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

FEB 18 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Vinclozolin. Magnitude of the Residue in Cherries. Reregistration Case No. 2740. Chemical No. 113201. MRID #42829801. DP Barcode D193694. CBRS #12,302.

FROM: Steven A. Knizner, Chemist *St A Knizner*
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THRU: Andrew Rathman, Section Head *AR*
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TO: Alan Dixon, PM Team 53
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The Vinclozolin Phase 4 Reviews (L. Cheng, 3/6/91) required additional field residue trials for cherries in NY/PA and UT/MT/ID to satisfy reregistration requirements for magnitude of the residue in stone fruit. In response, BASF Corporation has submitted a field residue study (1993; MRID 42829801) depicting the combined residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline (DCA) moiety in/on sweet and sour cherries. These data and MRID 92194049, a Phase 3 reformat of MRIDs 00085105, 00139008, and 40876701 which was submitted by BASF Corporation and considered in the Vinclozolin Phase 4 Reviews, have been reviewed by Dynamac Corporation under contract to the Agency, have undergone secondary review in CBRS, and been revised to reflect Branch policies.

BASF has submitted a petition for a reduction in the tolerance for stone fruit from 25 ppm to 5 ppm (PP#1F03976); this petition is currently under review at CBTS. The present submission is reviewed solely for adequacy in fulfilling reregistration data requirements.



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Final Report

VINCLOZOLIN
Shaughnessy No. 113201;
Case No. 2740
(CBRS No. 12302; DP Barcode
D193694)

TASK 4
Registrant's Response to Residue
Chemistry Data Requirements

November 12, 1993

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

Tolerances for residues in/on plant (including import commodities) and food/feed commodities are expressed in terms of the combined residues of vinclozolin (3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione) and its metabolites containing the 3,5-dichloroaniline moiety [40 CFR §180.380; §185.1850(a) and (b); and §186.1850].

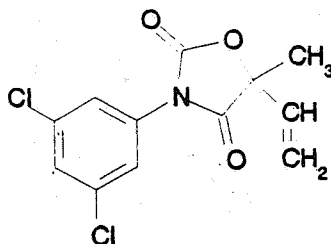
The available data indicate that the combined residues of vinclozolin and its DCA-containing metabolites will not exceed the established tolerance of 25 ppm in/on sweet and sour cherry samples harvested 0-14 days following the last of 4-7 foliar broadcast applications of the 50% DF, 50% WP, or 4.17 lb/gal FIC formulations at 1x the maximum seasonal rate for each type of formulation. No additional field residue data are required for cherries.

Combined residues of vinclozolin and its DCA-containing metabolites were less than the proposed tolerance of 5 ppm in/on all samples from the above-described trials except one sample from OR harvested 3 days following treatment at 1x the maximum seasonal rate for the 4.17 lb/gal FIC formulation.

If you need additional input please advise.

cc: S.F., circ., R.F., List B File, S.Knizner, DYNAMAC
RDI: A. Rathman, 2/15/94 M.Metzger, 2/16/94 E.Zager, 2/17/94
7509C:CBRS:CM#2:305-6903:SAK:sak:Vincol:2/3/94

VINCLOZOLIN



Shaughnessy No. 113201; Case 2740

(CBRS No. 12302; DP Barcode D193694)

Task 4

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

The Vinclozolin Phase 4 Reviews (L. Cheng, 3/6/91) required additional field residue trials for cherries in NY/PA and UT/MT/ID to satisfy reregistration requirements for magnitude of the residue in stone fruit. In response, BASF Corporation has submitted a field residue study (1993; MRID 42829801) depicting the combined residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline (DCA) moiety in/on sweet and sour cherries. These data and MRID 92194049, a Phase 3 reformat of MRIDs 00085105, 00139008, and 40876701 which was submitted by BASF Corporation and considered in the Vinclozolin Phase 4 Reviews, are reviewed in this document for adequacy in fulfilling outstanding reregistration data requirements. The Conclusions and Recommendations stated in this document pertain only to the magnitude of the residue in cherries. Other data requirements stated in the Phase 4 Reviews are not addressed herein. We note that MRID 92194049 contains data pertaining sweet and sour cherries, peaches, and plums; only the data for sweet and sour cherries are reviewed in this document.

BASF has submitted a petition for a reduction in the tolerance for stone fruit from 25 ppm to 5 ppm (PP#1F03976); this petition is currently under review at CBTS. The present submission is reviewed solely for adequacy in fulfilling reregistration data requirements.

The Vinclozolin Phase 4 Reviews concluded that no additional plant metabolism data are required based on metabolism studies conducted with lettuce, peaches, and strawberries.

Tolerances for residues in/on plant (including import commodities) and food/feed commodities are expressed in terms of the combined residues of vinclozolin (3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione) and its metabolites containing the 3,5-dichloroaniline moiety [40 CFR §180.380; §185.1850(a) and (b); and §186.1850]. No tolerances for residues in animal commodities have been established. Adequate methodology is available for the enforcement of tolerances for residues of vinclozolin in plant commodities. A GLC method with electron capture detection (GLC/ECD; Method I) is listed in Pesticide Analytical Manual (PAM) Vol. II for the determination of residues of vinclozolin and its DCA-containing metabolites in/on kiwi fruit and strawberries. Codex MRLs (Steps 5 through CXL) in plant and animal commodities are expressed in terms of the sum of residues of vinclozolin and all metabolites containing the 3,5-dichloroaniline

moiety, calculated as vinclozolin. Issues regarding the harmonization of the U.S. tolerances and Codex MRLs will be addressed when the reregistration eligibility decision for vinclozolin is made.

CONCLUSIONS AND RECOMMENDATIONS

- 1a. The available data indicate that the combined residues of vinclozolin and its DCA-containing metabolites will not exceed the established tolerance of 25 ppm in/on sweet and sour cherry samples harvested 0-14 days following the last of 4-7 foliar broadcast applications of the 50% DF, 50% WP, or 4.17 lb/gal FIC formulations at 1x the maximum seasonal rate for each type of formulation. No additional field residue data are required for cherries.
- 1b. Combined residues of vinclozolin and its DCA-containing metabolites were less than the proposed tolerance of 5 ppm in/on all samples from the above-described trials except one sample from OR harvested 3 days following treatment at 1x the maximum seasonal rate for the 4.17 lb/gal FIC formulation.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Samples of cherries from the submitted field residue studies were analyzed for residues of vinclozolin and its metabolites by ADPEN Labs, Inc. (Jacksonville, FL; MRID 42829801) or by Morse Laboratories (Sacramento, CA; MRID 92194049). A GLC method with electron capture detection (ECD) was used for analysis of vinclozolin and its DCA-containing metabolites. This method is a modified version of Method I of PAM Vol. II (BASF Method 25). Briefly, samples were hydrolyzed with potassium hydroxide to release 3,5-dichloroaniline (DCA), which was collected by steam distillation into 1 N sulfuric acid. Some cherry samples from MRID 92194049 were extracted with methanol prior to hydrolysis. The pH of the distillate was adjusted to <1 with 1 N sulfuric acid and the distillate was partitioned with methylene chloride. The distillate was then adjusted to pH 8-10 with saturated sodium bicarbonate solution and partitioned with methylene chloride. The methylene chloride extracts were combined and dried with sodium sulfate. A 4% solution of chloroacetyl chloride in methylene chloride was added to derivatize DCA to N-(3,5-dichlorophenyl)chloroacetamide. After derivatization, the extract was concentrated, taken up in hexane, concentrated again, and taken up in isooctane:methylene chloride (85:15, v:v). The extract was then cleaned on a silica gel solid phase extraction column eluted with isooctane:methylene chloride (1:1, v:v), concentrated, taken up in ethyl acetate:hexane and injected onto a GLC equipped with a DB-17 column and an electron capture detector. The limit of detection is 0.05 ppm.

The registrant provided concurrent method recoveries for the cherry field residue studies. Untreated control samples of cherries were fortified with vinclozolin at 0.05-20.0 ppm. The method recoveries are presented in Table 1. Sample calculations, raw data, and representative chromatograms were provided. These data indicate that the modified version of BASF Method 25 is adequate for data collection of residues of vinclozolin from cherry samples.

Table 1. Method recoveries from untreated cherry samples fortified with vinclozolin and analyzed using a modified version of BASF Method 25 (MRIDs 42829801 and 92194049).

Fortification-Level (ppm)	Number of samples	% Recovery *
		Range
0.05	19	61.2-138.7
0.10	1	76
0.50	2	84.6, 93.5
1.00	10	72.1-98.4
2.00	4	100.8-103.7
5.00	5	66-94.7
10.0	2	59, 89
20.0	1	72

* Method recovery values were corrected for apparent residues in control samples.

Storage Stability Data

Samples of cherries from the submitted field residue studies were stored frozen at -15 to -5 C for ca. 7 months (MRID 42829801) or at <-5 C for ca. 4-7 months (MRID 92194049) prior to analysis. The registrant cited previously submitted storage stability data for peaches to support these field residue data. These data were reviewed by CBTS under PP#1F03976 (CBTS Nos. 11396 and 12350, DP Barcodes D188198 and D194020, 8/20/93, W. Wassell); it was concluded that residues of vinclozolin and its metabolites B [3-(3,5-dichlorophenyl-carbamic acid-(1-carboxy-1-methyl)-allyl ester), E [N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenoic acid amide], and S [3-(3,5-dichlorophenyl)-5-methyl-1,3-oxazolidine-2,4-dione] are stable during up to 17 months of frozen storage. We conclude that the submitted field trial data are supported by adequate storage stability data.

Magnitude of the Residue in Cherries

A tolerance of 25 ppm has been established for residues of vinclozolin and its DCA containing metabolites in/on stone fruits [40 CFR §180.380].

A REFS search conducted 9/16/93 indicated that a 50% WP (Ronilan® WP; EPA Reg. No. 7969-53, 1/15/90) and a 4.17 lb/gal FIC (Ronilan® FL; EPA Reg. No. 7969-62) formulation are registered for application to cherries. Up to three foliar bloom applications and one pre-harvest foliar application (within three weeks of harvest) may be made to cherries at 0.5-1.0 lb ai/A/application. A maximum seasonal rate of 4 lb ai/A (3 lb ai/A at bloom and 1 lb ai/A preharvest) has been established for the 50% WP formulation and a maximum seasonal rate of 5.2 lb ai/A (3.1 lb ai/A at bloom and 2.1 lb ai/A preharvest) has been established for the 4.17 b/gal FIC formulation. Application may be made using ground and aerial equipment in a minimum of 50 gal/A and 15 gal/A of finished spray, respectively. A 14-day PHI is in effect for the 50% WP formulation and a 3-day PHI is in effect for the 4.17 lb/gal FIC formulation. The grazing or feeding of livestock cover crops from treated orchards is prohibited. *[These use directions were obtained from the following vinclozolin end-use products registered to BASF Corporation: 50% WP (EPA Reg. No. 7969-53,*

dated 4/30/93) and 4.17 lb/gal FIC formulation (EPA Reg. No. 7969-62, submitted in response to the 1/15/90 Product Label DCI).

BASF Corporation submitted data (1993; MRID 42828901) from 12 tests conducted in CA(5), MI(3), NY(1), UT(1), and WA(2) depicting the combined residues of vinclozolin and its DCA-containing metabolites in/on sweet and sour cherries harvested 0, 7, and 14 days following the last of 4 foliar broadcast applications of the 50% DF or 50% WP formulation at 1 lb ai/A/application (1x the maximum seasonal rate). Applications were made using ground equipment at the late popcorn, full bloom, petal fall, and harvest stages. Samples were frozen within 4 hours of harvest and shipped frozen by ACDS freezer truck to BASF Corporation (RTP, NC) and stored frozen at -15 to -5 C prior to analysis. Samples were hand-pitted and homogenized before shipping, and shipped in dry ice via overnight delivery to ADPEN Labs (Jacksonville, FL) for residue analysis.

BASF also submitted data (1990; MRID 92194049) from 8 tests conducted in CA(4), MI(2), and OR(2) during 1983 and 1987 depicting the combined residues of vinclozolin and its DCA-containing metabolites in/on sweet and sour cherries harvested 3 or 4 days following the last of 4-7 foliar applications of the 50% WP or 4.17 lb/gal FIC formulation at 0.75 or 1.0 lb ai/A/application (ca. 1x the maximum seasonal rate). Applications were made using ground (59.5-200 gal/A) and aerial equipment (10 or 20 gal/A). Samples were frozen soon after harvest and shipped frozen to Morse Laboratories (Sacramento, CA) for residue analysis.

The combined residues of vinclozolin and its DCA-containing metabolites, expressed as vinclozolin, in/on sweet and sour cherries are presented in Table 2. Apparent residues were <0.05(nondetectable)-0.14 ppm in/on 11 untreated sweet cherry samples and <0.05(nondetectable)-0.087 ppm in/on 5 untreated sour cherry samples. Residue values were not corrected for method recoveries.

Table 2. Combined residues of vinclozolin and its DCA-containing metabolites, expressed as vinclozolin, in/on sweet and sour cherries treated at ca. 1x the maximum seasonal rate (MRIDs 42829801 and 92194049).

MRID	State (Study #)	Type of Cherry	Formulation	# and Applic. Rate	Total Rate (lb ai/A)	PHI (days)	Residue (ppm)
139008	CA (4 trials)	Sweet	NS (not stated)	7 x 0.75	5.25	3	0.39, 0.46, 0.49/0.35, 1.2
40876701	CA	Sweet	NS	5 x 1.0	5.0	3	0.91, 0.88, 0.59, 0.12, 0.12, 0.15
	MI	Sweet	NS	5 x 1.0	5.0	4	1.7, 1.3, 1.0, 0.76, 0.66, 0.61

MRID	State (Study #)	Type of Cherry	Formulation	# and Applic. Rate	Total Rate (lb ai/A)	PHI (days)	Residue (ppm)
42829801	CA (92024)	Sweet	DF	3 x 1.0	3.0	45	0.09, 0.06, 0.06
			DF	4 x 1.0	4.0	0	2.40, 1.93, 1.60
						7	0.92, 0.90, 0.88
						14	0.79, 0.61, 0.51
			WP	4 x 1.0	4.0	0	3.53, 2.43, 1.59
						7	1.18, 1.11, 0.71
14	0.59, 0.44, 0.36						
42829801	CA (92025)	Sweet	DF	3 x 1.0	3.0	47	0.07, 0.05
			DF	4 x 1.0	4.0	0	2.35, 2.03, 1.55
						7	1.07, 1.06, 0.99
						14	0.94, 0.89, 0.81
42829801	WA (92026)	Sweet	DF	4 x 1.0	4.0	0	3.79, 2.74, 2.19
						7	1.62, 1.48, 1.24
						14	0.62, 0.61, 0.57
42829801	WA (92027)	Sweet	DF	4 x 1.0	4.0	0	2.34, 2.19, 2.10, 2.00, 1.90, 1.68, 1.42, 1.24
						7	1.13, 1.11, 1.06, 0.61, 0.43, 0.41, 0.27
						14	1.22, 0.41, 0.38

MRID	State (Study #)	Type of Cherry	Formulation	# and Applic. Rate	Total Rate (lb ai/A)	PHI (days)	Residue (ppm)
42829801	MI (92028)	Sour	DF	4 x 1.0	4.0	0	2.93, 2.42, 1.93
						7	1.30, 1.25, 1.07
						14	0.55, 0.52, 0.51
			WP	4 x 1.0	4.0	0	2.09, 1.68, 1.35
						7	1.27, 0.89, 0.89
						14	0.47, 0.36, 0.31, 0.31
42829801	MI (92029)	Sour	DF	4 x 1.0	4.0	0	0.73, 0.67, 0.65
						7	0.69, 0.60, 0.50
						14	0.33, 0.30, 0.29, 0.26
42829801	UT (92030)	Sour	DF	3 x 1.0	3.0	0	2.00, 1.86, 1.40
						7	0.69, 0.65, 0.59, 0.54
						14	0.30, 0.28, 0.26
42829801	NY (92031)	Sour	DF	4 x 1.0	4.0	0	2.69, 1.37, 1.17
						7	0.17, 0.13, 0.11
						14	0.37, 0.37, 0.33, 0.23, 0.18
139008	MI	Sour	NS	4 x 0.75	3.0	4	0.58
	OR	Sour	NS	7 x 0.75	5.25	3	9.7

Geographic representation is adequate since the test states of CA(24%), MI (15%), OR(26%), and WA(33%) collectively accounted for ca. 100% of the 1991 U.S. cherry production and the test states of MI(58%), NY(13%), OR(4%), and UT(14%) accounted for ca. 90% of the 1991 U.S. sour cherry production (Agricultural Statistics, U.S.D.A., 1992). The available data indicate that the

combined residues of vinclozolin and its DCA-containing metabolites will not exceed the established tolerance of 25 ppm in/on sweet and sour cherry samples harvested 0-14 days following the last of 4-7 foliar broadcast applications of the 50% DF, 50% WP, or 4.17 lb/gal FIC formulations at 1x the maximum seasonal rate for each type of formulation. No additional field residue data are required for stone fruit. Combined residues of vinclozolin and its DCA-containing metabolites were less than the proposed tolerance of 5 ppm in/on all samples from the above-described trials except one sample from OR harvested 3 days following treatment at 1x the maximum seasonal rate for the 4.17 lb/gal FIC formulation.

MASTER RECORD IDENTIFICATION NUMBERS

The citations for the MRID documents referred to in this review are presented below:

42829801 Jordan J. (1993) Magnitude of Vinclozolin Residues in Cherries: Lab Project Number: A9306: 93/5063. Unpublished study prepared by BASF Corp. 149 p.

92194049 Foushee J.; Single Y. (1990) BASF Corporation Phase 3 Reformat of MRID 00085105 and Related MRIDs 00139008 and 40876701. Magnitude of the Residue of Vinclozolin and Metabolites in Stonefruit: BASF Report Nos: PR-192, PR244 and A8816. Prepared by BASF CORP. 54 p.