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MEMORANDUM

SUBJECT: PP No. 4E4377. Vinclozolin on Cranberries. Review of Residue Data and Enforcement Methodology. CB No. 14035. DP No. 205273, MRID Nos. 432897-00, -01.

FROM: Stephanie H. Willett, Chemist *SHW*
Tolerance Petition Section 2
Chemistry Branch I-Tolerance Support
Health Effects Division (7509C)

THRU: Elizabeth Haerberer, Section Head *Elizabeth T. Haerberer*
Tolerance Petition Section 2 *11/14/94*
Chemistry Branch I-Tolerance Support
Health Effects Division (7509C)

TO: Hoyt Jamerson, PM Team 43
Registration Support Branch
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and
Albin Kocialski, Section Head
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The IR-4, on behalf of the state of Wisconsin, is requesting a 2 ppm tolerance for vinclozolin on cranberries. Vinclozolin is a fungicide which will be used to control tip blight and fruit rot stages of cottonball disease caused by Monilinia oxycocci. Presently there are no fungicides available for use in cranberries that control this disease.

Tolerances for vinclozolin [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] and its metabolites containing the 3,5-dichloroaniline moiety on several raw agricultural commodities range from 1 to 25 ppm, and are listed in 40 CFR 180.380. Food additive tolerances for raisins and prunes are established at 30 and 75 ppm in 40 CFR 185.1850. A feed additive tolerance has been established at 42 ppm in grape pomace in 40 CFR 186.1850.

Vinclozolin is a list B reregistration chemical. It is not a RED candidate for FY 1995.



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Conclusion

The residue chemistry database adequately supports this proposed use on cranberries. Residue levels are expected to be below the proposed tolerance level of 2 ppm when used according to the proposed label directions.

Recommendations

TOX considerations permitting, CBTS recommends for the establishment of a tolerance for the combined residues of vinclozolin and its metabolites containing the 3,5 DCA moiety in or on cranberries at 2 ppm.

Detailed Considerations

Product Chemistry

The manufacturing process for technical grade vinclozolin has been described in support of previously established tolerances (see PP No. 9F2205). Although additional information has been requested in support of reregistration (see 3/6/91 Phase 4 review of L. Cheng), at this time the manufacturing process has been sufficiently described in order to allow the consideration of a tolerance for cranberries. Presently no impurities are expected to cause residue concerns.

Ronilan™ DF (EPA Reg. No. 7969-85) which contains 50% vinclozolin will be used on cranberries. All of the inerts have been cleared for use.

Proposed Use

The present Ronilan™ DF label will be modified to specify 1 application to cranberries at 1 lb ai/acre prior to bloom beginning when most shoots are elongating, followed by 1 application at 10 to 20% bloom and 1 application at 60 to 100% bloom. A maximum of 3 applications per season (3 lb ai/A/season; 1 lb ai pre-bloom and 2 lb ai post-bloom), and a minimum 50 day PHI is specified.

Nature of the Residue

Plant metabolism studies on strawberries, grapes, lettuce, peanuts and peaches were previously reviewed and found to be acceptable. The studies produced similar results. Metabolism in plants results from the hydrolytic cleavage of the oxazolidinone ring and/or

loss of the ethenyl moiety. The residues to be regulated are parent vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety (see PP No. E3850, and 3/6/91 phase 4 review of L. Cheng).

The metabolism of vinclozolin in animals is not an issue related to this petition since no animals feed items are derived from cranberries. Also, confined rotational crop studies are not required to support this petition since cranberries are not a rotational crop.

Enforcement Methodology

Adequate enforcement methodology for the determination of vinclozolin and its metabolites in plant commodities is available in PAM II. The methodology involves base hydrolysis of samples to convert vinclozolin and its metabolites to 3,5-dichloroaniline (DCA). After steam distillation and organic solvent extraction, the isolated DCA is derivatized with chloroacetyl chloride. Quantitation is by gas chromatography equipped with an electron capture detector. The limit of quantitation is 0.05 ppm in most plant matrices.

Vinclozolin is completely recovered (>80%) using FDA multiresidue protocols D and E. The FDA multiresidue methodology also differentiates between vinclozolin and iprodione, a pesticide which also contains a 3,5-dichloroaniline moiety. The DCA metabolites of vinclozolin have also been tested using FDA multiresidue methodology, and forwarded to FDA (see 8/12/93 memo of W. Wassell).

Field Trial Data (MRID No. 43289701)

Six field trials were conducted in New Jersey (1), Massachusetts (1), Wisconsin (2), and Washington (2). Some test plots received 3 applications of vinclozolin a rate of 2 lb ai/A/application with a preharvest interval of 7 days (2X maximum label rate), while others received two, three or four applications at 1 lb ai/A/application (0.67X, 1X, 1.33X), or two applications at 3 lb ai/A/application (2X). In all trials ground equipment was used, and treatment intervals ranged from 10 to 95 days. Both dry flowable and wettable powder formulation were used. Cranberries were harvested at normal maturity 7 to 83 days following the last application. Samples were shipped cool or frozen to BASF for analysis. After receipt, the samples were maintained at less than -5°C until analyzed. All samples were analyzed within 15 months. Storage stability study data on strawberries and grapes indicates that parent vinclozolin and its B and D metabolites are stable in frozen storage for up to 40 months (see MRID 43289701 and 8/20/93 memo of W. Wassell, PP No. 1F3976).

Vinclozolin and its DCA metabolites were determined using BASF method 25F, which is essentially the same as the enforcement methodology (see previous section). To validate the results of these analyses, control samples of cranberries were fortified at levels ranging from 0.05 to 10 ppm. Recoveries averaged $85 \pm 21\%$ (N=4).

A summary of the residue data submitted is presented in the table that follows.

TABLE 1. RESIDUE FIELD TRIAL DATA SUMMARY: VINCLOZOLIN ON CRANBERRIES

Field Trial year/ST	Number of apps. ¹	Rate lb ai/A	Total lb ai applied	Treatment Interval (days)	Preharvest Interval = days to harvest after final app.	Maximum residue ppm
1984/WI	3	1.0	3.0 (1X)	13, 14	50	0.82
1984/MA	3	1.0	3.0 (1X)	10, 10	49	1.00
1984/NJ	3	1.0	3.0 (1X)	10, 10	49	0.67
1984/WA	3	1.0	3.0 (1X)	14, 14	7	0.64
	3	1.0	3.0 (1X)	14, 14	83	0.82
1985/WA	2	1.0	2.0 (0.67X)	95	7	0.50
	2	2.0	4.0 (1.33X)	95	7	1.20
	2	3.0	6.0 (2X)	95	7	2.00
1985/WI	2	1.0	2.0 (0.67X)	88	7	0.55
	2	2.0	4.0 (1.33X)	88	7	1.30
	2	3.0	6.0 (2X)	88	7	1.60

¹ In all field trials, first application was during June or July prior to or just at bloom.

The highest residue level found in any sample was 2.0 ppm vinclozolin equivalents, detected in a sample treated at 2X with a PHI of 7 days. In the remainder of the samples residue values ranged from 0.46 to 1.6 ppm vinclozolin equivalents. The petitioner concludes that by comparing the residue levels in cranberries treated at the 1, 2 and 3 lb rates, the data suggests that residues are attributable to the last application, and that early applications apparently had little effect on residue levels. Typical chromatograms, sample handling records and other supporting information were included in the submission.

CBTS concludes that the residue data are minimally adequate to support this minor use on cranberries. Residue levels are expected to be below the proposed tolerance level of 2 ppm when used according to the proposed label directions. We note that based on some of the discussion in the residue trial report, modified uses

on cranberries may be proposed in the future, and the residue trial design was intended to investigate residue levels from several use patterns.

There are no processed food or animal feed items derived from cranberries, therefore no food or feed additive tolerances are required. Also, since there are no animal feed items the adequacy of animal commodity tolerances is not an issue related to this petition.

cc: RF, PP No. 4E4377, S. Willett, E. Haerberer, Cir, List B File,
Subject File, K. Whitby (CCB/HED)

CM2:305-6380:RM 804C:7509C:SHWillett:shw-11/08/94
RDI:E. Haerberer, 11/9/94; M. Flood, 11/9/94; R. Loranger 11/9/94