

US EPA ARCHIVE DOCUMENT



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

Head 9-25-95

SEP 25 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Vinclozolin. Confined Rotational Crop Study. Reregistration Case #2740.
Chemical #113201 MRID #41496905 DP Barcode D219494 CBRS #16222

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

THRU: Andrew Rathman, Section Head *AR*
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

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

The EFED Phase 4 Review (A.Jones, 3/25/91) required a confined rotational crop study (Guideline 165-1) and reserved data requirements for a field rotational crop study (Guideline 165-2). 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.

Recommendations

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.

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.

Conclusions

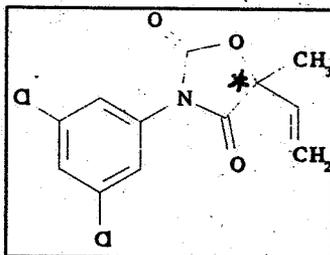
1. CBRS concludes that the position of the radiolabel in the test material is not appropriate. The test material should have been labeled in the phenyl ring. Additional guidance concerning labeling of test material and all other aspects of confined rotational crop studies can be found in the guidance 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.
2. Although TRR levels in rotated crops were >0.01 ppm, no attempts were made to characterize radioactive residues.

Detailed Considerations

Test Material

Radiolabeled vinclozolin [3-(3',5'-dichlorophenyl)-5-ethenyl-5-methyl-1,3-oxazolidine(5- ^{14}C)-2,4-dione] was synthesized by New England Nuclear and had a specific activity of 3.86 mCi/mMole. The position of the radiolabel is indicated in Figure 1.

Figure 1. ^{14}C -vinclozolin used in study. Asterisk denotes position of radiolabel.



CBRS concludes that the position of the radiolabel in the test material is not appropriate. The test material should have been labeled in the phenyl ring. Additional guidance concerning labeling of test material and all other aspects of 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.

Test System

Three rows of beans (target crop) were planted on 5/20/81. Application of the test material over the top of dried beans was made on 6/24, 7/7 and 7/16/81. One row of beans received only one application, another two applications, and the third three applications. Each application was made at 1 lb ai/A (1x proposed rate for succulent beans).

On 8/14/81, when the dry beans had reached a marketable stage, they were removed from the plot. After removal of the target crop, the soil was spaded to a depth of 15 cm and raked smooth. Winter wheat was planted one month after bean harvest (on 9/14/81). Red beets, sugar beets, orchard grass, soybeans, and spring wheat were planted the following spring (either on 5/5/82 or 5/7/82).

Analytical Methods

Samples of plants were ground in a blender. Subsamples were combusted and TRR determined by LSC. The limit of quantitation was 0.009 ppm and limit of detection 0.003 ppm.

Results

Results are summarized in Table 1. Although TRR levels in rotated crops were >0.01 ppm, no attempts were made to characterize radioactive residues. This is a deficiency.

Table 1. Results of Rotational Crop Study. Applications of ^{14}C -vinclozolin were made to dry beans at 1.0 lb ai/A either two or three times as indicated.

Type of Rotation	Number of Applic. to Primary Crop	Rotational Crop	ppm Vinclozolin equivalents found	Days from last applic. to sampling
Fall	2	Winter wheat straw grain	0.02 0.02	379
	3	Winter wheat straw grain	0.01 0.01	379
Annual	2	Red beets tops	0.01	379
		roots	0.01	
	tops	<0.009	402	
	roots	<0.009		
		Sugar Beets tops	<0.009	379
		roots	<0.009	

Type of Rotation	Number of Applic. to Primary Crop	Rotational Crop	ppm Vinclozolin equivalents found	Days from last applic. to sampling
		Orchard grass	0.02 0.02	379 402
		Soybeans pods beans	<0.009 <0.009	402
		Spring wheat straw grain	<0.009 <0.009	379
	3	Red beets tops roots tops roots	<0.009 <0.009 <0.009 <0.009	374 379
	Sugar Beets tops roots	<0.009 <0.009	379	
	Orchard grass	0.02 0.02	379 402	
	Soybeans whole plant	<0.009	379	
	Soybeans pods beans	<0.009 <0.009	402	
	Spring wheat straw grain	0.02 0.01	379	

cc: S.F., circ., R.F., List B File, S.Knizner

RDI: A.Rathman, 9/22/95 R.Perfetti, 9/22/95 E.Zager, 9/22/95

7509C:CBRS:CM#2:305-6903:SAK:sak:Vincmag:9/21/95