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PP#2F2650

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUN 11 1992

MEMORANDUM

Subject: PP#2F2650 Ronilan on peaches, cherries and plums. Evaluation of analytical method and residue data

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BASF Wyandotte Corporation proposes tolerances for the residues of the fungicide, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione, and its 3,5-dichloroaniline-containing metabolites in or on peaches and cherries, both at 4 ppm and plums at 1 ppm.

Tolerances for the residues of Ronilan are established for strawberries and Kiwi fruit, both at 10 ppm. Temporary tolerances were proposed for peaches (4 ppm), plums (1 ppm) and cherries (4 ppm) with PP#9G2204 but have not yet been established.

Conclusions:

1a. The nature of the residue is adequately understood. The residue of concern consists of parent plus metabolites containing the 3,5-dichloroaniline moiety.

1b. Since no feed items are involved with this use, the question of animal metabolism isn't pertinent here.

2. Adequate analytical techniques are available for enforcement of the proposed tolerances.

3a. The tolerance proposed for peaches (4 ppm) is not supported by the submitted residue data. A tolerance of 10 ppm would be appropriate if a 14 day PHI were imposed.

3b. For plums and cherries there is not enough residue data reflective of the proposed use. More residue data reflective of the maximum proposed use will be needed before we can make a conclusion as to an appropriate tolerance for these items.

3c. No residue data are submitted for dried prunes. Residue data for dried prunes processed from fresh fruit bearing residue at or near the proposed tolerance level is needed. An appropriate food additive tolerance should also be proposed, if needed, for the dried prunes.

4. Since no feed items are involved, there will be no problem of secondary residues in meat, milk, poultry and eggs.

5. An International Residue Limits Status sheet is attached. No Codex MRLs for Ronilan on stone fruit have been. established.

Recommendations:

We recommend against the proposed tolerance. For further consideration, we require the petitioner to submit the following.

1) A revised Section B in which a PHI of 14 days is proposed for peaches.

2) A revised Section F in which a tolerance of 10 ppm is proposed for peaches.

3) Residue data reflective of maximum proposed use for cherries and plums.

4. Residue data should be submitted for dried prunes processed from fresh fruit bearing residues at or near the proposed tolerance level. An appropriate food additive tolerance should be proposed, if needed, for dried prunes.

Detailed Considerations

Manufacturing Process and Formulation

The manufacturing process was described in our review of PP# 9F2205 (memo of 7/23/79 M. Nelson). Ronilan is prepared by the reaction [redacted]

The technical material is 93% pure. Impurities include a maximum of [redacted] We do not expect any residue problem from these impurities.

Ronilan fungicide is formulated as a 50% wettable powder. All inert ingredients are cleared under 40 CFR 180.1001(c).

Proposed Use

For control of brown rot blossom and twig blight in peach, cherry and plum orchards, up to 5 applications of 3/16 - 1/2 lb. act/100 gals (up to 1.0 lb a.i./A) may be made as follows: two applications at a 14 day interval, followed by three applications at 7-10 day intervals, if needed. Then two more applications at the same rate may be made to control fruit rot; the first at 21 days before harvest and the second at 10-14 days before harvest. No more than 14 lbs of product (7 lb. a.i.)/A may be applied per season. The PHI is 3 days.

Nature of the Residue

Metabolism studies using ^{14}C-uniformly ring labeled Ronilan on strawberries, grapes, rats and soil were detailed in our review of PP#8G2068 (memo of 1/19/79, G. Makhijani). Studies on peaches and lettuce were submitted with PP#9G2204 and were described in our review (memo of 1/18/80, B. Davis) of that petition. The results of the study are summarized below.

Approximately 90 peaches, 1-3 inches in diameter, were painted evenly with a 0.1% aqueous solution of ^{14}C Ronilan. Samples were taken 2 hours later, then at intervals of 7 days up to 35 days and finally once at 48 days. The total radioactivity ranged form 7.7 ppm for the two hour samples to 0.81 ppm for the 48 day samples. The major metabolic routes involved hydrolytic cleavage of the oxazolidinedione ring and/or loss of the ethenyl moiety. At day 48, 51% of the radioactive residue was in very polar materials. Enzymatic treatment of this material released 87% of the radioactivity as 3,5-dichloroaniline. Alkaline hydrolysis of peach flesh plus peel showed that about 85% of the radioactive residue can be determined as 3,5 dichlorophenylaniline.

We reiterate our conclusion (PP# 8G2204, memo of 1/18/80, B. Davis) that the residue of concern consists of parent plus metabolites containing the 3,5-dichloroaniline moiety.

Analytical Method

The analytical method involves release of 3,5-dichloroaniline from parent acid metabolites by alkaline hydrolysis. The 3,5-dichloroaniline is isolated by steam distillation, partitioned with chloroform for cleanup, then derivatized with chloroacetyl chloride. The derivative is determined by gas chromatography using an electron capture detector.

The following check and recovery data are presented:

		recovery		
fruit	check (ppm)	fort. (ppm)	range (%)	avg (%)
cherries	<0.05	0.05-5	76-103	89
peaches	<0.05	0.05-20.	74-92	85
plums	<0.05	0.05- 1.0	71-117	89

A successful method tryout was completed on strawberries. These results are applicable to the proposed tolerances in this petition.

Adequate analytical methodology is available for enforcement purposes.

Residue Data

No new residue data were submitted with this petition. All had been previously submitted with PP# 9G2204 and were recently discussed in our review of an amendment to that petition (memo of 3/18/82, W. Anthony).

Peaches

Residue experiments were carried out in Alabama, Arkansas, California, Georgia, Michigan, New Jersey, New York, Oregon, Pennsylvania, South Carolina, Tennessee, and Texas. The highest residue found was 27.5 ppm. This (plus a residue value of 21 ppm) resulted from 9 applications of 1.0 lb a.i./A at a one day PHI. Other high values (16.4 and 18.9 ppm) were found as the result of six applications of 1.0 lb a.i./A and a 0 day PHI. The highest residue found at PHI's of 3 days or longer was 3.5 ppm (3 applications of 1.0 lb a.i./A; 3 day PHI). Because of the high values at 0 and 1 day PHI we cannot support the proposed 4 ppm tolerance (3 day PHI). We could support a tolerance of 10 ppm if a 14 day PHI were imposed; for a 3 day PHI the tolerance would have to be 25 ppm. The petitioner could option to generate more residue data but should be advised that the high values already submitted will not easily be refuted and, in any case, will have to be accommodated by an appropriate tolerance level.

Cherries

Residue experiments were carried out in Oregon, California, Michigan and New York. Not much of the data is representative of the proposed use; only one experiment incorporated the 3 day PHI. These data are tabulated below:

State	rate (lb a.i./A)	no. appl.	PHI (days)	residue (ppm)
Oregon	1.0	4	7	1.4
	1.0	3	6	3.3
	1.0	4	7	2.9
	3.0	3	14	1.7
California	0.75	3	0	0.87
	0.75	3	3	0.78
	0.75	3	7	0.68
	0.75	3	13	0.63
Michigan	0.75	5	0	12.4
New York	0.75	3	7	0.07
	0.75	6	7	0.88
	0.75	3	0	14.8
	0.75	5	0	11.2

These data do not support the proposed tolerance. Before we can make a decision as to an appropriate tolerance we need more data representative of the propose use. That is, fruit receiving 7 applications of the maximum proposed rate should be harvested at a 3 day PHI, then analyzed for residues.

Plums

Residue experiments were carried out in California, Michigan and Oregon. These data are tabulated below:

State	rate (lb a.i./A)	no. appl.	PHI	residue (ppm)
California	1.0	1	132	0.05
	1.0	2	0	0.34
	1.0	2	12	0.65
	1.0	3	0	0.87
	1.0	3	3	0.86
	1.0	3	8	0.77
	1.0	3	15	0.56
	1.25	2	93	0.1
	.5	2	93	0.15
	1.0	2	93	0.36
	.25	2	118	0.05
	.5	2	118	0.12
	1.0	2	118	0.79
	0.75	3	16	0.4
Michigan	0.75	9	0	2.0
Oregon	1.0	4	7	0.87

Few of these data are representative of the proposed use and we can draw no conclusion on an appropriate tolerance level. For further consideration, the petitioner should submit residue data representative of the maximum proposed use.

No residue data were submitted for dried prunes. Residue data for dried prunes processed from fresh fruit bearing residues at or near the proposed tolerance are needed.

Meat, Milk, Poultry and Eggs

Since no animal feed items are involved there will be no problems of secondary residues in meat, milk, poultry and eggs.

TS-769:K:Arne:vg:CM#2:Rm810:X5577324:6/3/82
cc: RF, Circ., Arne, Thompson, FDA, TOX, EEB, EFB, PP#2F2650
RDI: Quick, 5/19/82; Schmitt, 5/19/182

INTERNATIONAL RESIDUE LIMIT STATUS

K. Arne

CHEMICAL Ronilan

PETITION NO. 2F2650

CCPR NO. none

CODEX STATUS

/X/ No Codex Proposal
Step 6 or above

RESIDUE (If Step 9): _____

Crop(s)	Limit (mg/kg)
none	

PROPOSED U.S. TOLERANCES

RESIDUE: parent plus metabolites containing 3,5-dichloroaniline moiety

Crop(s)	Tol. (ppm)
peaches	4
cherries	1
plums	1

CANADIAN LIMIT

RESIDUE: _____

Crop	Limit (ppm)
none	

MEXICAN TOLERANCIA

RESIDUE: _____

Crop	Tolerancia (ppm)
none	

NOTES: