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

OCT 17 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4E2998 Vinclozolin (Ronilan) in/on tomatoes and cucumbers. Amendment of 7/31/84 (Addition of peppers). Accession No. 072841

FROM: Cynthia Deyrup, Ph.D., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: John H. Onley, Section Head
Tolerance Petition Section 2
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Henry Jacoby, Product Manager No. 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Background

BASF Wyandotte proposed a permanent tolerance in PP# 4E2998 for residues of the fungicide Ronilan (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 commodities tomatoes at 2.0 ppm and cucumbers at 1.0 ppm.

Present Consideration

The petitioner proposes to amend PP# 4E2998 to establish a tolerance for residues of vinclozolin and its 3,5-dichloroaniline containing metabolites in/on imported green peppers at 3.0 ppm in addition to the proposed tolerances for tomatoes and cucumbers. The present amendment consists of a cover letter and revised Sections A, B, D, and F.

The present petition is in reject status because of a number of deficiencies (See RCB review of PP# 4E2998, memo of J. H. Onley, 3/30/84), which were not addressed in the present amendment and are still outstanding.

Revised Section A

Formulation

The formulation to be used on tomatoes and cucumbers is Ronilan Fungicide (50W). According to the labels submitted with this amendment, the formulation Ronilan FL as well as Ronilan (50W) are to be used on peppers.

Ronilan FL is registered, but this amendment represents the first proposed application of this formulation. Technical vinclozolin contains [redacted] which were not listed in previous composition descriptions of technical Ronilan. RCB foresees no residue problems arising from these impurities. The active ingredient constitutes 41.3% of the formulation Ronilan FL.

All inerts are cleared under 40 CFR 180.1001 (c)(d).

Revised Section B

The purpose of the proposed tolerance for vinclozolin/metabolites residues on green peppers is to cover residues which might occur on imported bell peppers. The petitioner states that Ronilan is registered for use on peppers in the following countries:

country	tolerance
Belgium	1 ppm
Costa Rica	no tolerance established
Hungary	3 ppm
Italy	1.5 ppm
Jordan	no tolerance established
Japan	5 ppm
Netherlands	1 ppm
Great Britain	no tolerance established

For Japan, the tolerance level for Ronilan residues on peppers is 5.0 ppm, which is higher than the tolerance level proposed by the petitioner. There appears to be a compatibility problem.

Of the above countries, labels for use in Hungary, the Netherlands, and Great Britain were submitted with the amendment. Also, the petitioner has submitted a label for use in France.

Great Britain

The British label imposes a 7 day PHI. RCB requests information on the treatment rate in terms of weight per unit area and the number of applications per growing season. Since this information is not on the label, RCB needs to know how this information will be conveyed to the applicator.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Other Countries

The petitioner should also submit labels, supported by residue data, for all other countries where he intends to use his product (Belgium, Costa Rica, Italy, Jordan, and Japan). Although the petitioner has included a label and residue data from France, Ronilan is not registered for use on peppers in that country. The petitioner will need to provide pertinent English translation of all labels. Dutch and Hungarian translations are needed for the labels submitted with this amendment. RCB will need information on the treatment rate in terms of weight per unit area, the number of applications per growing season, and the proposed PHI. If this information is not on the label, RCB needs to know how this information will be conveyed to the applicators.

Incidentally, there seems to be no reference for use on peppers on the Dutch label (personal communication, W. Boodee - EPA).

Revised Section D

Analytical Methodology

Recoveries from peppers fortified at levels of 0.5-1.0 ppm ranged from 71-85%.

The limit of determination is given as 0.05 ppm.

Representative chromatograms have not been submitted. The petitioner should submit sample chromatograms reflecting fortified and unfortified crop samples.

Residue Data

Storage conditions were not described for the English study in which samples were stored for 11 months before analysis, but all other samples were stored at frozen conditions. Samples were stored 2-11 months before analysis. Storage stability data submitted with PP# 9G 2204(memo of B.D. Davis, 1/18/80) indicate that residues of vinclozolin/metabolites on lettuce and peaches are stable for at least 6 months under frigid conditions. Storage stability data submitted with PP# 9F2205 (memo of M. Nelson, 7/23/79) show that residues of vinclozolin/metabolites are stable up to 19 months in/on frozen strawberries. Although RCB is satisfied that residues of vinclozolin/metabolites are stable on frozen samples, the petitioner will have to describe storage conditions for the English (Sussex) study in which samples were stored for 11 months.

Residue data were generated from field trials carried out in Great Britain and France. According to the petitioner (see Revised Section B of this review), neither Great Britain nor France has established a tolerance for vinclozolin/metabolite residues on peppers. However, a letter from the ministry of Agriculture, Fisheries, and Food in Great Britain approving the renewal of the provisional commercial clearance for use of Ronilan on peppers was included with this amendment. Ronilan is not registered for use on peppers in France.

Peppers received 3-4 applications at rates of 0.5, 0.6, 0.75, and 1.0 kg/HA. PHI's ranging from 0-7 days were observed. The results of the field trials are summarized below:

TREATMENT RATE (KG A.I./HA) AND COUNTRY	SAMPLED AT ...DAYS AFTER TREAT MENT	RESIDUE, ppm
four times at 1 in England	0 1 3 7	1.44 0.75 0.92 1.25
four times at 0.75 in England	7	0.30
four times at 0.75 in England	7	0.34
four times at 0.5 in England	1 7	2.27 2.22
three times at 0.6 in France	5	0.33

Control values for untreated crop are not given. Representative chromatograms of untreated and treated samples were not submitted. The petitioner should submit data from check samples as well as pertinent representative chromatograms of treated and untreated crop so that RCB can evaluate the residue data.

The petitioner should also supply residue data from field trials carried out in all other countries where he intends to use vinclozolin (i.e. Belgium, Costa Rica, Italy, Jordan, and Japan), since the climatic conditions vary widely among these countries. The residue data should reflect the petitioner's proposed use in terms of PHI, application rate (expressed in weight per unit area), and number of applications per growing season for each country. The petitioner should describe storage conditions before analysis and should provide representative chromatograms so that RCB can evaluate the residue data.

At this time RCB can draw no conclusions on the appropriateness of the proposed 3 ppm tolerance of vinclozolin/metabolite residues on green peppers until the deficiencies discussed in the present amendment have been addressed (i.e. a lack of a description of storage conditions in the Sussex study, a lack of data for control values and chromatograms, and a lack of residue data from the other countries where the petitioner intends to use Ronilan on peppers).

Neither Codex, Mexico nor Canada has established a tolerance for residues of vinclozolin and its metabolites containing the 3,5- dichloroaniline moiety in/on green peppers; there will be no compatibility problem.

Conclusions

1a. RCB requests information on the treatment rate in terms of weight per unit area and the number of applications per growing season in Great Britain. Since this information is not on the label, RCB needs to know how this information will be conveyed to the applicator.

1b. The petitioner should also submit labels, supported by residue data, for all other countries where he intends to use his product (Belgium, Costa Rica, Italy, Jordan, and Japan). Although the petitioner has included a label and residue data from France, Ronilan is not registered for use on peppers in that country. The petitioner will need to provide pertinent English translations of all labels. Dutch and Hungarian translations are needed for the labels submitted with this amendment. RCB will need information on the treatment rate in terms of weight per unit area, the number of applications per growing season, and the proposed PHI. If this information is not on the label, RCB needs to know how this information will be conveyed to the applicators. Also, there seems to be no reference for use on peppers on the Dutch label.

1c. For Japan, the tolerance level for Ronilan residues on peppers is 5.0 ppm, which is higher than the tolerance level proposed by the petitioner. There appears to be a compatibility problem.

2. The petitioner will need to submit sample chromatograms reflecting fortified and unfortified crop samples.

3a. The petitioner should describe storage conditions for the English (Sussex) study in which pepper samples were stored for 11 months.

3b. The petitioner should submit data reflecting analyses of check pepper samples.

3c. The petitioner needs to submit pertinent representative chromatograms of treated and untreated pepper samples so that RCB can evaluate the residue data.

3d. The petitioner should also supply residue data from field trials carried out in all other countries where he intends to use vinclozolin (i.e. Belgium, Costa Rico, Italy, Jordan, and Japan), since the climatic conditions vary widely among these countries. The residue data should reflect the petitioner's proposed use in terms of PHI, application rate (expressed in weight per unit area), and number of applications per growing season for each country. The petitioner should describe storage conditions before analysis and should provide representative chromatograms so that RCB can evaluate the residue data.

3e. At this time RCB can draw no conclusions on the appropriateness of the proposed 3 ppm tolerance of vinclozolin/metabolite residues on green peppers until the deficiencies discussed under Residue Data in the present amendment have been addressed (i.e. a lack of a description of storage conditions in the Sussex study, a lack of data for control values and chromatograms, and a lack of residue data from the other countries where the petitioner intends to use Ronilan on peppers).

4. Neither Codex, Canada, nor Mexico has established a tolerance for residues of vinclozolin/metabolites containing the 3,5-dichloroaniline moiety on peppers. There will be no compatibility problem.

Recommendations

RCB recommends against the establishment of a tolerance of 3.0 ppm for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety on peppers because of reasons given above in conclusions 1a, 1b, 1c, 2, 3a, 3b, 3c, 3d, and 3e.

All deficiencies outlined in RCB's 3/30/84 review of PP# 4E 2998 are still outstanding.

cc: R.F.., Circu, C. Deyrup:TOX, EEB,EAB, PP#4E2998:
FDA, Robert Thompson
RDI: J.O.: 10/05/84: RDS: 10/09/84
TS-769:CD:bj: Rm-810: CM#2 10/15/84

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Vinclozolin

CCPR NO.

PETITION NO. 4E2998

Reviewer: C. Deyrup

F.X 8/30/84

Codex Status

☑ No Codex Proposal Step 6 or above

Residue (if Step 9):

Crop(s)	Limit (mg/kg)

Proposed U.S. Tolerances

Residue: Vinclozolin + metabolites containing 3,5-dichloroaniline moiety

Crop(s)	Tol. (ppm)
green peppers	3.0

CANADIAN LIMIT

Residue:

Crop	Limit (ppm)
none	

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm
none	

NOTES: