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

DEC 20 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Vinclozolin.** Magnitude of the Residue in lettuce (Leaf/Head). Reregistration Case #2740. MRID #43255803 and 43255804 DP Barcode D204479 CBRS #13881

FROM: Steven A. Knizner, Chemist
Chemistry Pilot Review Team
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
Special Review and Reregistration Division (7508W)

Tolerances are established for the combined residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in/on head and leaf lettuce at 10.0 ppm each [40 CFR §180.380].

The Vinclozolin Phase 4 Review (L. Cheng, 3/6/91) required residue data reflecting aerial application of vinclozolin. However, a REFS search dated 9/16/94 identified three vinclozolin end-use products registered to BASF, all of which include only ground (broadcast) application for lettuce. That is, none of the current BASF vinclozolin labels permit aerial application for lettuce.

In the current submission, BASF Corporation has provided data (MRIDs 43255803 and 43255804) from six field residue trials conducted in AZ, FL, and CA depicting residues of vinclozolin and its metabolites containing the 3,4-dichloroaniline moiety in/on head and leaf lettuce.
Lettuce was treated with three foliar applications, at 14-17 day retreatment intervals, of the 50% DF formulation (RONILAN® DF; EPA Reg. No. 7969-85) at 1.0 lb ai/A/application (1x the maximum seasonal rate) using ground equipment. Head and leaf lettuce samples were harvested 27-28 days following the third application, in agreement with the label PHI of 28 days. These data have been summarized by Dynamac (data evaluation attached) under contract to the Agency.

Recommendations

The submitted study is adequate. No additional data are required for lettuce. The data support the established tolerances for the combined residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in/on head and leaf lettuce at 10.0 ppm each.

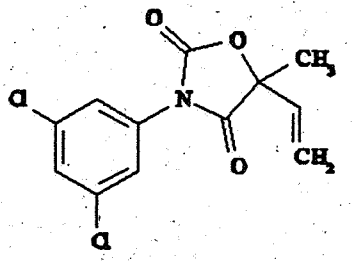
cc: S.F., circ., R.F., List B File, S.Knizner
RDI: P.Deschamp, C.Olinger, W. Smith, B. Cropp-Kohlligian, L.Edwards, 12/14/94 M.Metzger, 12/16/94
7509C:CBRS:CM#2:305-6903:SAK:sak:Vincloz:12/14/94

DATA EVALUATION RECORD

DP BARCODE(S):	D204479
CBRS NO.:	13881
STUDY TYPES:	Magnitude of the residue in/on leaf and head lettuce [Guideline Reference No. 171-4(k)].
STUDY SPONSOR:	BASF Corporation (Winston-Salem, NC)
MRID NOS.:	43255803 M. Smith, L. Sears, and S. Jackson. Magnitude of the Residue of Vinclozolin and Its Metabolites in Head Lettuce, Raw Agricultural Commodity Samples. BASF Project Number 92-0017. Study Completed on 11/16/93. 43255804 M. Smith, L. Sears, and S. Jackson. Magnitude of the Residue of Vinclozolin and Its Metabolites in Leaf Lettuce, Raw Agricultural Commodity Samples. BASF Project Number 92-0015. Study Completed on 11/16/93.
PERFORMING LABORATORIES:	Field: California Agricultural Research Inc. (Kerman, CA); West Consulting, Inc. (Yuma, AZ); and AG Consulting, Inc. (Mount Dora, FL). Analytical: EN-CAS Analytical Laboratories (Winston-Salem, NC).
TEST MATERIAL APPLIED TO CROP:	Vinclozolin; 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidine dione (CAS No. 50471-44-8)
EPA REG. NO.:	7969-85 (Ronilan® DF Fungicide)

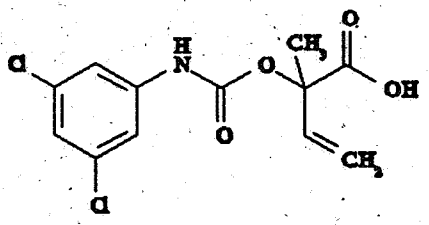
RESIDUES MEASURED:

Vinclozolin

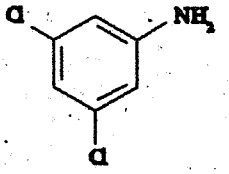


and its metabolites containing the 3,5-dichloroaniline moiety, such as:

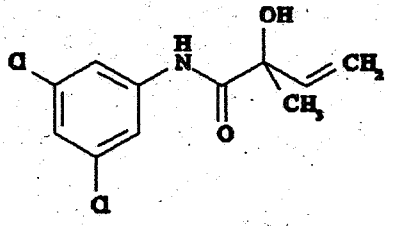
3-(3,5-dichlorophenyl)carbamic acid (1-carboxy-1-methyl)allyl ester (Metabolite B)



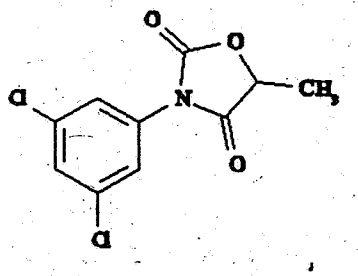
3,5-dichloroaniline (Metabolite D)



N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenoic acid amide (Metabolite E)



RESIDUES MEASURED (cont'd): 3-(3,5-dichlorophenyl)-5-methyl-1,3-oxazolidine-2,4-dione (Metabolite S)



DETAILED CONSIDERATIONS

BASF Corporation submitted data (1993; MRIDs 43255803 and 43255804) from six field residue trials conducted in 1991 depicting residues of vinclozolin and its metabolites containing the 3,4-dichloroaniline moiety in/on head and leaf lettuce grown in AZ(2), CA(2), and FL(2). Data from these submissions are described and presented in this Data Evaluation Record.

Established tolerances: Tolerances have been established for the combined residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in/on head and leaf lettuce at 10.0 ppm each [40 CFR §180.380].

Use patterns: A REFS search conducted 9/16/94 identified three vinclozolin end-use products registered to BASF for use on lettuce: a 50% WP formulation (EPA Reg. No. 7969-53, Ronilan® WP, dated 3/24/94); a 4.17 lb/gal FlC formulation (EPA Reg. No. 7969-62, Ronilan® FL, dated 3/24/94); and a 50% DF formulation (EPA Reg. No. 7969-85, Ronilan® DF, dated 4/1/94). A maximum of three foliar broadcast applications may be made at 0.5-1.0 lb ai/A/application per growing season with a 14-day retreatment interval. Applications may be made in a minimum of 100 gal/A using ground equipment. A 28-day PHI has been established.

Discussion of the data: In six tests conducted in AZ(2), CA(2), and FL(2), head and leaf lettuce were treated with three foliar applications, at 14-17 day retreatment intervals, of the 50% DF formulation (RONILAN® DF; EPA Reg. No. 7969-85) at 1.0 lb ai/A/application (1x the maximum seasonal rate) in 98-106 gal/A using ground equipment. At the time of treatments, the lettuce crops were at the 2- to 6-, 4- to 12-, and 8- to 18-leaf stages, respectively. Head and leaf lettuce samples were harvested 27-28 days following the third application.

The results of the lettuce residue trials are presented in Table 1; residues were not corrected for concurrent method recovery. Apparent residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety, expressed as vinclozolin equivalents, were nondetectable (<0.05 ppm) in/on three samples of untreated untrimmed head lettuce and one sample each of untreated trimmed head lettuce and the inner and outer wrapper leaves of

untreated head lettuce. Apparent residues were also non-detectable (<0.05 ppm) in/on two samples each of untreated untrimmed and trimmed leaf lettuce and one sample each of the inner and outer wrapper leaves of untreated leaf lettuce. One sample of untreated untrimmed leaf lettuce bore detectable residues of 0.067 ppm; no explanation for these detectable residues was provided.

Table 1. Residues of vinclozolin and its metabolites in/on head and leaf lettuce harvested 27-28 days following the last of three foliar applications of the 50% DF formulation at 1.0 lb ai/A/application (1x the maximum seasonal rate).

Matrix		Residues, ppm [a]		
		AZ	CA	FL
Head lettuce	untrimmed	2.08	7.01	0.234
	trimmed	0.558	1.35	0.113
	outer wrapper leaves	10.2	15.9	0.920
	inner wrapper leaves	3.07	6.09	0.132
Leaf lettuce	untrimmed	6.12	7.09	0.303
	trimmed	0.78	4.02	<0.05
	outer wrapper leaves	20.4	24.5	0.946
	inner wrapper leaves	10.0	14.0	0.148

[a] Determined as 3,5-dichloroaniline (3,5-DCA) and reported as vinclozolin equivalents; residues were not corrected for concurrent method recovery.

Geographic representation is adequate since the test states of AZ(22%), CA(72%), and FL(2%) accounted for 96% of the 1991 U.S. lettuce production (*1992 USDA Agricultural Statistics*).

Lettuce grown in AZ and CA recieved in-furrow irrigation (there was less than 0.5 inches rainfall from treatment to harvest), whereas rainfall in FL was sufficient so that no irrigation was needed following treatment (approximatley 2.3 inches from treatment to harvest).

Summary of studies: The submitted data indicate that the combined residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will not exceed the established 10-ppm tolerances in/on head or leaf lettuce harvested 28 days following the last of 3 applications of the 50% DF formulation at 1.0 lb ai/A/application (1x the maximum seasonal rate) using ground equipment. Residues in/on untrimmed samples were 0.234-7.01 ppm for head lettuce and 0.303-7.09 ppm for leaf lettuce (3 samples each); residues in/on trimmed samples were 0.113-1.35 ppm for head lettuce and <0.05(nondetectable)-4.02 ppm for leaf lettuce (3 samples each).

Residue Analytical Method

Residues of vinclozolin were analyzed by GC using a fused silica DB-17 column and a nitrogen-phosphorous detector (EN-CAS Method ENC-10/91). Briefly, samples were hydrolyzed with 5 M sodium hydroxide to convert vinclozolin and its metabolites to 3,5-dichloroaniline (3,5-DCA). The hydrolysate was then simultaneously steam-distilled and partitioned into hexane to collect 3,5-DCA residues. The aqueous layer was frozen and the hexane layer was removed and cleaned up on a silica gel solid phase extraction column, eluting with hexane:ethyl acetate (75:25, v:v). The eluate is then analyzed by GC. This method is similar to BASF Method 25 (PAM Vol II, Method I) except that dichloroaniline residues are partitioned into hexane instead of chloroform, and the residues are measured directly without derivitization. The limit of quantitation is 0.05 ppm 3,5-DCA, calculated as vinclozolin equivalents.

Concurrent method recoveries from untreated head lettuce samples fortified with vinclozolin *per se* at 0.05-20.0 ppm were 71-88% from five samples of untrimmed lettuce, 80 and 88% from two samples of trimmed lettuce, and 112% from one sample of outer wrapper leaves. The recoveries from untreated leaf lettuce samples fortified with vinclozolin *per se* at 0.05-30.0 ppm were 84-94% from four samples of untrimmed lettuce, 73-93% from three samples of trimmed lettuce, and 89% from one sample of outer wrapper leaves. Representative chromatograms and sample calculations were provided. No fortifications with any vinclozolin metabolites were made.

Storage Stability Data

The harvested head and leaf lettuce samples from the field residues trials were stored up to 40 days at -26 to -11 C prior to shipping to BASF, where the samples were homogenized and stored at ≤5 C for 49-117 days. The registrant reported that any partial thawing occurred during the homogenization was of short duration (<15 minutes). The subsamples were then shipped to EN-CAS Analytical Laboratories, where they were stored at ca -27 to -23 C until analysis. The total storage intervals from harvest until completion of analysis were 75-169 days (2.5-5.6 months). To support these storage intervals, the registrant cited data from a previously submitted storage stability study (MRID 42622702, CBRS Nos. 11396, 12350, DP Barcodes D188198, and D194020, dated 8/20/93) which indicated that residues of vinclozolin and its metabolites B, E, and S are stable in/on lettuce for up to 17 months of frozen storage.

Vinclozolin in/on head and leaf lettuce (foliar spray application) Formulation: 50% DF

MRID	Year	Loc	Number of Samples	Crop	RAC	PTI, days	Application Equip.	Gal/A	Retrtmnt interval, days	Appl. rate, lb ai/A	Number	Total rate, lb ai/A	Residues, ppm	Fortification Chemical	ppm	% Recovery	Storage interval, days	Temp., C
43255803	1991	CA	1	head lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	0.05	71	122	<-5
43255803	1991	CA	1 dup	head lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	10.0	71	131	<-5
43255803	1991	CA	1	head lettuce	untrimmed	28	ground	101-102	14	0.97-0.99	3	2.94	7.01				131	<-5
43255803	1991	CA	1	head lettuce	outer wrapper leaves	28	ground	101-102	14	0.97-0.99	3	2.94	15.9				131	<-5
43255803	1991	CA	1	head lettuce	inner wrapper leaves	28	ground	101-102	14	0.97-0.99	3	2.94	6.09				131	<-5
43255803	1991	CA	1	head lettuce	trimmed	28	ground	101-102	14	0.97-0.99	3	2.94	1.35				131	<-5
43255803	1991	AZ	1	head lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	5.00	88	75	<-5
43255803	1991	AZ	1 dup	head lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	10.0	88	86	<-5
43255803	1991	AZ	1	head lettuce	untrimmed	28	ground	101-106	16, 17	0.98-1.02	3	2.99	2.08				86	<-5
43255803	1991	AZ	1	head lettuce	outer wrapper leaves	28	ground	101-106	16, 17	0.98-1.02	3	2.99	10.2				86	<-5
43255803	1991	AZ	1	head lettuce	inner wrapper leaves	28	ground	101-106	16, 17	0.98-1.02	3	2.99	3.07				86	<-5
43255803	1991	AZ	1	head lettuce	trimmed	28	ground	101-106	16	0.98-1.02	3	2.99	0.558				86	<-5
43255803	1991	FL	1	head lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	0.50	79	144	<-5
43255803	1991	FL	1 dup	head lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05				160	<-5
43255803	1991	FL	1	head lettuce	untrimmed	27	ground	99-102	14	0.95-0.98	3	2.88	0.234				160	<-5
43255803	1991	FL	1	head lettuce	outer wrapper leaves	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	0.05	112	169	<-5
43255803	1991	FL	1	head lettuce	outer wrapper leaves	27	ground	99-102	14	0.95-0.98	3	2.88	0.920				160	<-5
43255803	1991	FL	1	head lettuce	inner wrapper leaves	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05				169	<-5
43255803	1991	FL	1	head lettuce	inner wrapper leaves	27	ground	99-102	14	0.95-0.98	3	2.88	0.132				160	<-5
43255803	1991	FL	1	head lettuce	trimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	0.50	80	169	<-5
43255803	1991	FL	1 dup	head lettuce	trimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	20.0	88	160	<-5
43255803	1991	FL	1	head lettuce	trimmed	27	ground	99-102	14	0.95-0.98	3	2.88	0.113				160	<-5
43255804	1991	CA	1	leaf lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	0.05	89	122	<-5
43255804	1991	CA	1 dup	leaf lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	10.0	94	130	<-5
43255804	1991	CA	1 dup	leaf lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	5.00	84		
		CA		leaf lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A			vinclozolin	10.0	92		
43255804	1991	CA	1	leaf lettuce	untrimmed	28	ground	98-102	14	0.95-0.99	3	2.90	7.09				130	<-5
43255804	1991	CA	1	leaf lettuce	outer wrapper leaves	28	ground	98-102	14	0.95-0.99	3	2.90	24.5				130	<-5
43255804	1991	CA	1	leaf lettuce	inner wrapper leaves	28	ground	98-102	14	0.95-0.99	3	2.90	14.0				130	<-5
43255804	1991	CA	1	leaf lettuce	trimmed	28	ground	98-102	14	0.95-0.99	3	2.90	4.02				130	<-5
43255804	1991	AZ	1	leaf lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05				86	<-5
43255804	1991	AZ	1	leaf lettuce	untrimmed	28	ground	101-106	16	0.97-1.03	3	3.02	6.12				86	<-5
43255804	1991	AZ	1	leaf lettuce	outer wrapper leaves	28	ground	101-106	16	0.97-1.03	3	3.02	20.4				86	<-5
43255804	1991	AZ	1	leaf lettuce	inner wrapper leaves	28	ground	101-106	16	0.97-1.03	3	3.02	10.0				86	<-5
43255804	1991	AZ	1	leaf lettuce	trimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	0.05	93	75	<-5
43255804	1991	AZ	1	leaf lettuce	trimmed	28	ground	101-106	16	0.96-0.97	3	2.89	0.78				86	<-5
43255804	1991	FL	1	leaf lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.051				144	<-5
43255804	1991	FL	1 dup	leaf lettuce	untrimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.067				159	<-5
43255804	1991	FL	1	leaf lettuce	untrimmed	27	ground	99-101	14	0.96-0.97	3	2.89	0.302				159	<-5
43255804	1991	FL	1	leaf lettuce	outer wrapper leaves	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	0.50	89	169	<-5
43255804	1991	FL	1	leaf lettuce	outer wrapper leaves	27	ground	99-101	14	0.96-0.97	3	2.89	0.946				159	<-5
43255804	1991	FL	1	leaf lettuce	inner wrapper leaves	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05				169	<-5
43255804	1991	FL	1	leaf lettuce	inner wrapper leaves	27	ground	99-101	14	0.96-0.97	3	2.89	0.148				159	<-5
43255804	1991	FL	1	leaf lettuce	trimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	0.50	87	169	<-5
43255804	1991	FL	1 dup	leaf lettuce	trimmed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	<0.05	vinclozolin	30.0	73	159	<-5
43255804	1991	FL	1	leaf lettuce	trimmed	27	ground	99-101	14	0.96-0.97	3	2.89	<0.05				159	<-5

Notes: Residues were determined as 3,5 DCA and reported in vinclozolin equivalents.
Residues were not corrected for concurrent method recovery.