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

MAY 18 1995

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: **Vinclozolin.** Magnitude of the Residue in lettuce (Leaf/Head). Reregistration Case #2740. MRID #43353101 and 43353102 DP Barcode D207132 CBRS #14322

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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 43353101 and 43353102) 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 14-15 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 record 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: A.Rathman, 5/10/95 F.Suhre, 5/18/95
7509C:CBRS:CM#2:305-6903:SAK:sak:Vincloz:5/10/95

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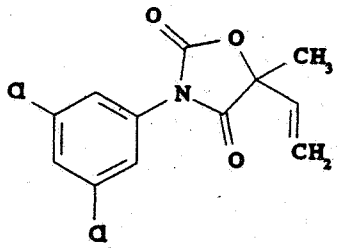
DATA EVALUATION RECORD

DP BARCODE:	D207132
CBRS NO.:	14322
STUDY TYPES:	Magnitude of the residue in/on leaf and head lettuce [Guideline Reference No. 171-4(k)].
STUDY SPONSOR:	BASF Corporation (Research Triangle Park, NC)
MRID NOS.:	43353101 M. Smith. Magnitude of the Residue of Vinclozolin and Its Metabolites in Leaf Lettuce, Raw Agricultural Commodity Samples. BASF Project Number 94-5081. Study Completed on 6/29/94. 43353102 M. Smith. Magnitude of the Residue of Vinclozolin and Its Metabolites in Head Lettuce, Raw Agricultural Commodity Samples. BASF Project Number 94/5082. Study Completed on 6/29/94.
PERFORMING LABORATORIES:	Field: Stewart Agricultural Research Services, Inc. (Macon, MO); Plant Sciences, Inc. (Watsonville, CA); Mini Plots (Phoenix, AZ); and Ag Consulting, Inc. (Mt. 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-oxazolidinedione (CAS No. 50471-44-8)
EPA REG. NO.:	7969-85 (Ronilan® DF Fungicide)

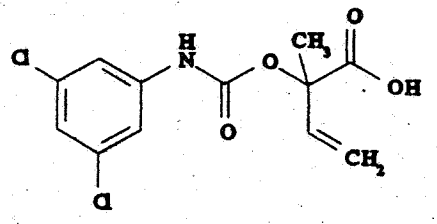
RESIDUES MEASURED:

Vinclozolin

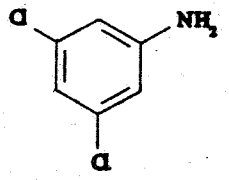


and its metabolites containing the 3,5-dichloroaniline moiety, such as:

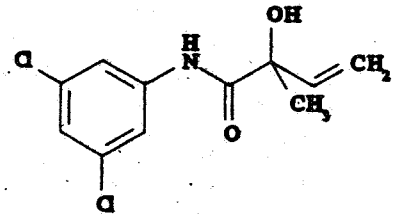
3-(3,5-dichlorophenyl)carbamic acid (1-carboxy-1-methyl)allyl ester (Metabolite B)



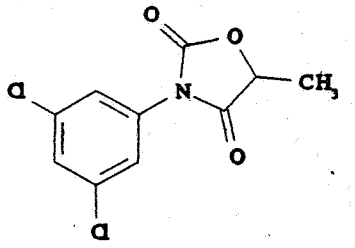
3,5-dichloroaniline (Metabolite D)



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 (1994; MRIDs 43353101 and 43353102) from six field residue trials conducted in 1992 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 4/6/95 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 4/11/94). 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 trials conducted in AZ(2), CA(2), and FL(2), head and leaf lettuce (three trials each) were treated with three foliar applications, at 14- to 15-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 97-102 gal/A using ground equipment. Lettuce crops were at the 3- to 7-, 5- to 10-, and 10- to 20-leaf stages, respectively, during the first, second, and third applications. 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 each of untreated untrimmed head lettuce,

untreated trimmed head lettuce, untreated untrimmed leaf lettuce, and untreated trimmed leaf lettuce.

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	0.33	0.09	0.06
	trimmed	0.11	<0.05	<0.05
Leaf lettuce	untrimmed	0.15	0.27	0.07
	trimmed	<0.05	0.11	<0.05

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

Lettuce grown in AZ, CA, and FL received irrigation in-furrow, by overhead sprinkler, or by overhead traveling gun, respectively. The registrant included tables of 10-year (CA and AZ) and 30-year (FL) rainfall averages and the combined total rainfall/irrigation received during the studies, but did not differentiate between irrigation and rainfall. Levels of rainfall/irrigation received in the CA and FL trials were similar to average rainfall levels, while levels received in the AZ trial were 5-10 times the average rainfall levels.

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*).

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 three foliar 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 0.06-0.33 ppm for head lettuce and 0.07-0.27 ppm for leaf lettuce (three samples each); residues in/on trimmed samples were <0.05(nondetectable)-0.11 ppm for head lettuce and <0.05(nondetectable)-0.11 ppm for leaf lettuce (three 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 and leaf lettuce samples fortified with vinclozolin *per se* at 0.05 ppm and 10.0 ppm were 74% and 82% from two samples of untrimmed head lettuce, 87% and 104% from two samples of trimmed head lettuce, 75% and 110% from two samples of untrimmed leaf lettuce, and 70% and 93% from two samples of trimmed leaf lettuce. 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 residue trials were stored for up to 22 days at -31 to -9 C prior to shipping to BASF, where the samples were homogenized and stored at ≤-5 C for 230-262 days. The registrant reported that any partial thawing which 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 -27 to -23 C until analysis. The total storage intervals from harvest until completion of analysis were 286-357 days (9.5-11.9 months). To support these storage intervals, the registrant cited data from a previously submitted storage stability study (MRID 42622702; CBTS Nos. 11396 and 12350, DP Barcodes D188198 and D194020, 8/20/93, W. Wassell) 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.