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

MAY 17 1988

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

113201

SUBJECT: PP#8E3620: Vinclozolin (Ronilan) In or On Chicory (Belgian endive). Evaluation of Analytical Method and Residue Data (Acc. #405429-0, -1; RCB #3610).

FROM: W. T. Chin, Chemist
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

W. T. Chin

THRU: Philip V. Errico, Section Head
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Philip V. Errico

TO: Lois Rossi, PM #21
Herbicide-Fungicide Branch
Registration Division (TS-769)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

BASF Corporation proposes a tolerance for 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 chicory (Belgian endive) at 5 ppm. The proposed tolerance is to permit the importation of vinclozolin-treated chicory from Belgium to the United States.

Tolerances have already been established under 40 CFR 180.380 for residues of vinclozolin and its metabolites in/on kiwifruit (10 ppm), lettuce, head (10 ppm), peppers (bell, 3 ppm), stone fruits (25 ppm) and strawberries (10 ppm). Several other tolerances are pending in connection with PP#1E2457, PP#4F2998, PP# 3F2934 and FAP#5H5462.

Vinclozolin has not yet been the subject of Registration Standard.

CONCLUSIONS

1a. According to Jim Akerman's 9/16/86 memo, review of inerts is now in the purview of RD. Therefore, RD should assure themselves that inerts are cleared for the proposed formulation, Ronilan FL.

1b. The original label is published in the Belgian language. If dipping treatment is proposed in this petition, it should be so stated and the preparation of dipping solutions should be specified in a revised Section B. In addition, the following restriction should be added to the label: "One application per season only."

2a. The nature of residue in chicory plant is adequately understood based on the metabolism data on other crops. Parent compound and its metabolites containing the 3,5-dichloroaniline moiety are the residues of concern.

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

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

4a. The petitioner is requested to revise Section F by clarifying whether the proposed tolerance covers chicory tops only, chicory roots only or both chicory tops and roots.

4b. The term "chicory samples" is used for the description of residue analysis in the section of "Residue Data." The petitioner is requested to clarify whether chicory tops, chicory roots, or both chicory tops and roots were analyzed.

5a. Based on residue data submitted and assuming the answers to Conclusions 4a and 4b are adequate, RCB considers that it is more appropriate to reduce the proposed tolerance from 5.0 to 3.0 ppm in or on chicory. However, since Codex has eatablished a 5 ppm tolerance on "chicory, roots", RCB will support the current 5 ppm proposal, TOX considerations permitting.

5b. There are no Mexican and Canadian tolerances established for vinclozolin in or on chicory tops, roots or both tops and roots.

RECOMMENDATIONS

At this time, RCB recommends against the proposed tolerance for combined residues of the fungicide vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in or on the raw agricultural commodity chicory at 5 ppm because of the reasons specified in Conclusions 1b, 4a and 4b.

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). RCB has concluded that the impurities in vinclozolin technical are not expected to cause a residue problem at the levels present.

Formulation

The currently proposed formulation is Ronilan FL, which is a suspension concentrate containing 500 grams of vinclozolin per liter. According to Jim Akerman's 9/16/86 memo, review of inerts is in the purview of RD. Therefore, RD should assure themselves that inerts are cleared for the Ronilan FL formulation.

Proposed Use

The original label submitted is published in the Belgian language. The attached English translation indicates different uses of Ronilan FL for the control of Botrytis and Sclerotinia in vegetable crops and ornamentals, Monilia on stone fruits, Helminthosporium and Corticium in lawns.

The English translation of the proposed use on chicory plant for the control of Sclerotinia in the beds reads:

> "Apply 20 ml/10 liters of water per 10 square meters, spray or drench the heads after the roots have been embedded. Then cover with soil. If a severe infection is to be expected, increase the application rate up to 40 ml per 10 square meters."

The petitioner should revise Section B by adding the following restriction: "One application per season only." In addition, if the petitioner intends to include dipping treatment in this petition, it should be so stated and the preparation of dipping solutions should be specified in the revised Section B.

Nature of the Residue

Plant Metabolism

No new plant metabolism studies are submitted with this petition. However, reports of metabolism studies using carbon-14 uniformly ring-labeled vinclozolin on strawberries, grapes, peaches, lettuce and peanut were submitted in connection with PP#8G2069, PP#9G2204, and PP#5F3237/FAP#5H5465 and reviewed in detail (see G. Makhijani's 1/19/79, B. Davis's 1/18/80 and M. P. Firestone's 6/28/85 memos).

Results indicated that parent compound and its metabolites containing the 3,5-dichloroaniline moiety are the major residues of concern. RCB considers that the metabolic pattern of vinclozolin in chicory will be similar to that in the plants studied above. Therefore, RCB concludes that the nature of the residue of vinclozolin in chicory is adequately understood.

Animal Metabolism

No new animal metabolism studies are submitted with this petition. However, the animal metabolism studies of vinclozolin in goats and hens were reported in connection with PP#5F3237/FAP# 5H5465 and reviewed in detail (see M. P. Firestone's 6/28/85 memo). Since chicory is not an animal feed item, this is not a relevant issue.

Analytical Methodology

The method used to generate chicory residue data is similar to that which has successfully passed a method trial in connection with PP#9F2205 (see G. Makhijani's 9/7/79 memo). Briefly: Crop samples are hydrolyzed with alkaline to convert vinclozolin and its metabolites to 3,5-dichloroaniline, which is quantitatively isolated by steam distillation. Following partition extraction, the residue is acylated, 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% is reported over the range of 0.3 - 4.0 ppm fortifications. Adequate examples of calculations and chromatograms are given. RCB, therefore, concludes that this method is adequate. Enforcement methods are available in PAM II.

Storage Stability Data

No storage stability data are submitted. However, available data on strawberries and stone fruits were submitted in connection with PP#9F2205 and 9G2204, respectively. Results indicated that under frozen conditions, vinclozolin residues are stable for more than 19 months.

Residue Data

Field trials were conducted in Wieringerwerf and Stryen, the Netherlands between 1978 and 1979. These trials involved a single application of Ronilan FL at rates of 5, 10 (1X), 15 and 20 kg ai/ha by spraying over chicory root crowns prior to the forcing stage. "Chicory samples" were taken at normal harvest (29 and 30 days after treatment) and maintained in a frozen condition and analyzed within 17 months. Results of spray applications are summarized in Table 1.

Table 1. Vinclozolin Residues in Chicory (by Spray) (PHI = 29-30 days)

Dosage (kg ai/ha)	Vinclozolin Equivalent (ppm) Low	High	Ave.
5	0.09	0.54	0.36
10 (1X)	0.11	1.40	0.40
15	0.17	0.65	0.43
20 (2X)	0.20	2.21	0.87

The petitioner is requested to specify whether the term "chicory samples" stands for chicory tops, roots or both tops and roots. In addition, the petitioner is requested to revise Section F by specifying whether the proposed tolerance covers chicory tops only, chicory roots only, or both chicory tops and roots.

In addition to spray or drench treatments, applications by dipping the chicory roots in a 0.25% or 0.50% suspension of Ronilan FL prior to the forcing stage were also conducted. "Samples" were taken at normal harvest 29 days after treatment. Results of the dipping treatments are summarized in Table 2.

Table 2. Vinclozolin Residues in Chicory (by Dipping) (PHI = 29 days)

Dosage (% of Ronilan)	Vinclozorin Equivalent (ppm) Low	High	Ave.
0.25%	0.08	0.41	0.26
0.50	0.14	0.27	0.20

In Section B, dipping treatment was not mentioned. If the petitioner intends to include dipping treatment in this petition, it should be so stated and the preparation of dipping solutions should be specified in a revised Section B.

Data shown in Tables 1 and 2 indicate that under the proposed conditions, vinclozolin residues are far less than the proposed 5.0 ppm tolerance. Since Codex has established a 5 ppm tolerance on "chicory, roots", RCB will support the current proposal if TOX considers the 5 ppm proposal adequate and the question above on chicory samples and tolerance equivalent are adequately addressed

Residues in Meat, Milk, Poultry and Eggs

There are no animal feed items associated with chicory plant. Therefore, there is no reasonable expectation of secondary residues of vinclozolin or its metabolites occuring in meat, milk, poultry or eggs as a result of the proposed use.

Other considerations.

There are no Mexican and Canadian tolerances established for vinclozolin in or on chicory tops, roots or both tops and roots. However, there is a Codex tolerance established for vinclozolin in or on "chicory, roots" at 5 ppm. RCB would expect no conflict between the proposed tolerance level and the Codex level if the currently proposed tolerance at 5 ppm is eventually established.

cc:Circu., R.F., PP#8E3620, PM#21, W.T.Chin, FAB, EEB, TOX, PMSD-ISB
RDI: P.V.Errico(5/16/88), R.D.Schmitt(5/16/88)
TS-769:RCB:CM#2, RM812, 557-4352, W.T.Chin,wc(5/17/88)

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Vinclozolin

CODEX NO. 159

5/3/88

CODEX STATUS:

[ ] No Codex Proposal
Step 6 or above

Residue(if Step 8): Sum of Vinclozolin and all metabolites containing 3,5-dichloroaniline, expressed as vinclozolin [4]

Crop(s)	Limit (mg/kg)
Chickory, roots	5 [3]

PROPOSED U.S. TOLERANCES:

Petition No. PP#8E3620

RCB Reviewer W. T. Chin

Residue: Vinclozolin + its metabolite containing 3.5-dichloroaniline moiety

Crop(s)	Limit (mg/kg)
Chicory	5.0

CANADIAN LIMITS:

[✓] No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

[✓] No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

[4] Codex may reconsider if parent compound methodology becomes available

NOTES:
[3] Temporary limits pending full ADI

Form revised 1986