 18 Exemption on Lima Beans in State of Washington (RCB #1062)

FROM: William L. Anthony
RCB/HED (TS-769)

TO: S.J. Austin/D. Stubbs
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THRU: Ed Zager, Section Head
Special Registration II
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The State of Washington, Department of Agriculture, requests a section 18 exemption under FIFRA for the use of vinclozolin (RONILAN®), 3-(3,5-dichlorophenyl)-5-ethenyl-methyl-2,4-oxazolidinedione on lima beans, to control the white mold Sclerotinia sclerotiorum.

It is estimated that about 2500 acres, located in the counties of Benton, Franklin, and Walla Walla, will be treated under this exemption.

The Department of Agriculture is requesting the use of 5000 lbs of the formulation, RONILAN®-50W (EPA Registration No. 7969-53), manufactured by BASF Wyandotte Corporation. This corresponds to 2500 lb ai.

A maximum of two applications will be made at the rate of 40 to 100 gals of water per acre by ground rigs or by air. The applications will be made approximately 7 to 10 days apart. There will be a 17-day PHI.

For consistency with other section 18 exemptions for vinclozolin on beans (e.g., 84-OR-08, snap beans, M. Loftus, June 5, 1984), and in view of the deficiencies in the available feeding studies (M. Firestone, PP#5F3237) a restriction against feeding treated lima bean vines and hay should be imposed on this use.

For the purposes of this section 18 exemption, residues of concern in lima beans consist of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety. Permanent tolerances exist for the residues of the parent and its metabolites in/on kiwi fruit, lettuce (head), and strawberries at 10 parts per million.

There are no permanent or temporary tolerances for lima beans.

All inerts in the formulation are cleared under 40 CFR 180.1001.

Analytical Method

No analytical method was submitted with this Section 18.

The analytical method for determination of residues in crops is method 25, in PAM II, Method I. Briefly, the alkaline hydrolysis of the parent and acid metabolites, releases 3,5-dichloroaniline which is collected in acid solution during steam distillation. The 3,5-dichloroaniline is partitioned with dichloromethane followed by formation of derivative with chloroacetyl chloride. The derivative is analyzed by GC/ECD. The PAM II method may be used for enforcement. The limit sensitivity is 0.05 part per million.

Residues in animal tissues and milk may be measured by a method included in Report III, "Residues of Vinclozolin (BAS 352F) in Milk and Tissues of Dairy Cows" by the Huntingdon Research Centre, Cambridgeshire, England which was submitted in connection with various section 18 exemption requests.

No residue data were submitted with this application.

Very limited data have been submitted on snap beans in section 18 #83-WA-09, (Memo: E. Zager, April 10, 1983). Following two applications of RONILAN® at the rate of 1 lb ai/A (2x proposed application on lima beans) completed in three studies from Oregon and Idaho, residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety, ranged from 0.24 to 0.68 ppm in/on snap beans at a 9 to 17 day PHI.

Residue data on several bean varieties have been submitted in PP#5F3237/5H5465. Residues in/on lima beans treated twice at the rate of 1 lb act/A (2x) ranged from 0.61 to 1.3 ppm at PHI's of 21 to 28 days.

Based on the very limited residue data submitted, we estimate that residues from the proposed use will not exceed 1 ppm in or on lima beans.

Meat, Milk, Poultry and Eggs

Provided the use of treated lima bean hay and forage for feed is prohibited, the only feed item involved in this use will be cannery waste.

Cannery bean waste to be used as feed is composed of 82 to 92 percent (18 to 24% of gross load) snips, defective pods and spills and 8 to 18 percent (2 to 4% of gross load) vines and leaves which have been thoroughly washed and separated from unusable product. In our judgment, residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in cannery bean waste which is used as a feed item will not exceed 1 part per million.

The available cattle feeding study has been found deficient (M. Firestone, PP#5F3237). In addition, the nature of the residue in large ruminants is not adequately understood. However, since the dietary burden from the use of cannery waste is low, we are willing to use this study as a basis to estimate secondary residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in animal tissues and milk.

In a cattle feeding study two groups of 3 cows each were administered 3 and 15 ppm vinclozolin in the diet for 28 days. Highest residues were found in liver samples up to 0.6 ppm and 2.3 ppm, respectively. Residues in the muscle ranged up to 0.05 ppm and 0.24 ppm respectively. Residues in the milk were non-detectable ($<$ 0.05 ppm) in the cows administered 3 ppm vinclozolin in their diet and ranged up to 0.19 ppm in the group of cows administered 15 ppm in their diet.

Cannery bean waste may comprise up to 20 percent of the dietary burden of beef and dairy cattle and its equivalent to 0.2 ppm vinclozolin. On the basis of the above feeding studies and the dietary burden, we estimate that secondary residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 0.05 ppm in milk, meat, fat and meat by-products of cattle, goats, hogs, horses and sheep from this use provided the use of treated bean vines and hay is prohibited.

Since cannery bean waste is not a feed item for poultry, there will be no problem of secondary residues in poultry and eggs.

Conclusions

1. For the purposes of this section 18 exemption, residues of concern in plants, animal tissues, and milk are the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety.

2a. The analytical methodology for determining residues of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety in plants is Method 25 entitled "Gas Liquid Chromatographic Determination of Residues of Vinclozolin and its 3,5-Dichloroaniline Containing-Metabolites in Strawberries and Soil", included in PAM II as Method I.

2b. The analytical methodology for determining residues of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety in animal tissues and milk is included in Report III "Residues of Vinclozolin (BAS 352F) in Milk and Tissues of Dairy Cows" by the Huntingdon Research Centre, Cambridgeshire, England which was submitted in connection with various section 18 exemption requests.

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

3a. Combined residues of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methy-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 1 ppm in/on lima beans as a result of the proposed use.

3b. Combined residues of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 1 ppm in cannery bean waste as a result of the proposed use.

3c. Secondary residues of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 0.05 ppm in milk, meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep from this use provided the use of treated bean vines and hay is prohibited.

3d. Since there are no poultry feed items involved in this use, there will be no problem with secondary residues in poultry and eggs.

Recommendation

Provided the feeding restriction specified in Conclusion 3c is imposed and TOX considerations permitting, we have no objections to the issuance of this section 18 exemption. An agreement should be made with the FDA and USDA regarding the legal status of the treated commodities in commerce.

cc: R.F., Circu., Anthony, Vinclozolin S.F., Section 18, PMSD/ISB

RDI:Zager:6/19/85:RDSchmitt:6/20/85:TS-769:RCB:WLA:Rm.810:CM-2:557-7484:6/26/85.

JOB:96798:HED/01:Kendrick & Co.:898-1270:6/26/85:dsg:Del:7/8/85.