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

FEB 9 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Pendimethalin Reregistration.** Storage Stability Data Submitted to Support Previously Submitted Sweet Corn Metabolism Data.
CBRS No.: 12673
DP Barcode No.: D195890
MRID No.: None
Chemical No.: 108501
Reregistration Case No.: 0187

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THRU: Paula A. Deschamp, Section Head
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TO: Lois Rossi/Walter Waldrop [PM 71]
Reregistration Branch
Special Review and Reregistration Division [7508W]

In response to storage stability deficiencies/concerns specified in a previous residue chemistry review (D189207, CBRS No. 11582, P. Deschamp dated 6/16/93) of a pendimethalin sweet corn metabolism study (1993; MRID 42686401), American Cyanamid Company has submitted a single volume of storage stability data (dated 10/8/93; prepared by Z. Ahmed as a 60-Day Response to the letter from L. Rossi of SRRD dated 8/3/93) to support the subject metabolism study. [NOTE: Although the current submission contains new data, no MRID number was assigned.]

CONCLUSIONS

1. The maximum total storage interval for [^{14}C]pendimethalin-treated samples from the subject sweet corn metabolism study (MRID 42686401) stored as crop matrices at approximately -20°C and as sample extracts at 0-5°C was 526 days. The submitted storage stability data demonstrate that: (i) radiolabelled residues in/on crop matrices from the subject metabolism study were stable for at least 348 days of storage at -20°C, (ii) radiolabelled residues in sample extracts from the subject metabolism study were stable for at least 187 days of storage at 0-5°C, and (iii) radiolabelled residues of pendimethalin in the organosoluble fraction of sample extracts were stable for at least 506 days of storage at 0-5°C.

   Since the registrant has provided evidence that reasonable diligence was exercised in the conduct of the subject sweet corn metabolism study to limit degradation of residues by appropriate storage of matrices and extracts during the analytical portion of the study and in the absence of any evidence of instability, it is appropriate to extrapolate the submitted storage stability data to support the maximum possible storage interval of test samples/extracts which was 526 days. CBRS is convinced that the storage intervals and conditions of test samples/extracts does not invalidate the results of the previously submitted pendimethalin sweet corn metabolism study (MRID 42686401).

2. The registrant must resubmit the new storage stability data (a single volume of data dated 10/8/93; prepared by Z. Ahmed as a 60-Day Response to the letter from L. Rossi of SRRD dated 8/3/93), including all raw data, to the Agency and request the assignment of an MRID number to the submission.

3. Radiovalidation data as specified in the previous residue chemistry review (D189207, CBRS No. 11582, P. Deschamp dated 6/16/93) remain outstanding.

RECOMMENDATIONS

Contingent on the registrant's resubmission of the new storage stability data (dated 10/8/93; prepared by Z. Ahmed as a 60-Day Response to the letter from L. Rossi of SRRD dated 8/3/93) to the Agency and application for the assignment of an MRID number to the submission, the subject storage stability data are adequate to support the previously submitted pendimethalin sweet corn metabolism data (1993; MRID 42686401).

Radiovalidation data from the subject sweet corn metabolism study remain outstanding.

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DETAILED CONSIDERATIONS

BACKGROUND

Previously, the registrant submitted pendimethalin sweet corn metabolism data (1993; MRID 42686401) which were reviewed by the Agency (D189207, CBRS No. 11582, P. Deschamp dated 6/16/93) and deemed insufficient, but upgradeable provided that acceptable storage stability and radiovalidation data were submitted. In their response (dated 10/8/93; prepared by Z. Ahmed as a 60-Day Response to the letter from L. Rossi of SRRD dated 8/3/93), the registrant has submitted a single volume of storage stability data to support the subject metabolism study and has committed to provide radiovalidation data in a separate submission by January 1994.

Supporting Storage Stability Data

The previous CBRS review (D189207, CBRS No. 11582, P. Deschamp dated 6/16/93) of the subject pendimethalin sweet corn metabolism data (1993; MRID 42686401) concluded that [^{14}C]pendimethalin-treated whole green plant, stalk/husk, and cob/grain samples were stored at approximately -20°C for up to 526 days, 466 days, and 345 days following harvest, respectively, and that sample extracts were also stored at 0-5°C prior to analysis for unspecified intervals. However, the current submission explains that the storage intervals specified in the previous residue chemistry review actually constitute the total storage intervals for test samples stored as crop matrices and sample extracts.

A summary of [^{14}C]pendimethalin-treated sample history is provided below in TABLE I.

TABLE I: [^{14}C]Pendimethalin-treated Sample History.

Sample Commodity	Harvest Date	Initial Extraction Date[a]	Final Analysis Date	Storage Interval of Crop Matrix Prior to First Extraction (days)[b]	Maximum Interval of Storage as Sample Extract Prior to Analysis (days)[c]
Whole Green Plant-14 DAT[d] Postemergence	8/1/91	8/28/91	1/8/93	27	499
Whole Green Plant-30 DAT Post/Preemergence	8/17/91	9/20/91	11/14/92	34	421
Whole Green Plant-60 DAT Post/Preemergence	9/16/91	10/29/91	12/16/92	43	414
Stalk/Husk-81 DAT Postemergence	10/7/91	11/22/91	12/14/92	46	388
Stalk/Husk-91 DAT Preemergence	10/17/91	1/14/92	1/15/93	89	367
Cob/Grain-81 DAT Postemergence	10/7/91	11/6/91	9/16/92	30	315
Cob/Grain-91 DAT Preemergence	10/17/91	11/1/91	9/16/92	15	320

[a] Samples from the initial extraction may/may not have been those which were actually analyzed to provide the subject pendimethalin sweet corn metabolism data (MRID 42686401) previously reviewed by CBRS (D189207, CBRS No. 11582, P. Deschamp dated 6/16/93).

[b] Samples stored at -20°C.

[c] Samples stored at 0-5°C.

[d] Abbreviation for Days After Treatment.

The current submission provides extraction profiles of [^{14}C]pendimethalin-treated whole green plant and stalk/husk samples and chromatographic profiles of [^{14}C]pendimethalin-treated whole green plant sample extracts conducted at several storage intervals for comparison to provide evidence that the storage intervals and conditions of [^{14}C]pendimethalin-treated test samples/extracts did not invalidate the results of the subject sweet corn metabolism study. Since the total radioactive residues (TRRs) determined in/on cob/grain samples in the subject study were very low (0.02 ppm), no storage stability data have been provided in these commodities.

Treated whole green plant (14 DAT postemergence) and stalk/husk (81 DAT postemergence and 91 DAT preemergence) test samples were extracted at various storage intervals to determine the effects (if any) of storage on the radiolabelled residues in/on stored crop matrices. A summary of these data are provided below in TABLE II.

TABLE II: Extraction of Treated Whole Green Plant and Stalk/Husk Samples.

Sample Commodity	Date of Extraction (Days Extracted After Harvest)	%TRR		
		$CHCl_3$	$MEOH/H_2O$	PES-1
Whole Green Plant-14 DAT[a] Postemergence	8/28/91 (27 days)	14.66	44.68	40.66
	3/2/92 (214 days)	11.34[b]	42.42[b]	46.24[b]
	5/26/92 (299 days)	11.48	44.43	44.08
Stalk/Husk-81 DAT Postemergence	11/22/91 (46 days)	8.23[b]	57.13[b]	34.64[b]
	11/4/92 (394 days)	11.15	49.57	39.28
Stalk/Husk-91 DAT Preemergence	1/4/92 (89 days)	13.25	49.87	36.88
	11/5/92 (385 days)	13.03	50.49	36.49

[a] Abbreviation for Days After Treatment.

[b] Value reported in previous residue chemistry review of pendimethalin sweet corn metabolism study.

The extraction data (TABLE II) indicate that the basic profile of radiolabelled residues in/on [^{14}C]pendimethalin-treated whole green plant samples was consistent for up to 272 days and in/on stalk/husk samples for up to 348 days when storage at -20°C.

TLC radiochromatographic profiles of the organosoluble ($CHCl_3$ extract) and polar ($MeOH/H_2O$ extract) radiolabelled residues extracted from the treated whole green plant-14 DAT sample on 8/28/91 (27 days after harvest) and 3/2/92 (214 days after harvest) were substantially similar. HPLC chromatographic profiles of the polar ($MeOH/H_2O$ extract) radiolabelled residues extracted from the treated whole green plant-14 DAT sample on 3/2/92 (214 days after harvest) and 5/20/92 (299 days after harvest) were substantially similar. These data indicate that the basic profile of radiolabelled residues in/on stalk/husk extracts was consistent for at least 187 days.

As further evidence, a sample of untreated whole green plant-14 DAT was fortified with [^{14}C]pendimethalin and extracted 8/20/91. The organosoluble fraction ($CHCl_3$ extract)was stored at 0-5°C for 506 days following extraction. TLC analysis of the sample revealed that only radiolabelled pendimethalin residues were present in the sample after storage, thus demonstrating that the parent compound is stable as a plant extract at 0-5°C for at least 506 days.

CBRS's Comment

The submitted storage stability data demonstrate that: (i) radiolabelled residues in/on crop matrices from the subject metabolism study were stable for at least 348 days of storage at -20°C, (ii) radiolabelled residues in sample extracts from the subject metabolism study were stable for at least 187 days of storage at 0-5°C, and (iii) radiolabelled residues of pendimethalin in the organosoluble fraction of sample extracts were stable for at least 506 days of storage at 0-5°C.

Since the registrant has provided evidence that reasonable diligence was exercised in the conduct of the subject sweet corn metabolism study to limit degradation of residues by appropriate storage of matrices and extracts during the analytical portion of the study and in the absence of any evidence of instability, it is appropriate to extrapolate the submitted storage stability data to support the maximum possible storage interval of test samples/extracts which was 526 days. CBRS is convinced that the storage intervals and conditions of test samples/extracts does not invalidate the results of the previously submitted pendimethalin sweet corn metabolism study (MRID 42686401).

cc: BLCKohlligian (CBRS), Pendimethalin Reg. Std. File, Pendimethalin SF, RF, Circulate.

RDI: PDeschamp:2/2/94 MMetzger:2/8/94 EZager:2/8/94

7509C:CBRS:BLCKohlligian:CM#2:Rm 805B:703-305-7462:2/1/94.