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

MAR 30 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#422998 (Accession #072159). BAS 352F (Ronilan) in or on Tomatoes and Cucumbers. Evaluation of Analytical Methodology and Residue Data.

FROM: John H. Onley, Ph.D., Chemist *John H. Onley*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Chief *CT*
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)

BASF Wyandotte Corporation proposes that tolerances be established for residues of the fungicide 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.

The aforementioned fungicide is also known as vinclozolin. Currently, vinclozolin (Ronilan) tolerances exist for strawberries, lettuce, and kiwi fruit under 40 CFR 180.380.

The tomatoes and cucumbers are to be grown in the Netherlands, Federal Republic of Germany, Spain, Greece, and Italy and then exported to the United States.

Conclusions

1. The petitioner will need to provide pertinent English translations of the proposed product labels from the Netherlands, Federal Republic of Germany, Spain, and Italy. The application rate(s) on each label should be given in terms of active ingredient per ha since the residue data are rightfully reported in this way.

2. We conclude that the nature of the residue is adequately understood for the proposed use of Ronilan on tomatoes and cucumbers.

3. We conclude that adequate methodology is available for regulatory purposes.

4a. In relation to conclusion 1 above, we are not able to conclude whether or not the proposed tolerances on tomatoes and cucumbers grown in Spain, Greece, and Italy are adequate since no residue data reflecting the proposed use in those countries were submitted; the petitioner will need to submit residue data on the subject crops grown and harvested in Spain, Greece, and Italy. ✓

4b. The petitioner will need to submit residue data reflecting the analyses of some cucumber controls. ✓

5. The petitioner's tomato fractionation study showed a maximum Ronilan concentration of about 3X in tomato puree. In view of this, the petitioner should propose a food additive tolerance (which needs to be 3 times the value of the proposed tolerance on whole tomatoes) as follows:

Processed tomato products.....X ppm.

6. Since imported tomatoes treated with Ronilan would be sold on the fresh market, we do not expect any residue problems of secondary residues in meat, milk, poultry and eggs from the proposed use.

7. An International Tolerance Status Sheet is attached to this review. No Codex, Mexican or Canadian tolerances for Ronilan on tomatoes and cucumbers have been established.

Recommendations

We recommend against establishment of the proposed Ronilan tolerances on tomatoes and cucumbers because of the reasons cited in conclusions 1, 4a, 4b and 5 above.

Detailed Considerations

Manufacture and Formulations

Technical BAS 362F (Vinclozolin) contains at least 93% 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione. The manufacturing process for technical BAS 352F has been discussed favorably in our review of PP#8G2068 (1/19/79-G Makhijani). The impurities of technical BAS 352F are not likely to cause a residue problem.

The technical product is formulated as a 50% wettable powder under the trade name Ronilan Fungicide (50W). All of the inerts are cleared under 40 CFR 180.1001(c).

Proposed Use

Notice to the Petitioner: The proposed labels from the various countries contain (proposed) uses for Ronilan on several raw agricultural commodities, our considerations in this review are given only to the proposed use of Ronilan on tomatoes and cucumbers.

In Greece

"Tomatoes and cucumber plants are to be sprayed at the appearance of first inflorescence and there after according to infection at a rate of 50-100 grams/100 liters of water. A PHI of 3-days is to be observed."

In other Countries

No English translations of the "Directions for Use" were provided for the product labels from the Netherlands, Federal Republic of Germany, Spain and Italy.

Our Comments/Conclusions

The petitioner will need to provide pertinent English translations of the proposed product labels from the Netherlands, Federal Republic of Germany, Spain and Italy.

We notice in the translation of the proposed Greek label that the instructions for application states "Start spraying ... at a rate of 50-100 grams per 100 liters of water." The preceding instructions are not specific. In the forthcoming amendment, the application rate(s) on each label should be given in terms of active ingredient per ha since the residue data (see the Residue Data section of this review) are rightfully reported in this way.

Nature of the Residue

Radiolabel plant metabolism studies have been carried out in strawberries (PP#8G2068, memo of 1/19/79, G., Makhijani) and in lettuce and peaches (PP#9G2204, memo of 1/18/80, B. Davis). A rat metabolism study was also discussed in our review of PP#82068. These studies demonstrated that the residue of concern consists of parent and metabolites containing the 3,5-dichloroaniline moiety.

We conclude that the nature of the residue is adequately understood for the proposed use of Ronilan on tomatoes and cucumbers.

Analytical Methods

The residue method for Ronilan (vinclozolin) involves alkaline hydrolysis of parent and metabolites to form free 3,5-dichloroaniline. The 3,5-dichloroaniline is removed from the hydrolysis mixture by steam distillation and collected in a solution of sulfuric acid. The 3,5-dichloroaniline is extracted from the aqueous solution by using chloroform. After drying, the 3,5-dichloroaniline is derivatized with chloroacetyl chloride. The derivative is determined by GC using an electron capture detector, and the residue is reported as parent.

Recoveries from tomato samples fortified with 0.05- 2 ppm Ronilan ranged from 53-107%. Recoveries from cucumbers samples fortified with 0.05 to 2.0 ppm Ronilan ranged from 60 to 96%.

A successful EPA method trial was completed on strawberries. We conclude that adequate methodology is available for regulatory purposes.

Residue Data

Ronilan was applied at various rates to tomatoes and cucumbers grown in West Germany, Denmark, England, and the Netherlands. Summaries of residue data for these raw agricultural commodities are given below:

Tomatoes

<u>Treatment Rate(kg ai/ha)</u>	<u>Sampled at (PHI)</u>	<u>Residue (PPM)</u>
once at 0.6 plus (0.5 lb ai/A)	0	1
once at 0.9 plus (0.8 lb ai/A)	3	1.6
3 times at 1.05 (0.9 lb ai/A in West Germany)	7	1.3
once at 0.9 plus (0.8 lb ai/A)	0	0.9
4 times at 1.05 (0.9 lb ai/A) in West Germany)	3	1
	7	0.7
twice at 0.3 plus (0.3 lb ai/A)	0	0.4
once at 0.5 plus (0.4 lb ai/A)	3	0.2
2 times at 0.6 (0.5 lb ai/A in West Germany)	7	0.3
5 times at 1 (0.9 lb ai/A in West Germany)	0	0.3-1.4
	3	0.8-1.2
	7	0.3-0.7
3 times at 0.75 (0.7 lb ai/A in the Netherlands)	3	0.5-1
once at 1.9 (1.7 lb ai/A)	1	0.6-1.3
or at 3.8 (3.4 lb ai/A)	3	0.6-1
in Denmark	6	0.2-1

Cucumbers

<u>Treatment Rate (kg ai/ha)</u>	<u>Sampled at (PHI)</u>	<u>Residue (PPM)</u>
4 or 5 times at 1.0 (0.9 lb ai/A) in England	0	0.2-0.4
	3	0.4-0.7
	7	0.2-0.5
4 or 5 times at 0.5 (0.4 lb ai/A) in West Germany	0	0.06-0.5
	3	0.1-0.2
	7	0.1-0.3
3 times at 0.3 to 0.5 (0.3-0.4 lb ai/A) in West Germany	0	0.2
	3	0.1-0.3
	7	0.1-0.2
one time at 0.8 (0.7 lb ai/A) in the Netherlands	3	0.8-1

No control values were reported for the cucumber samples; these controls are needed. Residual backgrounds for untreated tomatoes were reported as less than 0.05 ppm.

Fractionation Studies

Some tomatoes grown in West Germany were processed into juice, puree, and ketchup. No concentration of Ronilan was observed in the juice and ketchup. Residue in the whole tomatoes ranged from 0.35 to 0.91 ppm. Residues in puree ranged from 0.40 to 1.05 ppm. There is some concentration of Ronilan in tomato puree. A maximum Ronilan concentration of 3X is observed in tomato puree (whole tomatoes - 0.35 ppm to tomato puree - 1.0 ppm).

Our Comments/Conclusions

The petitioner has submitted proposed product labels from the Netherlands, Federal Republic of Germany, Spain, Greece and Italy. The residue data were generated in the sovereign countries of England, Denmark, West Germany, and the Netherlands.

Thus, we are not able to conclude whether or not the proposed tolerances on tomatoes and cucumbers grown in Spain, Greece and Italy are adequate since no residue data reflecting the proposed use in those countries were submitted. If it is still the intent for the petitioner to use Ronilan on tomatoes and cucumbers that are to be grown in Spain, Greece and Italy, then he will need to submit residue data on the subject crops grown and harvested in Spain, Greece, and Italy; after a proper review of that residue data, we will draw our conclusion on the adequacy of the proposed tolerances.

Finally, with regard to processed tomatoes, the Agricultural Statistics of 1975, for example, showed over 30 million pounds of tomato paste were imported. If Ronilan is approved for use in any country from which we import processed tomatoes, then it would be quite possible that such imports could contain Ronilan residues. The petitioner's tomato fractionation study showed a maximum Ronilan concentration of about 3X in tomato puree. In view of this, the petitioner should propose a food additive tolerance (which needs to be 3 times the proposed tolerance on whole tomatoes) as follows:

Processed tomato productsX ppm.

Meat, Milk, Poultry and Eggs

Since imported tomatoes treated with Ronilan will be sold on the fresh market, there should be no problems of secondary residues in meat, milk, poultry and eggs from the proposed use.

Other Comments

No Codex, Mexican or Canadian Ronilan tolerances on tomatoes and cucumbers have been established.

cc: R.F., Circu, Reviewer, S.F.(Ronilan, PP#4E2998)
RDI:JHO:3/26/84:RDS/3/27/84
TS-769:RCB:Reviewer:JHO:wh:RM810:CM#2:3/29/84

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Vinlozolin

PETITION NO FF2998

CCPR NO. _____

Reviewer: J. Onley
J. Jones 4/26/84

Codex Status

Proposed U. S. Tolerances

No Codex Proposal
Step 6 or above

Residue (if Step 9): _____

Residue: Benilan (vinlozolin)
and metabolites

Crop(s) Limit (mg/kg)

Crop(s) Tol. (ppm)

Tomatoes 2.0
Cucumbers 1.0

CANADIAN LIMIT

MEXICAN TOLERANCIA

Residue: _____

Residue: _____

Crop Limit (ppm)

Crop Tolerancia (ppm)

none

none

Notes: