12-29-86

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

29 12/29/86

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP #1E2457 (RCB # 1761). Vinclozolin (Ronilan) in or on Grapes. Amendment of 12/4/86. No Accession No.

FROM: [redacted] Ph.D., Chemist Nancy Dodd for
Tolerance Petition Section 2
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch R D Schmitt for
Hazard Evaluation Division (TS-769)

TO: L. Rossi, Product Manager No. 21
Registration Division

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

This review has been expedited on the request of J. Akerman, Acting Director of Registration Division (memo to J. Melone, 9/8/86).

Background

BASF Wyandotte Corporation had proposed a tolerance of 6 ppm for residues of the fungicide vinclozolin [Ronilan; 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] and its metabolites containing the 3,5-dichloroaniline moiety in or on table grapes.

RCB had questioned the petitioner's contention that imported table grapes would be used solely for that purpose and had therefore requested a grape fractionation study (see RCB's 4/27/81 review of PP #1E2457, memo of J.H. Onley). In the amendment of 8/11/86, the petitioner proposed that boxes containing Chilean grapes bear labels prohibiting the use of the grapes for processing or feed. After consulting with

the Office of General Counsel, RCB concluded that such a label was not enforceable. RCB also pointed out that Chile is now exporting processed grape commodities to the US, including raisins, and no residue data on processed grape commodities are available (memo of C. Deyrup, 9/23/86).

Present Consideration

The present consideration consists of a cover letter from J. Graham, BASF Wyandotte Corporation to L. Rossi, RD, a copy of the 5/3/83 letter from H.M. Jacoby, RD, to D.V. Yoder, BASF, a revised Section F, and a grape processing study. The present amendment addresses Deficiencies 5 and 7 from RCB's memo of 4/13/83 (PP #1E2457, memo of J. Onley). These deficiencies will be restated below, followed by the Petitioner's Response and RCB's Comments/Conclusions.

Deficiency 5

We find the proposed tolerance for table grapes to be impractical. There is no assurance that imported table grapes will be used solely for that purpose (telephone conversation between Bernadine Baker, U.S. Dept. of Agriculture and J. Onley, EPA-March 30, 1981). The petitioner needs to provide a revised Section F wherein the tolerance is proposed on grapes.

Petitioner's Response re: #5

The petitioner has submitted a revised Section F in which a tolerance of 6.0 ppm for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety on grapes is proposed.

RCB's Comments/Conclusions re: #5

The revised Section F proposes tolerances on grapes and wet and dry grape pomace. Since the petitioner did not propose a tolerance for residues of vinclozolin/metabolites in/on raisins, and since RCB has reason to believe that residues of vinclozolin/metabolites could concentrate in raisins (see RCB's Comments/Conclusions under Deficiency 7), RCB could recommend that a tolerance with a one year expiration date be established on grapes at 6.0 ppm vinclozolin/metabolites. This tolerance would expire after one year if residue data on raisins have not been submitted. Therefore the petitioner will need to submit a revised Section F in which he proposes that a tolerance with an expiration date of one year be established on grapes at 6.0 ppm.

Deficiency 7

The petitioner needs to submit a grape fractionation study. Residue data on juice, and wet and dry pomaces should be submitted. If any

of these fractions should show BAS 352F concentrations greater than the maximum residue value for grapes, then appropriate food additive tolerances should be proposed.

Petitioner's Response re: #7

The petitioner has submitted additional residue data from 5 field trials conducted in CA, NY, and WA, a grape processing study, and a revised Section F.

The residue data reflect 2 to 6 applications of Ronilan® at rates of 0.75-1.0 lb. a.i./A with PHI's of 9-79 days. The proposed use permits 5 applications. The latest revised supplementary text in Section B (7/31/81), which permits treatment at rates of up 1.0 kg. a.i./ha (0.89 lb. a.i./A) appears to disagree with the submitted label, which permits treatment at rates of up to 1.5 kg/ha (0.75 kg a.i./ha or 0.67 lb. a.i./A). The raw data sheets submitted with the Chilean field trials indicate the use of 1.0-1.5 kg formulation/ha.

The residue data were generated by a modification of the analytical method previously described in RCB's memo of 4/27/81 (PP #1E2457, memo of J. Onley). The recoveries of vinclozolin from processed grape fractions are given below.

Commodity	Fortification level (ppm)	% Recovery
Grape juice	0.05-10.0	65-91
Wet grape pomace	1.0-30.0	67-94
Dry grape pomace	1.0-50.0	58-93

The levels of vinclozolin ranged from <0.05-<0.10 ppm in check samples of grapes and grape juice, ranged from <0.05-0.27 ppm in check samples of wet pomace, and ranged from <0.10-0.50 ppm in check samples of dry pomace.

The residue data on grapes are tabulated below.

Treatment Rate (lb. a.i./A)	PHI (days)	Vinclozolin Equivalents (ppm)
2 x 0.75	9	5.9
4 x 0.75	9	8.9
2 x 0.75	18	5.4
4 x 0.75	18	6.7

Treatment Rate (lb. a.i./A)	PHI (days)	Vinclozolin Equivalents (ppm)
4 x 0.75	21	0.45
4 x 0.75	52	0.40
2 x 1.0	9	7.6
4 x 1.0	9	8.5
2 x 1.0	79	0.40
4 x 1.0	11	13.4
5 x 1.0	11	17.3
6 x 1.0	11	12.2

RCB's Comments/Conclusions re: Residue Data, #7

The purpose of the field trials was to provide samples which could be processed so that the concentration factors for the various fractions could be determined. However, RCB notes that the field trial from Valois, NY (4 x 0.75 lb. a.i./A; PHI, 18 days) exhibited vinclozolin residue levels of 6.7 ppm. The supplementary text in Section B permits 5 applications of up to 0.89 lb. a.i/A whereas the submitted label permits 0.67 lb. a.i./A. If the proposed use is actually reflected in the 0.89 lb. a.i./A application rate, the result from NY could mean that the proposed use for Chilean grapes could lead to residue levels which are over tolerance in US grapes if the same application rate is used. Since the lower rate (0.67 lb. a.i./A) was used in the Chilean field trials, RCB suggests that the petitioner revise Section B so that it agrees with the label.

Fractionation Study

Grapes from the field trials described above were harvested, frozen within 24 hours, and stored frozen for about 2 years before processing.

The stemmed grape samples were permitted to thaw in plastic bags. The released juice was decanted from the bags, holes were made in the bags, and the bags were hand squeezed to produce more juice. The sample was transferred to a ricer, a metal basket with small holes, and the sample was squeezed with the top of the ricer. The juice was filtered through four layers of cheesecloth, and the residue was added to the marc. About 1/3 of the wet pomace was dried in an oven at 115°C for about 16 hours. At the end of this time, the pomace had dried to a constant weight.

The moisture content of the wet pomace ranged from 28-36%. The moisture content of wet grape pomace is given as 37% in

the Harris Guide.

The concentration factors for the processed grape fractions are given below.

Commodity	Concentration Factor
Juice	0.20-0.76
Wet Pomace	1.50-3.55
Dry Pomace	2.08-6.69

The petitioner has submitted a revised Section F which is based on the average of the concentration factors found in the processing studies (2.6 and 4.5 for wet and dry pomace, respectively). Therefore, the revised Section F proposes tolerances of 16.0 ppm vinclozolin/metabolites for wet grape pomace and 27 ppm for dry grape pomace, in addition to the 6 ppm tolerance proposed for grapes.

RCB's Comments/Conclusions, re: Fractionation Studies and Revised Section F, #7

RCB first asked for a processing study in 1981; at this time Chilean raisins were not a significant US import item. In fact, in 1981, the US imported no raisins from Chile (R. Gifford, Foreign Agricultural Service, USDA), and RCB requested no residue data on raisins. However, in 1985, Chile exported 197.5 tons of raisins to the US (US Imports for Consumption and General Imports, 1985).

The data submitted with this amendment demonstrate that vinclozolin residues concentrate as the water content of the commodity decreases. A similar tendency was shown in the petitioner's tomato processing study (PP #4E2998). Also, a food additive tolerance of 75 ppm has been established on prunes, whereas the established tolerance on stone fruit is 25 ppm. In fact, all the available data indicate that a food additive tolerance for raisins is needed. The theoretical dry down factor for raisins is 4.7. Therefore, RCB recommends that a food additive tolerance with an expiration date of one year be established for residues of Ronilan on raisins. During this period the petitioner will need to generate residue data on raisins to support this food additive tolerance. If, after one year, the necessary residue data on raisins have not been submitted, the food additive tolerance on raisins will expire.

Therefore, the petitioner will need to submit a revised Section F in which he proposes a food additive tolerance with an expiration date of one year for residues of vinclozolin/metabolites on raisins. Since residue data on raisins are not available, the proposed tolerance should reflect the 5-fold theoretical dry down factor.

The petitioner has also proposed tolerances of 16 and 27 ppm vinclozolin/metabolites on wet and dry pomace, respectively. A tolerance on wet grape pomace is not needed, as the residues on wet pomace would be covered by the proposed feed additive tolerance on dry pomace. However, the proposed tolerance of 27 ppm is based on an average concentration factor of 4.5 ppm. In the 12 sets of samples of grapes and dry pomace, the concentration factor exceeded 5 in 1/3 of the sets of samples. The concentration factor for dry grape pomace ranged up to 6.7.

RCB concludes that the proposed feed additive tolerance of 27 on dry grape pomace is not adequate. The petitioner will therefore need to propose a feed additive tolerance with a one year expiration date for residues of vinclozolin/ metabolites on dry grape pomace. The proposed tolerance should reflect a concentration factor of at least 6.7. RCB recommends that the proposed tolerance should expire in one year, if the required residue data on raisins have not been submitted.

Other Considerations

The impact of the proposed tolerances on Codex, Mexico, and Canada will be discussed after the submission of a revised Section F.

Recommendations

RCB recommends against establishing the proposed permanent tolerances for residues of vinclozolin/metabolites on grapes, and wet and dry pomace. The petitioner will need to submit a revised Section B clarifying the application rate. TOX and EAB considerations permitting, RCB could recommend for vinclozolin/ metabolites tolerances with one year expiration dates on the subject commodities. Therefore, the petitioner will need to submit a revised Section F in which the petitioner proposes appropriate tolerances with one year expiration dates on grapes, raisins, and dry grape pomace. RCB recommends that the tolerances expire after one year if the residue data on raisins have not been submitted.

Note to PM: If cancellation is necessary, the registration on grapes should be cancelled before the tolerances are cancelled so that commodities moving through commerce will not immediately be seized.

cc: TOX, EAB, PMSD/ISB-Eldredge, PP #1E2457, R.F., Circu, Reviewer-Devrup, PM #21, EEB, FDA

RDI: NDodd:12/23/86:RDSchmitt:12/24/86
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