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

JUN 25 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#9E3808: Vinclozolin In/On Domestic Belgian Endive (Chicory) Tops. Evaluation of Analytical Methods and Residue Data (DEB #5947).

FROM: W. T. Chin, Ph.D., Chemist
Tolerance Petition Section III
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Philip V. Errico, Section Head
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TO: Hoyt Jamerson, PM #43
Minor Uses Officer
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and

Toxicology Branch
Health Effects Division (H7509C)

The petitioner, IR-4, and the Agricultural Experiment Stations of California and New York request that the import tolerance for the combined residues of the fungicide vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione, and its metabolites containing the 3,5-dichloroaniline moiety in or on the raw agricultural commodity Belgian endive tops at 5 ppm be extended to include the domestic production of Belgian endive tops in the United States without the need for domestic residue data.

Tolerances have been established under 40 CFR 180.380 for the combined residues of vinclozolin and its metabolites in or on kiwi fruit (10 ppm), lettuce, head (10 ppm), lettuce (leaf, 10 ppm), onion (dry bulb, 1.0 ppm), peppers (bell, 3 ppm), stonefruits (25 ppm), strawberries (10 ppm), raspberries (10 ppm), grapes (6 ppm) and Belgian endive tops (5 ppm).

CONCLUSIONS

1. The nature of residue in Belgian endive plant is adequately understood. Parent compound and its metabolites containing the 3,5-dichloroaniline moiety are the residues of concern.

2. There are no animal feed items associated with Belgian endive plant. Therefore, there is no reasonable expectation of secondary residues of vinclozolin and its metabolites occurring in animal commodities as a result of the proposed use.

3. Adequate analytical methodology is available in PAM II to enforce the proposed tolerance.

4. The rate proposed for domestic use on Belgian endive roots for producing Belgian endive tops is less than 2X at which rate a 2.21 ppm residue level was obtained in Europe. DEB, therefore, concludes that the 5.0 ppm tolerance for imported Belgian endive tops is adequate to support the domestic use without additional domestic residue data.

5. The petitioner is requested to revise Section B adding the following restriction: "Treat only Belgian endive roots used for the production of Belgian endive tops."

6. There are no Mexican and Canadian tolerances established for vinclozolin in or on Belgian endive tops, roots or both tops and roots. However, there is a Codex tolerance established for vinclozolin in or on Belgian endive tops (sprouts) at 2 ppm. Therefore, DEB cannot harmonize with the Codex tolerance.

RECOMMENDATION

Pending resolution of the deficiency specified in Conclusion 5 and TOX considerations permitting, DEB will recommend for the request that the import tolerance for the combined residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in or on the raw agricultural commodity Belgian endive tops at 5 ppm be extended to include the domestic use for production of Belgian endive tops in the U. S. without the need for domestic residue data.

Detailed Considerations

Manufacturing Process

A description for the manufacturing process of technical vinclozolin was submitted in connection with PP#9F2205 and reviewed in detail (see M. Nelson's 7/23/79 memo). DEB has concluded that the impurities in vinclozolin technical are not expected to cause residue problems at the levels present.

Formulation

Two formulations are proposed:

1. Ronilan® WP (EPA Reg. No. 7969-53): A wettable powder containing 50% of active ingredient.

2. Ronilan® FL (EPA Reg. No. 7969-62): A flowable suspension concentrate containing 41.3% (500 grams/liter) of active ingredient.

Only Ronilan® FL is registered in Europe for use on Belgian endive roots. For the domestic use, however, Ronilan ® WP is also proposed. DEB expects no great difference between these two formulations for the proposed minor crop use on Belgian endive roots.

Proposed Use

For control of Sclerotinia sclerotiorum, use either: (1) as a spray to the roots on conveyor line immediately before placing them in cold storage or (2) as a spray to the roots after set up of roots in the forcing trays according to the following timing and rates:

Timing	Rate, Volume and Site
Prior to Storage	Spray to roots: 32 g Ronilan® WP (16 g ai) or 2 fl oz Ronilan® FL to 2000 lb of roots (=1X) in sufficient water (@ 30 liters) for complete coverage.
After set up of roots in forcing trays before placing them in growing room.	Spray to roots: 20 g of Ronilan® WP or 1.33 fl Ronilan FL per 10 square meters of forcing tray (=1X) in 20-30 liter water for complete coverage.

The proposed 1X rate in Europe is 10 g ai/10 m^2 (=10 kg ai/ha). The reviewer called Mr. J. Graham of BASF (1-800-669-1770 Ext. 5480) on 6/6/90 and was told that the weight of 10 m^2 of Belgian endive roots is approximately 1250 lbs. Therefore, the proposed rate for domestic use corresponds to 1X of the European dosage.

The proposed restrictions are: Do not apply to roots more than once. Do not apply Ronilan through any type of irrigation system. Do not feed treated roots to livestock.

Since Belgian endive roots is not limited to production of tops only and residue data generated from Ronilan-treated Belgian endive roots are not available, the petitioner is requested to revise Section B adding the following restriction: "Treat only Belgian endive roots used for the production of Belgian endive tops."

Nature of the Residue

Metabolism studies of vinclozolin in plants have been reviewed in detail in connection with PP#8G2069, PP#9G2204 and PP#5F3237/ FAP#5H5465 (see G. Makhijani's 1/19/79, B. Davis's 1/18/80 and M. P. Firestone's 6/28/85 memos). Results indicate that parent compound and its metabolites containing the 3,5-dichloroaniline moiety are the residues of concern. DEB has concluded that the metabolic pattern of vinclozolin in Belgian endive plant is similar to the established pathway in other plants studied (see W. T. Chin's 5/17/88 memo, PP#8E3620).

Analytical Methodology

Adequate methodology for enforcement purposes is available in PAM II. Briefly: Crop samples are hydrolyzed with alkaline to convert vinclozolin and its metabolites to 3,5-dichloroaniline, which is quantitatively isolated by steam distillation, determined with a GC equipped with an electron capture detector, and expressed in terms of vinclozolin equivalents. The sensitivity of this method is 0.05 ppm. An average recovery of 70% was reported over the range of 0.3 to 4.0 ppm fortifications. Adequate examples of calculations and chromatograms have been submitted and reviewed in connection with PP#8E3620. Under frozen conditions, vinclozolin residues are stable for at least 19 months (see W. T. Chin's 5/17/88 memo).

Residue Data

No residue data are submitted. The petitioner claims that the residue data developed in Europe in support of the 5 ppm import tolerance for the combined residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in or on Belgian endive tops in connection with PP#8E3620 are adequate to support the proposed domestic production of Belgian endive tops, without the need for additional domestic residue data because of the following reasons:

1, The growing conditions for Belgian endive plants and the treatment of Belgian endive roots with vinclozolin for producing tops in the U.S. are similar to those in Europe.

2. Weather and soil factors should not affect vinclozolin residues because only the Belgian endive roots are treated and the tops are grown in forcing rooms under controlled conditions.

3. Belgian endive roots are treated and then stored for at least 30 days. Therefore, residues would likely be much lower then the established tolerance of 5.0 ppm in Belgian endive tops.

4. The European residue data generated at 2X should cover the proposed domestic uses.

5. Belgian endive is a minor crop grown only in New York and California.

The European residue data submitted in connection with PP#8E3620 are cited below:

Table 1. Vinclozolin Residues in Belgian Endive Tops (After spray to roots)

Dosage ($g\ ai/10m^2$)	Vinclozolin Equivalent (ppm)		
	Low	High	Ave.
5	0.09	0.54	0.36
10 (1X)*	0.10	1.40	0.40
15	0.17	0.65	0.43
20 (2X)	0.20	2.21	0.87

*The proposed domestic rate, 16 g ai/2000 lbs roots, equals 1X of European rate, 10 g $ai/10m^2$; $10m^2$ of roots weigh approximately 1250 lbs.

The European data shown in Table 1 indicate that at a rate of 2X, the maximum residue level is 2.21 ppm which is much less than the established tolerance of 5 ppm for imported Belgian endive tops. Since the maximum rate proposed for domestic use on Belgian endive roots is also 1X and the forcing conditions in the U. S. are the same as in Europe, DEB, therefore, concludes that the 5.0 ppm import tolerance for Belgian endive tops is adequate to support the domestic production of Belgian endive tops without additional domestic residue data.

Meat, Milk, Poultry and Eggs

There are no animal feed items associated with Belgian endive plant. Therefore, there is no reasonable expectation of secondary residues of vinclozolin and its metabolites occurring in animal commodities as a result of the proposed use.

Other Considerations

There are no Mexican and Canadian tolerances established for vinclozolin in or on Belgian endive tops, roots or both tops and roots. However, there is a Codex tolerance established for vinclozolin in or on Belgian endive tops (sprouts) at 2 ppm. Therefore, DEB cannot harmonize with the Codex tolerance.

cc: Circu, RF, PP#8E3620, PP9E3808, W.T.Chin, R.D.Schmitt, PIB/FOD (C.Furlow)
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