



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

Read 10-4-95

OCT 4 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Vinclozolin.** Product and Residue Chemistry Chapters of the RED.
Reregistration Case #2740 DP Barcode D212383 CBRS #15294

FROM: Steven A. Knizner, Chemist
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

THRU: Edward Zager, Chief
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

TO: Mark Wilhite, PM Team 53
Special Review and Reregistration Division (7508W)

and

Kathryn Boyle
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Attached are the Product Chemistry Chapter and the Residue Chemistry Chapter for the Vinclozolin Reregistration Eligibility Document (RED). The chapters were prepared by Dynamac Corporation under supervision of CBRS, HED. The chapters have undergone secondary review in the Branch and have been revised to reflect Branch policies.

Attachments.

cc: S.F., circ., R.F., Reg. Std. File, S.Knizner
RDI: A.Rathman, 9/27/95 R.Perfetti, 9/29/95 E.Zager, 10/3/95
7509C:CBRS:CM#:305-6903:SAK:sak:vinclozolin.red:9/27/95

VINCLOZOLIN

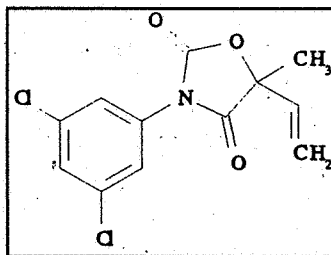
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

Shaughnessy No. 113201; Case No. 2740

DESCRIPTION OF CHEMICAL

Vinclozolin [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] is a fungicide used on fruits, vegetables, and ornamentals.



Empirical Formula: C₁₂H₉Cl₂NO₃
Molecular Weight: 286.11
CAS Registry No.: 50471-44-8
Shaughnessy No.: 113201

IDENTIFICATION OF ACTIVE INGREDIENT

Vinclozolin is a colorless to white crystalline solid with a melting point of 108 C. Technical vinclozolin is slightly soluble in water (< 1 g/kg), and more soluble in benzene (146 g/kg), ethyl acetate (253 g/kg), chloroform (319 g/kg), and acetone (435 g/kg). Vinclozolin hydrolyzes slowly in alkaline solutions.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 5/22/95 identified two vinclozolin manufacturing-use products (MPs) registered under Shaughnessy No. 113201, the BASF Corporation 96% technical (T; EPA Reg. No. 7969-57) and the Scotts-Sierra Crop Protection Company 50% formulation intermediate (FI; EPA Reg. No. 58185-21). Only the BASF

96% T is subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Vinclozolin Phase IV Review dated 3/6/91 by L. Cheng determined that BASF data submissions for 63 series requirements met the acceptance criteria for Phase V review for all GLNs except 63-8. Subsequent data submissions pertaining to 61, 62, and 63 series requirements were evaluated in an RD Review dated 8/14/91 by A. Acierto. Selected data submissions from the Phase IV Review have since undergone Phase V review to address outstanding data requirements.

The current status of the product chemistry data requirements for the BASF vinclozolin 96% T is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All product chemistry data requirements except certification of ingredient limits (Guideline 62-2) are satisfied for the BASF 96% T. Provided that the registrant submits the data required in the attached data summary table for the vinclozolin technical product, and either certifies that the suppliers of beginning materials and the manufacturing process for the vinclozolin technical product have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, CBRS has no objections to the reregistration of vinclozolin with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

Subject: RSB Phase IV Review - Vinclozolin
From: A. Acierto
To: F. Rubis
Dated: 8/14/91
MRID(s): 41888901-41888903

CBRS No. : 15641
DP Barcode: D215812
Subject: Product Chemistry for Vinclozolin.
From: S. Knizner
To: M. Wilhite
Dated: 6/1/95
MRID(s): 41626801 and 41626802

CBRS No. : 16223
DP Barcode: D219496
Subject: Product Chemistry for Vinclozolin.
From: S. Knizner
To: M. Wilhite
Dated: 9/25/95
MRID(s): 41471003

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

41471003, Patel, J. (1987) Partition Coefficient - (1-octanol/water) of ^{14}C -vinclozolin at $25\text{ C} \pm 1\text{ C}$: Lab Project Number: 87/5073: Unpublished study prepared by BASF Corp. 28 p.

41626801 Panek, E. (1990) Determination of the Color, Physical State, Odor, Melting Point, Bulk Density, and PH of Vinclozolin TGAI: Lab Project Number: F9020. Unpublished study prepared by BASF Corp. 11 p.

41626802 Fersch, J. (1990) Stability of Vinclozolin When Exposed to Heat, Sunlight, and Some Metals and Metal Ions: Lab Project Number: F9011. Unpublished study prepared by BASF Corp. 22 p.

41888901 Akers, R. (1991) Data Concerning the Product Identity, Beginning Materials and Manufacturing Process, and Formation of Impurities for the Technical Grade of Vinclozolin Fungicide: Lab Project Number: 91/5073. Unpublished study prepared by BASF Aktiengesellschaft. 44 p.

41888902 Akers, R. (1991) Report on the Preliminary Analysis, Certification of Limits, and Analytical Method to Verify Certified Limits for Vinclozolin, the Technical Grade of Active Ingredient of Ronilan Fungicide: Lab Project Number: 91/5074. Unpublished study prepared by BASF Aktiengesellschaft. 147 p.

41888903 Redeker, J. (1991) Determination of the Solubility of Vinclozolin in Organic Solvents at 20 Degrees Centigrade: Lab Project Number: 91/10055. Unpublished study prepared by BASF Aktiengesellschaft. 18 p.

Case No. 2740
Chemical No. 113201

Case Name: Vinclozolin
Registrant: BASF Corporation
Product(s): 96% T (EPA Reg. No. 7969-57)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ^a	MRID Number ^b
61-1	Product Identity and Disclosure of Ingredients	Y	41888901
61-2	Starting Materials and Manufacturing Process	Y	41888901
61-3	Discussion of Formation of Impurities	Y	41888901
62-1	Preliminary Analysis	Y	41888902
62-2	Certification of Ingredient Limits	N ^c	41888902
62-3	Analytical Methods to Verify the Certified Limits	Y	41888902
63-2	Color	Y	41888903
63-3	Physical State	Y	41888903
63-4	Odor	Y	41888903
63-5	Melting Point	Y	41888903
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	41626801
63-8	Solubility	Y	41888903
63-9	Vapor Pressure	Y	41888903
63-10	Dissociation Constant	N/A	
63-11	Octanol/Water Partition Coefficient	Y	41471003
63-12	pH	Y	41626801
63-13	Stability	Y	41626802

^a Y = Yes; N = No; N/A = Not Applicable.

^b **Bolded** citations were reviewed under CBRS No. 15641, D215812, 6/1/95, S. Knizner or CBRS No. ,D , 9/1/95, S. Knizner; and all other citations were reviewed under an RD. Review dated 8/14/91 by A. Acierto.

^c These data do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference Nos. 62-2). We note that the same value is listed for the nominal concentration and the upper certified limit of the active ingredient on the CSF. The registrant must submit a revised CSF which resolves this discrepancy. In addition, we note that the label claim for the technical product should reflect the nominal concentration of the active ingredient listed on the CSF.

VINCLOZOLIN

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 113201; Case 2740

(CBRS No. None; DP Barcode None)

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VINCLOZOLIN

REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 113201; Case 2740

CBRS No. 15294; DP Barcode D212383

INTRODUCTION

Vinclozolin [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] is a contact fungicide federally registered for use on lettuce, chicory tops (radicchio), onions, raspberries, stone fruits, and strawberries. Tolerances with no US registrations (in the past known as "import tolerances") are established for Belgian endive tops, bell peppers, grapes, kiwifruit, cucumbers, and tomatoes. Vinclozolin is manufactured by BASF Corporation under the trade name Ronilan®.

Vinclozolin formulations registered for use on food and feed crops include a wettable powder (WP), a flowable concentrate (FIC), and a dry flowable (DF). The WP, DF, and FIC formulations may be applied as broadcast foliar sprays using ground or aerial equipment.

The Agency has recently updated the Livestock Feeds Table [Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, Table II (September 1995)]. Vinclozolin residue data requirements have changed as a result of changes in Table II (September 1995) and these changes have been incorporated into this document. The changes in Table II (September 1995) should not impinge on the reregistration eligibility decision for vinclozolin, but the registrant should amend pending tolerance petitions to reflect the new data requirements.

REGULATORY BACKGROUND

Vinclozolin is a list B reregistration chemical and was the subject of a Phase 4 Review (3/5/91) that summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Several submissions of data have been received since the Phase 4 Review. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of vinclozolin.

Tolerances for residues in plants (including import commodities) and food/feed commodities are established for the combined residues of vinclozolin and its metabolites containing the 3,5 dichloroaniline moiety [40 CFR §180.380, §185.1850 (a) and (b), and §186.1850]. Tolerances have not been established for residues of vinclozolin in animal commodities.

Adequate methods are available for plant tolerance enforcement and data collection. A GLC/electron capture detection (ECD) enforcement method for vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety (DCA) in strawberries and kiwifruit is published in PAM, Vol. II as Method I. Data from analysis of residues of vinclozolin and its DCA-containing metabolites have been collected using BASF Methods 25, 25D, and 25F, which are similar to Method I in PAM.

In conjunction with a pending petition (PP#9F3750), BASF proposed tolerances on meat, milk, and eggs and submitted Method A9004, a GC/ECD method, as the proposed enforcement method for animal tissues and Method A9207, as a confirmatory HPLC method. These methods have undergone successful validation trials by the Beltsville Analytical Chemistry Laboratory, however, numerous revisions are required before the methods will be considered fully acceptable.

SUMMARY OF SCIENCE FINDINGS

GLN 171-3: Directions for Use:

A search of the Agency's Reference Files System (REFS) on 4/6/95 indicated that there are three vinclozolin end-use products (EPs) with food/feed uses registered to BASF Corporation. These Eps are presented below.

EPA Reg. No.	Acceptance Date	Formulation Class	Product Name
7969-53 ^a	3/24/94	50% WP	Ronilan® WP
7969-62 ^b	3/24/94	4.17 lb/gal FIC	Ronilan® FL
7969-85 ^c	4/11/94	50% DF	Ronilan® DF

^a Including SLN No. SC90000500.

^b Including SLN No. SC90000600.

^c Including SLN Nos. CA83004400 and CA89003000.

A comprehensive summary of the registered food/feed use patterns of vinclozolin, based on the product labels registered to BASF Corporation, is presented in Table A. A tabular summary of the residue chemistry science assessments for reregistration of vinclozolin is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of vinclozolin food/feed uses are based on the use patterns registered by the basic producer, BASF Corporation. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

GLN 171-4 (a): Plant Metabolism:

For purposes of reregistration and risk assessment, the qualitative nature of the residue in plants is adequately understood based on metabolism studies on strawberries (PP#8G2068), lettuce, and peaches (PP#9G2204). Plant metabolism studies on grapes (PP#8G2068), peanuts (PP#5F3237/FAP#7H5531), and potatoes (PP#1F04008/2H05623) have also been submitted. The submitted plant metabolism studies indicate that metabolism in plants results from the hydrolytic cleavage of the oxazolidinedione ring and/or loss of the ethenyl moiety. The residues to be regulated in plants are vinclozolin *per se* and its metabolites containing the 3,5-dichloroaniline (DCA) moiety. These metabolites are designated as B, D, E, and S and are presented in Figure A.

Figure A. Vinclozolin and its plant metabolites.

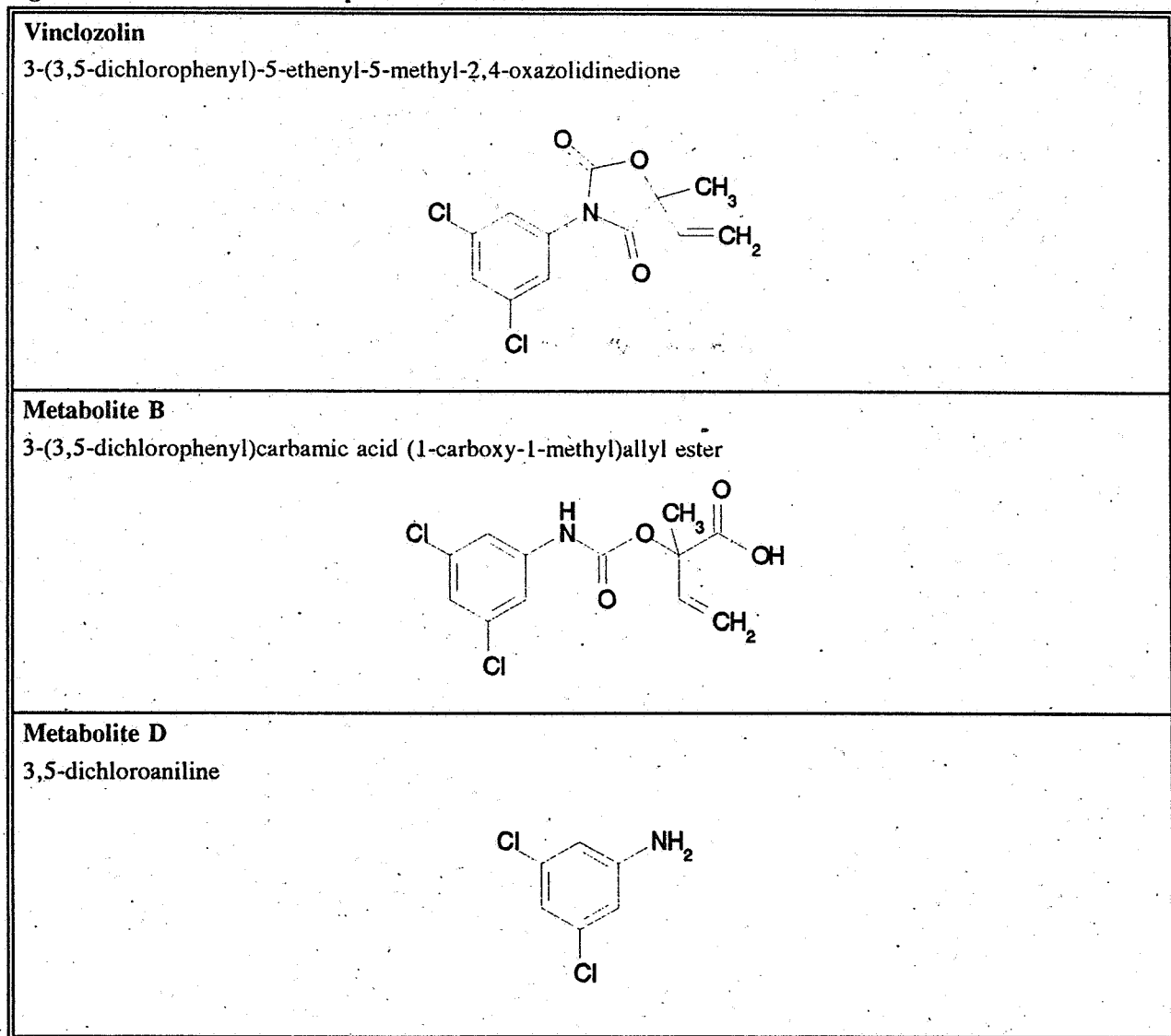
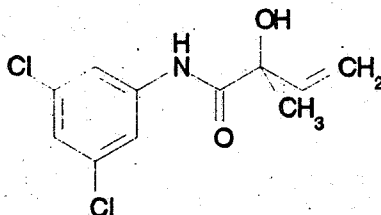


Figure A. Continued.

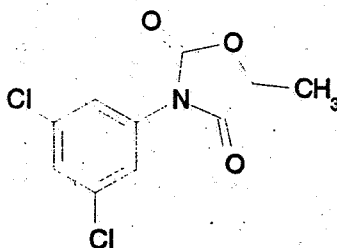
Metabolite E

N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenamide



Metabolite S

3-(3,5-dichlorophenyl)-5-methyl-1,3-oxazolidin-2(1H)-one



GLN 171-4 (b): Animal Metabolism:

For purposes of reregistration and risk assessment, the qualitative nature of the residue in animals is adequately understood based on adequate ruminant and poultry metabolism studies submitted in conjunction with PP#7H5531 and PP#9F3750. The residues of concern are vinclozolin, a mixture of the diastereomers of N-(3,5-dichlorophenyl)-2-methyl-2,3,4-trihydroxybutyramide (BF 352-25), and a mixture of diastereomers derived by dihydroxylation of the vinclozolin vinyl group (BF 352-37). These metabolites are covered by the present tolerance expression.

GLN 171-4 (c) and (d): Residue Analytical Methods - Plants and Animals:

For purposes of reregistration, adequate analytical methodology is available for data collection and enforcing tolerances of vinclozolin *per se* and its metabolites containing the 3,5-DCA moiety in/on plant commodities. Method I in PAM, Vol. II, which underwent a successful EPA method validation on strawberries, involves base hydrolysis of residues to convert vinclozolin and its metabolites to 3,5-DCA. After steam distillation and organic solvent extraction, the isolated DCA is derivatized with chloroacetyl chloride prior to quantitation by GC/ECD. The limit of quantitation is 0.05 ppm.

Data from analysis of residues of vinclozolin and its 3,5-DCA-containing metabolites in plants have been collected using BASF Methods 25, 25D, and 25F, which are comparable to Method I in PAM, Vol. II.

The Phase 4 Review (3/91) did not require data for animal analytical methods because no tolerances existed for animal commodities. In conjunction with PP#9F3750, BASF proposed tolerances on meat, milk, and eggs and submitted Method A9004, a GC/ECD method as the proposed enforcement method for animal tissues and Method A9207, as a confirmatory HPLC method. Method A9004 is based on conversion of vinclozolin and its metabolites to 3,5-DCA. Method A9207 measures BF 352-25, the major metabolite of vinclozolin in animal commodities. Successful method validation trials have been completed by the Beltsville Analytical Chemistry Laboratory (ACL) for both methods. CBTS concluded that the methods will be suitable for enforcement purposes once standards are submitted to the EPA repository at RTP and method revisions recommended by ACL are incorporated. BASF Corporation has subsequently submitted (1994; MRID 43505902) data from Method A9004A, which is a modification of Method A9004; these data are currently under CBTS review (DP Barcode D215790).

The FDA PESTDATA database dated 1/94 (Pam Vol. I, Appendix II) indicates that vinclozolin is completely recovered (>80%) using FDA Multiresidue Protocols D and E (oily and non-oily matrices). Vinclozolin metabolite B is completely recovered using Protocols D and E (for oily matrices) and only partially recovered (50-80%) using Protocol E for non-oily matrices. Metabolite E is completely recovered using Protocol D. Metabolite F is recovered using Protocol D but no quantitative information is available. Metabolite S is partially recovered using Protocol E (non oily matrices). The FDA multiresidue methodology differentiates between vinclozolin and iprodione, a pesticide which also contains a DCA moiety.

GLN 171-4 (e): Storage Stability:

The requirements for storage stability data are satisfied for purposes of reregistration. In general, vinclozolin residues in plants are stable for 17-40 months under frozen conditions. Storage stability data submitted in conjunction with petition PP#9F3750 indicated that vinclozolin residues are stable in animal matrices for up to 2 years at -20 C.

For pending petitions, acceptable storage stability studies have been conducted using fortified control samples of succulent beans (PP#9F3762/FAP#9H5585) and potatoes (PP#1F4008/FAP#2H5623). These data indicate that residues of vinclozolin *per se* are stable in frozen succulent beans for up to 68 days and in potatoes for up to 6 months.

In conjunction with the pending petition for reduction of tolerances in stone fruits (PP#1F3976/FAP#1H5615), additional frozen storage stability data on metabolite D residues in peaches are required. Storage stability data are also required to support the residue data submitted for almonds and almond hulls in conjunction with PP#9F3788.

GLN 171-4 (k and l): Magnitude of the Residue in Plants and Processed Food/Feed:

The reregistration requirements for magnitude of the residue in plants are fulfilled for the following commodities: Belgian endive, red chicory, grapes, kiwifruit, lettuce (leaf and head), bulb onions (dry), bell peppers, stone fruits, strawberries, tomatoes and raspberries. In addition, adequate magnitude of the residue data are available for pending petitions pertaining to uses on blueberries, caneberries, cranberries, and succulent beans. Adequate field trial data depicting residues of vinclozolin following applications made according to the maximum or proposed use patterns have been submitted for these commodities. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted.

A processing study was supplied for grapes (N.Dodd, 1/28/88, PP#7H5529, CB No. 3016, MRID #40403201). Concentration factors of 2.1 and 2.4x were obtained (average concentration factor 2.3X). Based on the existing import tolerance of 6.0 ppm for grapes, the tolerance for raisins should be revised to 15 ppm. The 75 ppm tolerance for prunes, established in conjunction with PP#5H5462, is based on a dry down factor for fresh prunes (K.Arne, 3/6/84, PP#2F2650).

Pending petitions for almonds, hops, peanuts, potatoes, and meat/milk/poultry/eggs are in reject status pending resolution of various deficiencies.

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs:

There are no established tolerances for residues of vinclozolin and its 3,5-DCA moiety in eggs, milk, animal fat, meat, and meat by-products. Feeding studies and animal tolerances were not required for purposes of reregistration because there are no established tolerances on relevant feed items.

A poultry feeding study was reviewed in conjunction with PP#9F3750 (7/2/90, W. Chin).

In conjunction with the petition (PP#9F3750) for a domestic tolerance on grapes, BASF proposed tolerances on animal commodities and submitted ruminant and poultry feeding studies. The proposed tolerances for animal commodities are as follows:

Milk	0.2 ppm	Eggs	0.05 ppm
Fat *	0.6 ppm	Poultry Fat	0.1 ppm
Meat *	0.3 ppm	Poultry Meat	0.1 ppm
Meat By-Products *	1.2 ppm	Poultry Meat By-Products	0.1 ppm

(* of cattle, goats, horses, hogs, and sheep)

As was previously noted, grape pomace is no longer considered a grape processed commodity or animal feedstuff [Table II (September 1995)], therefore, meat/milk tolerances are not required in conjunction with PP#9F3750.

Tolerances on livestock commodities would be required in conjunction with the pending petitions on potatoes (PP#1F04008/ FAP#2H05623) and almonds (PP#9F3788) because processed potato waste and almond hulls are considered livestock feed items. Because none of the existing tolerances or pending petitions include any poultry feed items, BASF may withdraw the proposed tolerances on eggs and poultry meat and meat by-products.

Based on the proposed almond and potato tolerances, the maximum theoretical dietary exposure for beef and dairy cattle is approximately 0.35 ppm, as shown in Table 1.

Table 1. Calculation of the maximum theoretical dietary exposure for cattle.

Commodity	Proposed Tolerance (ppm)	% Dry matter	% in Diet		Dietary exposure (ppm)	
			Beef cattle	Dairy cattle	Beef cattle	Dairy cattle
Almond, hulls	3	90	10	10	0.33	0.33
Potato culls	0.1	20	75	40	0.38	0.20

A ruminant feeding study was reviewed in conjunction with PP#9F3750 (7/2/90, W. Chin). Four groups of 3 lactating cows each were dosed for 28-30 days with [¹⁴C]vinclozolin at levels of 0, 100, 300, and 1,000 ppm. Results for tissue analyses are summarized in Table 2. Residues in milk plateaued in 10-14 days with reported maximum residues of 2.3, 7.9, and 31.2 ppm at the 100, 300, and 1,000 ppm feeding levels, respectively.

Table 2. Vinclozolin levels in tissues following dosing (28-30 days) at the indicated levels.

Feeding Level (ppm)	Vinclozolin Residues (ppm)				
	Liver	Kidney	Muscle	Peritoneal Fat	Subcutaneous Fat
0	0.09	0.08	<0.05	0.11	0.14
100	9.02	8.45	2.10	5.64	3.64
300	48.2	22.6	5.91	17.4	6.22
1000	141	87.7	27.9	181	127

Based on the results of this dairy cattle feeding study, CBRS recommends that the petitioner propose tolerances for meat, meat by-products, and milk of cattle, goats, horses, hogs, and sheep at 0.05 ppm in conjunction with the pending almond (PP#9F3788) and/or potato (PP#1F04008/ FAP#2H05623) tolerance petitions.

GLN 165-1: Confined Rotational Crops:

The EFED Phase 4 Review (A.Jones, 3/25/91) required a confined rotational crop study and reserved data requirements for a field rotational crop study. The EFED Phase 4 Environmental Fate Summary Table for Vinclozolin (A. Jones, 3/20/91) noted that MRID #41496905 (dated January, 1984) was not cited in the registrants Phase 3 Response, although it was summarized in the summary for the confined rotational crops (MRID #9219030). EFED concluded that MRID #41496905 should be reviewed in Phase 5.

MRID #41496905 has been reviewed and was found to be inadequate and not upgradeable (CBRS No. 16222, DP Barcode D219494, 9/25/95, S.Knizner). The registrant should conduct a new study to fulfill Guideline 165-1 data requirements. Guidance concerning confined rotational crop studies can be found in the guidance document entitled "Follow Up Guidance for Conducting Rotational Crop Studies", E.Zager and D.Edwards, 2/23/93, EPA 738-B-93-001, February 1993.

EFED has previously established rotation intervals in conjunction with review of data submitted in MRID #00136385 (3/25/80). The intervals established should be used until acceptable confined and/or field rotational crop studies are submitted. The requirement for a new confined rotational crop study will not impede making the reregistration eligibility decision for vinclozolin.

GLN 165-2: Field Rotational Crops:

Data requirements for a field rotational crop study are reserved pending receipt of an adequate confined rotational crop study.

TABLE A. FOOD/FEED USE PATTERNS SUBJECT TO REREGISTRATION FOR VINCLOZOLIN (CASE 2740).

Site	Application Type Application Timing Application Equipment ^a	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations ^b
Apricot						
Foliar broadcast application Bloom and preharvest Ground or aerial equipment		50% WP [7969-53]	1 lb/A or 0.25 lb/100 gal (based on 400 gal/A)	3 (bloom)	Not specified (NS)	Applications may be made in a minimum of 50 gal/A by ground or 15 gal/A by air. Grazing or feeding of cover crops from treated orchards to livestock is prohibited. A 14-day PHI has been established. The maximum seasonal rate is 4 lb ai/A (3 lb ai/A at bloom and 1 lb ai/A preharvest).
		4.17 lb/gal FIC [7969-62]		1 (preharvest)	Not applicable (NA)	
		50% DF [7969-85]				
Cherry						
Foliar broadcast application Bloom and preharvest Ground or aerial equipment		50% WP [7969-53]	1 lb/A or 0.25 lb/100 gal (based on 400 gal/A)	3 (bloom)	NS	See "Apricot."
		4.17 lb/gal FIC [7969-62]		1 (preharvest)	NA	
		50% DF [7969-85]				

Table A. Continued.

Site Application Type Application Timing Application Equipment *	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations ^b
Chicory (roots used for the production of Belgian endive)					
Spray application on roots before cold storage Ground equipment	50% DF [CA89003000]	10 gm (0.02 lb) ai diluted in 15-20 liters (4-5 gal) of water per metric ton of roots	1	NA	Use limited to CA counties of Solano, Stanislaus, Merced, and Lassen. A 30-day PHI has been established.
		1 gm (0.002 lb) ai diluted in 3 liters (0.8 gal) of water per square meter forcing tray	1	NA	
Kiwifruit					
Foliar broadcast application Bloom through preharvest Ground equipment	50% WP [SC90000500] 4.17 lb/gal FIC [SC90000600] 50% DF [CA83004400]	1 lb/A	4	7-8	Use limited to CA and SC. Applications may be made in a minimum of 100 gal/A. A 7-day PHI has been established. The maximum seasonal rate is 4 lb ai/A.

Table A. Continued.

Site Application Type Application Timing Application Equipment *	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations ^b
Lettuce					
Foliar broadcast application. Ground equipment	50% WP [7969-53] 4.17 lb/gal FIC [7969-62] 50% DF [7969-85]	1 lb/A	3	14	Applications may be made in a minimum of 100 gal/A. A 28-day PHI has been established. The maximum seasonal rate is 3 lb ai/A.
Nectarine					
Foliar broadcast application Bloom and preharvest Ground or aerial equipment	50% WP [7969-53] 4.17 lb/gal FIC [7969-62] 50% DF [7969-85]	1 lb/A or 0.25 lb/100 gal (based on 400 gal/A)	3 (bloom) 1 (preharvest)	NS NA	See "Apricot."

Table A. Continued.

Site Application Type Application Timing Application Equipment ^a	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations ^b
Onion, dry bulb					
Soil drench or soil band treatment at planting, and postemergence foliar broadcast application(s) Ground equipment	50% WP [7969-53]	1 lb/A	NS	NS	Minimum application volumes are 100 gal/A for band or broadcast applications and 400 gal/A for the soil drench treatment. An 18-day PHI has been established. The maximum seasonal rate is 5 lb ai/A. Use of the 50% WP and the 4.17 lb/gal FIC have not been approved in CA.
	4.17 lb/gal FIC [7969-62]				
	50% DF [7969-85]				
Peach					
Foliar broadcast application Bloom and preharvest Ground or aerial equipment	50% WP [7969-53]	1 lb/A or 0.25 lb/100 gal (based on 400 gal/A)	3 (bloom) 1 (preharvest)	NS NA	See "Apricot."
	4.17 lb/gal FIC [7969-62]				
	50% DF [7969-85]				

Table A. Continued.

Site Application Type Application Timing Application Equipment *	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations ^b
Raspberry					
Foliar broadcast application Bloom through bearing Ground equipment	50% WP [7969-53] 4.17 lb/gal FIC [7969-62] 50% DF [7969-85]	1 lb/A	NS	7	Applications may be made in a minimum of 100 gal/A. A 9-day PHI has been established. The maximum seasonal rate is 4 lb ai/A.
Stone fruit					
Foliar broadcast application Bloom and preharvest Ground or aerial equipment	50% WP [7969-53] 4.17 lb/gal FIC [7969-62] 50% DF [7969-85]	1 lb/A or 0.25 lb/100 gal (based on 400 gal/A)	3 (bloom) 1 (preharvest)	NS NA	See "Apricot."

Table A. Continued.

Site Application Type Application Timing Application Equipment ^a	Formulation [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations ^b
Strawberry ^c					
Foliar broadcast application Ground or aerial equipment	50% WP [7969-53] 4.17 lb/gal FIC [7969-62] 50% DF [7969-85]	1 lb/A	NS 4 (CA)	7	Applications may be made in a minimum of 100 gal/A by ground or 20 gal/A by air. The maximum seasonal rate is 4 lb ai/A in CA and 6 lb ai/A in all other states. No PHI is specified for strawberries.

Note: REI = Reentry interval; PHI = Preharvest interval; and PBI = Plant-back interval.

^a Labels for the 50% WP (EPA Reg. No. 7969-53), 4.17 lb/gal FIC (EPA Reg. No. 7969-62), and 50% DF (EPA Reg. No. 7969-85), and the associated SLNs SC900005, SC900006, and CA830044 prohibit applications through any type of irrigation system.

^b The labels for the 50% WP and the 4.17 lb/gal FIC specify a 12-hour REI; and the labels for the 50% DF and the SLNs SC900005, SC900006, and CA830044 state that treated areas can be reentered once the spray has dried.

^c The following rotational crop restrictions have been established for strawberries for the 50% WP, the 4.17 lb/gal FIC, and the 50% DF formulations in states other than CA: (i) lettuce (all types) and dry bulb onions may be planted after strawberries; (ii) a 20-day PBI for any rotational crops following treatments not exceeding 3 lb ai/A; (iii) a 6-month PBI for leafy vegetables following treatments not exceeding 6 lb ai/A; (iv) a 2-month PBI for cucurbits following treatments not exceeding 6 lb ai/A; (v) a 2-month PBI for corn, grown only for grain, following treatments not exceeding 6 lb ai/A; and (vi) a 9-month PBI for other grain crops following treatments not exceeding 6 lb ai/A.

The following rotational crop restrictions have been established for strawberries for the 50% WP, the 4.17 lb/gal FIC, and the 50% DF formulations in CA: (i) lettuce (all types) and dry bulb onions may be planted after strawberries; (ii) a 20-day PBI for any rotational crops following treatments not exceeding 3 lb ai/A; (iii) a 6-month PBI for leafy vegetables following treatments not exceeding 4 lb ai/A; (iv) a 2-month PBI for cucurbits following treatments not exceeding 4 lb ai/A; (v) a 2-month PBI for corn, grown only for grain, following treatments not exceeding 4 lb ai/A; and (vi) a 9-month PBI for other grain crops following treatments not exceeding 4 lb ai/A.

Table B. Residue Chemistry Science Assessments for Reregistration of Vinclozolin.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
171-3: Directions for use	N/A	No ²	See Table A.
171-4 (a): Plant Metabolism	N/A	No	00067055 ³ 00135148 00150895 ⁴ 00157427 00140835 41040007 ³ 41961701 ⁵
171-4 (b): Animal Metabolism	N/A	No	40410201 ⁶ 40854401 ⁷ 40854402 ⁷ 41064501 ⁸ 41064502 ⁸
171-4 (c and d): Residue Analytical Methods - Plants and Animals	N/A	Yes ⁹	00108958 00136382 00085103 00129563 41040007 ⁸ 41064503 ⁸ 41080601 ¹⁰ 41080602 ¹⁰ 41496906 41188001 ¹¹ 41749601 ⁹ 42597901 ⁹ 42622701 ¹² 42829801 ¹³ 43272802 ¹⁴ 43505902 ¹⁵ 92194049 ¹³ 41961702 ⁵
171-4 (e): Storage Stability	N/A	Yes ¹⁶	00085101 00085105 00108958 00139008 40876701 00129563 40297401 40297402 40297403 40297404 41040003 ⁸ 41040005 ⁸ 41040006 ⁸ 41080600 ¹⁰ 41496906 41927901 ¹⁷ 42622702 ¹²
171-4 (k): Magnitude of the Residue in Plants			
<u>Tuber Vegetable Group</u>			
- Potato	None	Yes ¹⁸	41961703 ¹⁸
<u>Bulb Vegetables Group</u>			
- Onion (dry bulb)	1.0 [§180.380]	No ¹⁹	00129563 40297403 42593701 ¹⁹
<u>Legume Vegetables (Succulent or Dried) Group</u>			
- Succulent beans	None	No ²⁰	PP#9F3762/FAP#9H5585 ²⁰ 41080601 ¹⁰ 43505903 ²¹ 43505904 ²¹
<u>Leafy Vegetables Group (Except Brassica Vegetables)</u>			
- Belgian endive (tops)	5.0 [§180.380]	No	PP##8E3620 ²² PP#9E3808 ²²
- Chicory, red (tops) (Radicchio)	5.0 [§180.380]	No	PP##8E3620 ²² PP#9E3808 ²²

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Lettuce (leaf and head)	10.0 [§180.380]	No	00085101 40297402 40297404 43255803 ²³ 43255804 ²³ 43353101 ²⁴ 43353102 ²⁴
<u>Fruiting Vegetables (Except Cucurbits)</u>			
- Pepper, bell	3.0 [§180.380]	No	PP#4E2998 ²⁵
- Tomato	3.0 [§180.380]	No	PP#8E3688 ²⁶
<u>Cucurbit Vegetables</u>			
- Cucumber	1.0 [§180.380]	No	PP#8E3688 ²⁶
<u>Stone Fruits Group</u>			
- Apricot	25 [§180.380]	Yes ²⁷	PP#1F3976 ²⁸
- Cherry		Yes ²⁸	PP#1F03976 ²⁸
- Peach		No ²⁸	00085105 00139008 40876701 42829801 ¹³
- Plum		Yes ²⁹	00085105 00139008 40876701 43505905 ²¹
<u>Small Fruits and Berries Group</u>			
- Blueberry	None	No ³¹	41417501 ³² 41417502 ³²
- Caneberry	None	No ³³	PP#OE3903 ³³
- Cranberry	None	No ³⁴	43289701 ³⁶
- Grape	6.0 [§180.380]	Yes ⁹	41040006 ⁸
- Raspberry	10.0 [§180.380]	No	00129563 40297401
- Strawberry	10.0 [§180.380]	No	00108958 40297404
<u>Tree Nuts Group</u>			
- Almond	None	Yes ¹⁷	41188001 ¹¹ 41927901 ¹⁷ 43272801 ³⁵ 43703302 ³⁵ 43703304 ³⁵
<u>Miscellaneous Commodities</u>			
- Hops	None	Yes ³⁶	PP#7H5531 ³⁶
- Kiwifruit	10.0 [§180.380]	No	PP#OE2380 ³⁷
- Peanut	None	No ³⁸	PP#5F3237 ³⁹
171-4(l): Magnitude of the Residues in Processed Food/Feed			
- Grape, pomace, dried	42.0 [§186.1850]	No	
- Potato, granules/flakes	None	Yes ¹⁸	42100201 ¹⁸
- Potato, peel, dried	None	Yes ¹⁸	42100201 ¹⁸

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Prunes	75.0 [§185.1850]	Yes ⁴⁰	00139008 40297404
- Raisins	30.0 [§185.1850]	No	
171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	None	No	41040001 ⁸ 41040002 ⁸ 41040004 ⁸ 41040005 ⁸
171-4(f): Nature and Magnitude of the Residue in Drinking and Irrigation Water	N/A		
171-4(i): Magnitude of the Residue in Food Handling Establishments	N/A		
165-1: Rotational Crops (Confined)	None	Yes ⁴¹	41496905 ⁴¹
165-2: Rotational Crops (Field)	None	Reserved ⁴²	

- Bolded** references were cited in the Vinclozolin Phase 4 Review (3/5/91). Unbolded references were reviewed as noted.
- As domestic use of vinclozolin on plums/fresh prunes is not being supported, the label should be amended to state *stone fruits, except plums/fresh prunes*. A PHI for strawberries must be specified. Data support a 0-day PHI.
- Reviewed in conjunction with PP#8G2068 (1/19/79, Makhijani).
- Reviewed in conjunction with PP#5F3237/FAP#7H5531 (CB Nos. 968 and 969, DP Barcodes None, 6/28/85, M. Firestone).
- Reviewed in conjunction with PP#1F04008/FAP#2H05623 (CBTS Nos. 9105 and 9106, DP Barcodes D172133 and D172412, 4/7/93, M. Bradley).
- Reviewed in conjunction with PP#7H5531 (1/6/88, N. Dodd).
- Reviewed in conjunction with PP#7H5531 (1/6/89, C. Deyrup).
- Reviewed in conjunction with PP#9F3750 (CBTS Nos. 5238, 5239, and 5240, DP Barcode None, 7/2/90, W. Chin).
- The submission of analytical standards and revised analytical enforcement methodology for animals are required (CBTS No. 11280, DP Barcode D187409, 6/14/94, G. Kramer).
- Reviewed in conjunction with PP#9F3762/FAP9H5585 (CBRS Nos. 5336 through 5339, DP Barcode None, 11/15/89, R. Cook).
- Reviewed in conjunction with pending petition PP#9F3788 (CB No. 5696, 1/8/90, L. Rodriguez).

Table B (continued).

12. CBTS Nos. 12310 and 12311, DP Barcode Nos. D193892 and D193893, 8/11/93 and 8/12/93, W. Wassell
13. CBRS No. 12302, DP Barcode D193694, 2/18/94, S. Knizner.
14. CBTS No. 14018, D205224, 1/12/95, R. Cook.
15. These data are currently under CBTS review (DP Barcode D215790).
16. Adequate data are available for reregistration purposes, however, additional data must be submitted in conjunction with pending petitions. Data depicting the frozen storage stability of metabolite D in peaches are required to support the residue data submitted in conjunction with reduction of the tolerance in stone fruits (PP#1F03976/FAP#1H05615; CBTS Nos. 11396 and 12350, DP Barcode Nos. D188198 and D194020, 8/20/93, W. Wassell). Storage stability data are also required to support the residue data submitted for almonds and almond hulls in conjunction with PP#9F3788 (CB No. 5696, 1/8/90, L. Rodriguez and CBTS No. 8227, DP Barcode 165976, 8/15/91, G. Herndon).
17. Reviewed in conjunction with pending petition PP#9F3788 (CBTS No. 8227, DP Barcode D165976, 8/15/91, G. Herndon). MRID 43273801 pertaining to magnitude of the residue on almond nutmeats and hulls, awaits CBTS review in conjunction with pending petition PP#9F3788.
18. A petition (PP#1F04008/FAP#2H05623) for tolerances on potatoes (0.1 ppm), potato dry peel (3 ppm) and potato granules/flakes (0.2 ppm) is pending. Additional data/information pertaining to specificity of the enforcement method and plant metabolites are required (CBTS Nos. 9105 and 9106, DP Barcodes D172133 and D172412, 4/7/93, M. Bradley).
19. The registrant must submit a petition to increase the tolerance for vinclozolin in/on bulb onions from 1.0 ppm to 6.0 ppm (CBRS No. 11283, DP Barcode D187397, 9/23/93, F. Fort).
20. TOX considerations permitting, CBTS recommends for the establishment of a tolerance (with an expiration date) on succulent beans at 3.0 ppm. The establishment of a permanent tolerance for succulent beans had been pending, awaiting revision of enforcement analytical methods for animal commodities and establishment of adequate meat and milk tolerances (CBTS No. 14018, DP Barcode D205224, 1/12/95, R. Cook). However, Table II (September 1995) no longer lists animal feedstuffs for beans, so these deficiencies would no longer prevent CB from recommending for a permanent tolerance.
21. CBRS No. 14997, DP Barcode D211118, 6/5/95, S. Knizner.
22. CBTS No. 5947, DP Barcode None, 6/25/90, W. Chin and CBTS No. 6932, DP Barcode None, 8/17/90, W. Chin.
23. CBRS No. 13881, DP Barcode D204479, 12/16/94, S. Knizner.
24. CBRS No. 14322, DP Barcode D207132, 5/18/95, S. Knizner.
25. CB No. 770, DP Barcode None, 11/17/86, C. Deyrup and CB No. 1952, DP Barcode None, 3/16/87, C. Deyrup.
26. CB No. 4452 and 4453 DP Barcode None, 3/9/89, W. Chin and No CB No., DP Barcode None, 10/3/89, W. Chin.

Table B (continued).

27. A petition (PP#1F03976/FAP#1H05615) for a decrease in tolerances on stone fruits and prunes is pending. Residue data on apricots are required (CBTS No. 7910, DP Barcode No. D163699, 7/25/91, W. Wassell and CBTS Nos. 11396 and 12350, DP Barcodes Nos. D188198 and D194020, 8/20/93, W. Wassell). In addition, as BASF is no longer supporting the domestic use of vinclozolin on plums, the established tolerance for stone fruits should be revised to *stone fruits, except plums/fresh prunes*.
28. CBTS Nos. 11396 and 12350, DP Barcodes D188198 and D194020, 8/20/93, W. Wassell.
29. In conjunction with the pending petition (PP#1F3976/FAP#1H5615) to lower tolerances on stone fruit, BASF stated that they do not wish to support domestic use of vinclozolin on plums but wish to retain the current tolerance for import purposes only. Additional data on plums are required in conjunction with the pending petition.
30. CBRS did not review the submitted plum residue data because all data were generated domestically and the registrant only desires plum tolerances for import purposes (CBRS No. 14997, DP Barcode D211118, 6/5/95, S. Knizner).
31. 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 blueberries at 4.0 ppm (CB No. 7965, No DP Barcode No., 7/22/91, F. Griffith).
32. CB No. None, DP Barcode None, 7/24/90, F. Griffith and CB No. 7965. DP Barcode None, 7/22/91, F. Griffith.
33. 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/on caneberries at 10 ppm. Caneberries as defined in 40 CFR §180.1(h) include raspberries. When the caneberries tolerance is established, it will supplant the presently existing 10 ppm tolerance in §180.380 on raspberries (CB No. 7953, DP Barcode D164076, 5/10/91, M. Nelson).
34. 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/on cranberries at 2 ppm (CB No. 14035, DP Barcode No. 205273, 11/9/94, S. Willett).
35. MRID 43272801, 43703302, and 43703304 pertaining to magnitude of the residue on almond nutmeats and hulls await CBTS review in conjunction with pending tolerance petition PP#9F3788.
36. A petition (PP#7H5531) for tolerances on dried hops at 40 ppm is pending. Additional data/information are required pertaining to analytical methodology (CB Nos. 1870 and 4659, DP Barcodes None, 2/25/87 and 1/6/89, C. Deyrup).
37. CBRS No. None, DP Barcode None, 10/15/80, M. Nelson.
38. BASF sent the Agency a letter dated 4/26/89 requesting withdrawal of proposed tolerances in dry beans and peanuts (PP#5F3237/FAP#5H5469) (R. Cook, CB Nos. 5336, 5337 and 5338, DP Barcode None, 11/15/89), however, no FR Notice to this effect has been published.
39. CBTS Nos. 968 and 969, DP Barcodes None, 6/28/85, M. Firestone.

Table B (continued).

40. In conjunction with the pending petition (PP#1F3976/FAP#1H5615) to lower tolerances on stone fruit, BASF stated that they do not wish to support domestic use of vinclozolin on plums/prunes. BASF indicated that a vinclozolin tolerance for imported prunes was being sought at 15.0 ppm. Additional data on prunes, including a processing study, are required in conjunction with the pending petition.
41. CBRS No. 16222, DP Barcode D219494, 9/25/95, S. Knizner. The submitted study is inadequate and cannot be upgraded. The registrant should conduct a new study to fulfill Guideline 165-1 data requirements. Guidance concerning confined rotational crop studies can be found in the guidance document entitled "Follow Up Guidance for Conducting Rotational Crop Studies", E. Zager and D. Edwards, 2/23/93, EPA 738-B-93-001, February 1993.
42. Requirement for field rotational crop trials will be determined following receipt and evaluation of required confined rotational crop data.

TOLERANCE REASSESSMENT SUMMARY

All tolerances for vinclozolin residues are currently expressed in terms of vinclozolin *per se* and its metabolites containing the 3,5-DCA moiety [40 CFR §180.380, §185.1850 (a) and (b), and §186.1850]. A summary of the vinclozolin tolerance reassessment and recommended modifications in commodity definitions are presented in Table C.

NOTE: 40 CFR §180.380 currently states "There are no U.S. registrations for cucumbers or tomatoes as of April 13, 1990." This statement should be modified to note: "There are no U.S. registrations for cucumbers, grapes, kiwifruit, peppers (bell), or tomatoes as of September 22, 1995."

Tolerances Listed Under 40 CFR §180.380:

Sufficient data are available to ascertain the adequacy of the established tolerances and/or reassess tolerances listed for Belgian endive, chicory (radicchio), cucumbers (imported), grapes (imported), kiwifruit (imported), lettuce (leaf and head), bulb onions, bell peppers (imported), raspberries stonefruits, strawberries, and tomatoes (imported).

Over-tolerance residues of vinclozolin and its 3,5-DCA metabolites in/on onions were reported by BASF. CBRS concluded that a petition to increase the tolerance for vinclozolin residues in bulb onions from 1.0 ppm to 6.0 ppm must be submitted. For this RED, the onion tolerance has been reassessed at 6.0 ppm.

In conjunction with PP#1F3976/FAP#9H5585, BASF has stated that they do not wish to support domestic use of vinclozolin on plums. The established tolerance on stone fruits should be revised to *stone fruits, except plums/fresh prunes*. Until deficiencies in PP#1F3976/FAP#9H5585 are resolved, the tolerance for imported plums shall remain 25 ppm.

Tolerances Listed Under 40 CFR §185.1850 (a) and (b):

Sufficient data are available to reduce the established tolerance listed for raisins from 30 ppm to 15 ppm.

Although BASF has stated that they do not wish to support domestic use of vinclozolin on plums/prunes, the established tolerance of 75 ppm on prunes should remain in effect to take into account residues on imported prunes. This tolerance may be lowered pending resolution of a deficiencies associated with PP#1F3976/FAP#1H5615.

NOTE: Subsections (a) and (b) of 40 CFR §185.1850 should be combined; there is no reason to have separate subsections for prunes and raisins. 40 CFR §185.1850 should be modified to read as follows, "Tolerances are established for the combined 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 on the following food commodities:

Food	Parts per million
Prunes	75
Raisins	15

Tolerances Listed Under 40 CFR §186.1850:

The established feed additive tolerance listed for dry grape pomace should be revoked because Table II (September 1995) no longer lists grape pomace as a processed commodity or feedstuff. Because there are no other feed additive tolerances, 40 CFR §186.1850 should be deleted.

Pending Tolerances Under 40 CFR §180.380:

Tolerance petitions are currently pending for almonds (PP#9F3788), blueberries (PP#OE3850), caneberries (PP#OE3903), cranberries (PP#4E4377), hops (PP#7H5531), peanuts (PP#5F3237), potatoes (PP#1F04008/2H05623), stone fruit (PP#1F3976/FAP#1H5615) and succulent beans (PP#9F3762/FAP#9H5585).

Sufficient data are available to ascertain the adequacy of the proposed tolerance for caneberries; CBTS has recommended for permanent tolerances in/on caneberries at 10 ppm. According to the commodity definition section of 40 CFR, §180.1(h), a tolerance established for caneberries would include blackberries, youngberry, loganberry, red and black raspberries, and their various varieties and hybrids. The proposed revision to the current crop groupings would establish caneberries as a separate subgroup (13A). Once the 10 ppm tolerance for caneberries is established, the tolerance on raspberries should be revoked.

Sufficient data are available to ascertain the adequacy of the proposed 4.0 ppm tolerance for blueberries, 2.0 ppm for cranberries, and 3.0 ppm for succulent beans; CBTS has recommended that these tolerances be established, toxicological considerations permitting. Additional data are required for the pending petitions on almonds, hops, peanuts, and potatoes.

The adequacy of the proposed tolerances for animal commodities cannot be fully determined until issues involving pending petitions containing animal feedstuffs (almonds and potatoes) are resolved. Additionally, revisions must be made to the enforcement methods for animal commodities.

CBRS is not considering feedstuffs derived from peanuts because the registrant submitted a letter dated 4/25/89 requesting withdrawal of proposed peanut tolerance. However, no FR Notice to this effect has been published.

Based on the results of a dairy cattle feeding study and proposed tolerances for almond hulls and potatoes, CBRS recommends that the petitioner propose tolerances for meat, meat by-products, and milk of cattle, goats, horses, hogs, and sheep at 0.05 ppm in conjunction with either the pending almond (PP#9F3788) or potato (PP#1F04008/ FAP#2H05623) tolerance petitions. These levels will be used for meat/milk dietary exposure estimates in conjunction with the DRES analysis for pending petitions.

Table C. Tolerance Reassessment Summary for Vinclozolin.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR 180.380:			
Belgian Endive (tops)	5.0	2.0	<i>Belgian endive, leaves.</i> At the 1x treatment rate (10 g ai/ 10 m ²) combined residues of vinclozolin and its 3,5-DCA metabolites were 0.10-1.40 ppm (average 0.40 ppm) (W. Chin, CBTS No. 5947, PP#9E3808). Reducing tolerance to 2 ppm also harmonizes with the CODEX MRL of 2 mg/kg.
Chicory, Red (tops)	5.0	2.0	<i>Radicchio.</i> Data for Belgian Endive also support tolerance reduction for radicchio.
Cucumber	1.0	1.0	
Grape	6.0	6.0	
Kiwifruit	10.0	10.0	
Lettuce (leaf and head)	10.0	10.0	
Onion, dry bulb	1.0	6.0	Over-tolerance residues of vinclozolin in/on onions were detected from 4 field trials in CA. Combined residues 0.12-14.93 ppm in/on onions (bulbs and tops) receiving 5 applications of the WP formulation at 1.0 lb ai/A/application (1x) at 14-day intervals and harvested 18 days after the final application. Reanalysis of only bulbs (without tops) detected residues of 3.33-5.84 ppm in/on bulbs from one test in which residues in/on tops plus bulbs were 9-14.93 ppm. CBRS concluded that the tolerance for vinclozolin in/on bulb onions should be increased from 1.0 ppm to 6.0 ppm.
Pepper, bell	3.0	3.0	

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR 180.380: (continued)			
Raspberry	10.0	5.0	Combined residues were 0.15-4.6 ppm in/on 24 samples of raspberries receiving 4 applications of vinclozolin at 1.0 lb ai/A/application (1x) and harvested 5-11 days after treatment. These data support reassessment of the tolerance to 5.0 ppm. If the 10 ppm tolerance for caneberries is established, the tolerance on raspberries should be revoked.
Strawberry	10.0	10.0	
Stone Fruits	25.0	5.0	Since BASF is no longer supporting the use of vinclozolin on domestically grown plums, the tolerance should be revised to <i>stone fruits, except plums/fresh prunes</i> . Although a petition for decreasing stone fruit (except plums/fresh prunes) tolerances is in reject status (PP#1F3976/FAP#1H5615), the use pattern requested [4 applications at 1 lb ai/A instead of 5, and an increase in the preharvest interval from 3 to 14 days] supports decreasing tolerance to 5 ppm.
Tomato	3.0	3.0	
Food Additive Tolerances listed under 40 CFR 185.1850 (a):			
Prunes	75	75	Tolerance at 15 ppm on imported prunes has been requested, however, PP#1F3976/FAP#9H5585 is in reject status.

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Food Additive Tolerances listed under 40 CFR 185.1850 (h):			
Raisin	30	15	Concentration factors of 2.1 and 2.4x were obtained (average concentration factor 2.3X) from processing studies. Based on the existing import tolerance of 6.0 ppm for grapes, the tolerance for raisins should be revised to 15 ppm.
Feed Additive Tolerances listed under 40 CFR §186.1850:			
Grape, pomace, dry	42.0	Revoke	Table II (September 1995) no longer considers dry grape pomace to be a grape processed commodity or animal feedstuff
Tolerances Required under 40 CFR 180.380:			
Plum	25	25	Currently included in stone fruits tolerance. The registrant wishes to keep the plum tolerance for imported plums only. PP#1F3976/FAP#9H5585 is in reject status.
Proposed or Pending Tolerances			
Commodity	Current Tolerance (ppm)	Proposed or Pending Tolerance (ppm)	Comments
Pending or Proposed Tolerances under 40 CFR §180.380:			
Almond	None	0.2	PP#9F3788 is in reject status.
Almond, hulls	None	3.0	PP#9F3788 is in reject status.
Bean, succulent	None	3.0	CBTS recommended for tolerance, toxicological considerations permitting (PP#9F3762).

Table C (continued).

Commodity	Current Tolerance (ppm)	Proposed or Pending Tolerance (ppm)	Comments
Pending or Proposed Tolerances under 40 CFR §180.380:			
Bean, forage Bean, straw/hay	None		Tolerances are no longer required. Commodities are not listed in Table II (September 1995) as feedstuffs.
Blueberry	None	4.0	CBTS recommended for tolerance, toxicological considerations permitting (PP#0E3850).
Caneberry	None	10.00	CBTS recommended for tolerance, toxicological considerations permitting (PP#0E3903).
Cranberry	None	2.0	CBTS recommended for tolerance, toxicological considerations permitting (PP#4E4377).
Eggs	None	TBD ^a	If tolerances for commodities containing poultry feed items are established, egg tolerance may be necessary.
Hops	None	40	PP#7H5531 is in reject status.
Fat ^b Meat ^b Meat by-products ^b Milk	None	0.05 0.05 0.05 0.05	Based on proposed tolerances for almond and potato, and on the results of a dairy cattle feeding study, CBRS recommends that the petitioner propose tolerances for meat, meat by-products, and milk of cattle, goats, horses, hogs, and sheep at 0.05 ppm.
Peanut Peanut, hulls Peanut, meal Peanut, soapstock	None	3.0 15.0 12.0 24.0	PP#5F3237/FAP#5H5465 is in reject status. The petitioner submitted a letter dated 4/25/89 requesting withdrawal of proposed peanut tolerance, but no FR Notice to this effect has been published.

Table C (continued).

Commodity	Current Tolerance (ppm)	Proposed or Pending Tolerance (ppm)	Comments
Pending or Proposed Tolerances under 40 CFR §180.380:			
Potato, tuber	None	0.1	PP#1F4008/FAP#2H5623 is in reject status.
Poultry, fat Poultry, meat by-products	None	TBD	If tolerances for commodities containing poultry feed items are established, poultry fat tolerance may be necessary.
Pending or Proposed Food Tolerances under 40 CFR §185.1850			
Potato, granules/flakes	None	0.2	PP#1F4008/FAP#2H5623 is in reject status.
Potato, peel, dried	None	3	Dried potato peel is no longer considered a potato processed commodity [Table II (Sept 1995)]. Petition should be amended to request tolerances for potato, peel, wet.

TBD = To be determined. Tolerance cannot be determined at this time.

^b Fat, milk, and meat of cattle, goats, horses, hogs, and sheep.

CODEX HARMONIZATION

Maximum residue limits (MRLs; Steps 5 through CXL) have been established by Codex in plant and animal commodities. Codex MRLs and the applicable reassessed U.S. tolerances are listed in Table D. Codex and U.S. tolerance definitions are presently equivalent as both are expressed as the sum of residues of vinclozolin and all metabolites containing the 3,5-DCA moiety.

Codex MRLs and U.S. tolerances (established and proposed) are in harmony for the following commodities: cucumbers, hops (dried), kiwifruit, onions, peppers, potatoes, eggs, strawberries, and tomatoes.

Compatibility with the Codex tolerance limit for vinclozolin in/on apricots, cherries, and peaches is not possible at this time as the Codex MRL is 5 ppm on these fruits and the U.S. tolerance is 25 ppm on the stone fruit crop grouping. However, there is a pending petition to lower the 25 ppm U.S. stone fruit tolerance to 5 ppm, the same as Codex.

Codex has established tolerances for vinclozolin in cattle milk and meat, and poultry eggs and meat each at 0.05 ppm. There are no US meat/milk tolerances. In the pending grape tolerance petition (PP#9F3750) tolerances on eggs and poultry commodities (fat, meat, liver, and kidney) are proposed at 0.05 and 0.1 ppm, respectively. On livestock, pending U.S. tolerances are as follows: milk, 0.2 ppm; fat, 0.6 ppm; meat (except liver & kidney), 0.3 ppm and liver and kidney, 1.2 pm.

If tolerances for commodities containing livestock feed items are established, meat, meat byprdt, and milk tolerances may be necessary. Based on proposed tolerances for almond and potato, and on the results of a dairy cattle feeding study, CBRS recommends that the petitioner propose tolerances for meat, meat by-products, and milk of cattle, goats, horses, hogs, and sheep at 0.05 ppm.

The following U.S. tolerances cannot be made compatible with the Codex values because data indicate the need for higher values: grapes, lettuce, caneberries (pending) and succulent beans (pending).

Table D. Codex MRLs and Applicable U.S. Tolerances.

Commodity	CODEX MRL (mg/kg)	Reassessed or Proposed U.S. Tolerance (ppm)	Recommendation/ Comments
Almonds	None	0.2 *	
Almond hulls	None	3.0 *	
Beans, succulent	2.0	3.0 *	
Belgian Endive, Tops	2.0	2.0	
Blueberries	5.0	4.0 *	
Cattle meat and milk	0.05	TBD	
Chicory, Red (Tops) (Radicchio)	2.0	2.0	
Caneberries	5.0	10.0 *	
Cranberries	None	2.0 *	
Cucumbers	1.0	1.0	
Eggs	0.05	TBD	
Grapes	5.0	6.0	
Hops (dried)	40.0	40.0 *	
Kiwifruits	10.0	10.0	
Lettuce, Head and Leaf	5.0	10.0	
Onions, Dry Bulb	6.0	1.0	
Peppers, Bell	3.0	3.0	
Potato	0.1	0.1 *	
Potato granules/flakes	None	0.2 *	
Poultry meat	0.05	TBD	
Plum	5.0	25.0	
Prunes	None	75.0	
Raisins	None	15.0	
Raspberries	5.0	10.0	
Stone Fruits	5.0	5.0	U.S. tolerance recommended for stone fruit, except plums/fresh prunes
Strawberries	10.0	10.0	
Tomatoes	3.0	3.0	

* Tolerance petitions are currently proposed or pending.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CB No: None
DP Barcode: None
Subject: PP#8G2068. BAS 352F on strawberries. Evaluation of analytical method and residue data.
From: G. Makhijani, CB
To: PM Team 21 and TOX
Dated: 1/19/79
MRID(s): None

CB No: None
DP Barcode: None
Subject: PP#4E2998. BAS 352F (Ronilan) in or on Tomatoes and Cucumbers. Evaluation of Analytical Methodology and Residue Data.
From: J. Onley, CB
To: H. Jacoby, RD
Dated: 3/30/84
Acc. No: 072159

CB No(s): 968 and 969
DP Barcode: None
Subject: PP#5F3237/FAP#5H5465. Vinclozolin (Ronilan®) on Peanuts and Beans (Succulent and Dry). Evaluation of Analytical Methods, Residue Data, and Proposed Tolerances for Residues in Animal commodities (Accession Numbers 073480 and 073481).
From: M. Firestone, CB
To: H. Jacoby, RD
Dated: 6/28/85
Acc. Nos.: 073480 and 073481

CB No: 770
DP Barcode: None
Subject: PP#4E2998. Vinclozolin (Ronilan®) in/on tomatoes, cucumbers, and peppers. Amendment of 8/29/86.
From: C. Deyrup, CB
To: H. Jacoby, RD
Dated: 11/17/86
MRID(s): None

CB No: None
DP Barcode: None
Subject: Vinclozolin (Ronilan®) Residue Methods.
From: F. Griffith, CB

To: CB Files
Dated: 12/2/86
MRID(s): None

CB No: 1870
DP Barcode: None
Subject: BASF Corporation's PP#7H5531 for Vinclozolin (Ronilan®) on Dried Hops.
From: C. Deyrup, CB
To: A. Lindsay, OPP/L. Rossi, RD
Dated: 2/25/87
MRID(s): None

CB No: 1952
DP Barcode: None
Subject: PP#4E2998. Vinclozolin (Ronilan) in or on Peppers and Tomatoes.
Amendment of 1/12/87.
From: C. Deyrup, CB
To: L. Rossi, RD
Dated: 3/16/87
MRID(s): None

CB No: 4659
DP Barcode: None
Subject: PP#7H5531. Vinclozolin (Ronilan®) on Dried Hops. Amendment of
10/17/88.
From: C. Deyrup, CB
To: L. Rossi, RD
Dated: 1/6/89
MRID(s): 40854400

CBRS Nos: 5336, 5337, 5338, and 5339
DP Barcodes: None
Subject: PP#9F3762/FAP#9H5585. Vinclozolin on Succulent Beans. Evaluation of
Analytical Method and Residue Data.
From: R. Cook, CBRS
To: G. LaRocca, RD
Dated: 11/15/89
MRID(s): 41080601 and 41080602

CB No: 5696
DP Barcode: None
Subject: PP#9F3788. Vinclozolin (RONILAN) on almonds. Residue Data and
Method Evaluation.
From: L. Rodriguez, CB

To: S. Lewis, RD
Dated: 1/8/90
MRID(s): 41188000, 41188001, and 41188002

CBTS No: 5947
DP Barcode: None
Subject: PP#9E3808: Vinclozolin In/On Domestic Belgian Endive (Chicory) Tops.
Evaluation of Analytical Methods and Residue Data

From: W. Chin, CBTS
To: H. Jamerson, RD
Dated: 6/25/90
MRID(s): None

CBTS Nos: 5238, 5239 and 5240
DP Barcode: None
Subject: PP#9F3750, Vinclozolin: Request for Establishment of Meat, Milk and
Egg tolerances and Registration on Domestic Grapes. Evaluation of
Analytical Method and Residue Data.

From: W. Chin, CBTS
To: S. Lewis, RD
Dated: 7/2/90
MRID(s): 41040001 to -07 and 41064500 to -03

CB No: 6558
DP Barcode: None
Subject: Petition Review for Establishment of Tolerance(s). Evaluation of Analytical
Method(s) and Residue Data.

From: F. Griffith, CB
To: H. Jamerson, RD
Dated: 7/24/90
MRID(s): 41417500 to -02

CBTS No: 6932
DP Barcode: None
Subject: PP#9E3808: Vinclozolin In/On Domestic Belgian Endive (Chicory) tops.
Amendment of 7/20/90.

From: W. Chin, CBTS
To: H. Jamerson, RD
Dated: 8/17/90
MRID(s): None

CB No: 7953
DP Barcode: D164076

Subject: PP#0E3903. Vinclozolin (Ronilan®) in/on Caneberries. Amendment of April 9, 1991.
From: M. Nelson, CB
To: H. Jamerson, RD
Dated: 5/10/91
MRID(s): None

CBRS No(s): 7880
DP Barcode: D163362
Subject: EPA Reg. No. 7969-85. Amendment to registration of Ronilan® DF Fungicide (Vinclozolin) to include aerial application to stone fruits.
From: B. Cropp-Kohlligan, CBRS
To: S. Lewis, RD
Dated: 5/31/91
MRID(s): None

CB No: 7965
DP Barcode: None
Subject: PP# 0E3850 - vinclozolin (Ronilan®) in/on Blueberries. Review of the April 10, 1991 Amendment.
From: F. Griffith, CB
To: H. Jamerson, RD
Dated: 7/22/91
MRID(s): None

CBTS No(s): 7910
DP Barcode: D163699
Subject: PP#1F03976. Vinclozolin (Ronilan® Fungicide, EPA Reg. Nos. 7969-53, 7969-62, 7969-85) in or on Stonefruit. Evaluation of analytical methods and magnitude of residue data.
From: W. Wassell, CBTS
To: S. Lewis, RD
Dated: 7/25/91
MRID(s): None

CBTS No(s): 8227
DP Barcode: D165976
Subject: PP#9F3788 Vinclozolin for Use in/on Almonds. Amendment of 7/1/91.
From: G. Herndon, CBTS
To: S. Lewis, RD
Dated: 8/15/91
MRID(s): 41927900 and 41927901

CBRS Nos: 8280, 8281, and 8299

DP Barcodes: D166259, D166245, and D166246
Subject: Vinclozolin. Extension of Established Import Tolerance in/on Belgian Endive Tops to include Domestically Produced Belgian Endive Tops.
From: J. Smith
To: S. Lewis/R. Rose, RD
Dated: 9/18/91
MRID(s): None

CBTS Nos: 9105 and 9106
DP Barcodes: D172133 and D172412
Subject: PP#1F04008/2H05623 Vinclozolin (113201 Ronilan) on Potatoes. Evaluation of Analytical Method and Residue Data.
From: M. Bradley, CBTS
To: B. Chambliss, RD and Kocialski, HED
Dated: 4/7/93
MRID(s): 41961700 - 03, 42100200, and 42110201

CBRS No: 12179
DP Barcode: D192963
Subject: WA-90-0036: Special Local Need Label [24(c)] for Vinclozolin (Ronilan WP) for Use in Washington State in/on Chicory Roots (Belgian Endive).
From: J. Garbus
To: S. Lewis/D. Greenway, RD
Dated: 7/26/93
MRID(s): None
CBTS No: 12310
DP Barcode: D193893
Subject: Multiresidue Method (MRM) Validation Data for the Metabolites of Vinclozolin (Ronilan Fungicide).
From: W. Wassell, CBTS
To: H. Hundley, BEAD
Dated: 8/11/93
MRID(s): 42622701

CBTS No: 12311
DP Barcode: D193892
Subject: Multiresidue Method (MRM) Validation Data for the Metabolites of Vinclozolin (Ronilan Fungicide).
From: W. Wassell, CBTS
To: B. McMahon, FDA
Dated: 8/12/93
MRID(s): 42622701

CBTS Nos: 11396 and 12350

DP Barcodes: D188198 and D194020
Subject: PP#1F03976/FAP#1H05615. Vinclozolin (Ronilan® Fungicide, EPA Reg. Nos. 7969-53, 7969-62, 7969-85) in or on Stone Fruit. Amendment of 1/8/93.
From: W. Wassell, CBTS
To: J. Fairfax, HFB
Dated: 8/20/93
MRID(s): 42622701, 42622702, and 42622703

CBRS No: 11283
DP Barcode: D187397
Subject: Vinclozolin. Over-tolerance Residues in/on Onions.
From: F. Fort, CBRS
To: J. Fairfax/S. Lewis, RD
Dated: 9/23/93
MRID(s): 42593701

CBRS No: 12302
DP Barcode: D193694
Subject: Vinclozolin. Magnitude of the Residue in Cherries.
From: S. Knizner, CBRS
To: A. Dixon, SRRD
Dated: 2/18/94
MRID(s): 42829801

CBTS No: 11280
DP Barcode: D187409
Subject: PP#9F03750. Vinclozolin in or on meat, milk and eggs. Results of Petition Method Validation (PMV).
From: G. Kramer, CBTS
To: S. Robbins
Dated: 6/14/94
MRID(s): 42597901 and 41749601

CBTS No: 14035
DP Barcode: D205273
Subject: PP#4E4377. Vinclozolin on Cranberries. Review of Residue Data and Enforcement Methodology.
From: S. Willett, CBTS
To: H. Jamerson/A. Kocialski, RD
Dated: 11/9/94
MRID(s): 43289700 and 43289701

CBRS No: 13881

DP Barcode: D204479
Subject: Vinclozolin. Magnitude of the Residue in lettuce (Leaf/Head).
From: S. Knizner, CBRS
To: M. Wilhite, SRRD
Dated: 12/16/94
MRID(s): 43255803 and 43255804

CBTS No: 14018
DP Barcode: D205224
Subject: PP#9F3762/FAP#9H5585. Vinclozolin (Ronilan®) in or on Succulent Beans. Submission if ILV and Magnitude of the Residue: Vinclozolin in Almond Nutmeats and Hulls. Letter of 5/11/94.
From: R. Cook, CBTS
To: S. Jackson, RD
Dated: 1/12/95
MRID(s): 43272801 and 43272802

CBRS No: 14322
DP Barcode: D207132
Subject: Vinclozolin. Magnitude of the Residue in lettuce (Leaf/Head).
From: S. Knizner, CBRS
To: M. Wilhite, SRRD
Dated: 5/18/95
MRID(s): 43353101 and 43353102

CBRS No: 14997
DP Barcode: D211118
Subject: Vinclozolin. Residue Analytical Methods - Animal Commodities and Magnitude of the Residue in/on Succulent Beans, Peaches, and Plums.
From: S. Knizner, CBRS
To: M. Wilhite, SRRD
Dated: 6/5/95
MRID(s): 43505902, 43505903, 43505904, 43505905, and 43505906

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00085105 Foushee, J.A.; Carter, C.; Daniel, J.W.; et al. (1979) Determination of BAS 352F and Its 3,5-Dichloroaniline-containing Metabolite Residues in Stonefruit Samples: Report No. PR-192. (Unpublished study received May 1, 1979 under 7969-EX-13; submitted by BASF Wyandotte Corp., Parsippany, N.J.; CDL:098251-P)

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00157427 Clark, J.; Louis, C. (1978) Metabolism of BAS 352F in Lettuce: Laboratory Report PM-25. Unpublished study prepared by BASF Wyandott Corp. 37 p.

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40297402 Paulick, R. (1987) Magnitude of the Residue of Vinclozolin and Metabolites in Leaf Lettuce: Registration Document # BASF: 87/5028. Unpublished compilation prepared by BASF Corporation Chemicals Division. 46 p.

40297403 Paulick, R. (1987) Magnitude of the Residue of Vinclozolin and Metabolites in Onions: Registration Document # BASF: 87/5024. Unpublished study prepared by BASF Corporation Chemicals Division. 53 p.

40297404 Paulick, R. (1987) Freezer Storage Stability of Vinclozolin and Its Metabolites, B, D, E and S in Grapes, Strawberries, Lettuce and Soil: Registration Document # BASF: 87/5018. Unpublished compilation prepared by BASF Corporation Chemicals Division. 48 p.

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40876701 Single, Y. (1988) Magnitude of the Residues of Vinclozolin and its Metabolites in Peaches, Cherries and Plums (Aerial vs. Ground Application): Document No. 88 5105. Unpublished study prepared by Morse Laboratories, Inc. 47 p.

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