Shaughnessy No.: 108501

Date Out of EFBWB: 8/22/90

TO: T. Stowe
Product Manager #74
Registration Division (H7505C)

FROM: Henry Nelson, Ph.D., Acting Section Chief H Nelson
Environmental Chemistry Review Section #3
Environmental Fate & Ground Water Branch/EFED (H7507C)

THRU: Hank Jacoby, Chief Hank Jacoby
Environmental Fate & Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Attached, please find the EFGWB review of...

Reg./File # : Case #0187

Chemical Name: Pendimethalin

Type Product : Herbicide

Product Name : PROWL Herbicide

Company Name : American Cyanamid

Purpose : Review Aquatic (sediment) Field Dissipation data.

Date Received: 7/19/90 EFGWB#: 900713

Action Code: 665 Total Review Time (days): 1.5

Deferrals to: _____ Ecological Effects Branch, EFED

_____ Science Integration & Policy Staff, EFED

_____ Non-Dietary Exposure Branch, HED

_____ Dietary Exposure Branch, HED

_____ Toxicology Branch I, HED

_____ Toxicology Branch II, HED

Use this form for individual studies & to submit pesticide applications.

United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain National Security Information (E.O. 12065)

Pack Number	Date Received
50788	7/23/90

1. Product Name: PROWL

Chemical Name: PENDIMETHALIN (108501-8)

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
CASE # 0187	267552	~~660~~ 665	41245601	164-2

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
1	8/17/89	T. STOWE	74	7/19/90	8/19/90	

Instructions

PLEASE REVIEW PROPOSED PROTOCOL FOR 164-2, THIS STUDY WAS ~~ORIGINALLY~~ COMBINED W/ 72-4 AND 72-7, REGISTRANT REVISED GUIDELINE 164-2 PROTOCOL.

This Section Applies to Review of Studies Only

14. Check Applicable Box

- [ ] Adverse 6(a)(2) Data (405)
- [ ] Special Review Data (870)
- [x] Generic Data (Reregistration)(660)
- [ ] Product Specific Data (Reregistration)(655)

15. No. of Individual Studies Submitted: 1

16. Have any of the above studies *(in whole or in part)* been previously submitted for review?

- [ ] Yes *(Please identify the study(ies))*
- [x] No

17. Related Actions

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	SAC, PC	A. Policy Note No. 31
		Toxicology/HFA	TOX/HFA, PL	
		Toxicology/IR	TOX/IR	[ ] 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
		Dietary Exposure	DEB, EA	
		Nondietary Exposure	NDE, AC	
EFED		Ecological Effects	BA	[x] 2 = data of particular concern from registration standard
	X	Environmental Fate & Groundwater	EEB	
SRRD		Special Review	EFGWB	[ ] 3 = data necessary to determine tiered testing requirements
		Reregistration		
		Generic Chemical Support	SR	
RD		Insecticide-Rodenticide	RER	B. Section 18
		Fungicide-Herbicide	GSC	[ ] 1 = data in support of section 3 in lieu of section 18
		Antimicrobial		
		Product Chemistry	IR	C. Inert Ingredients
		Precautionary Labeling	FH	[ ] 1 = data in support of continued use of List 1 inert
BEAD		Economic Analysis	AM	
		Analytical Chemistry		
		Biological Analysis		

- [ ] Confidential Statement of Formula (EPA Form 8570-4) Attached *(Trade Secrets)*
- [ ] Label Attached

EPA Form 8570-17 (Rev. 11-88) Previous editions are obsolete.

White - Data Coordinator
Yellow - Data Review Section
Pink - PM/RM/DCI
Green - Return with completed review

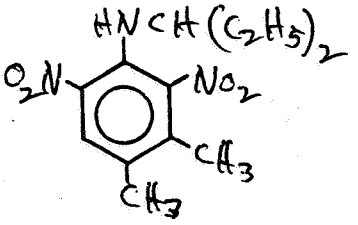
1.0 CHEMICAL:

Common Name- Pendimethalin

Chemical Name- N-(1-ethylpropyl)-3, 4-dimethyl-2,6-dinitrobenzenamine

Trade Name- PROWL Herbicide

Chemical structure-



2.0 Test Materials: Ground application of PROWL plus propanil (1.0 + 3.0 lb ai/A, respectively).

3.0 Study/Action Type: American Cyanamid is submitting an Aquatic (sediment) Field Dissipation study (164-2) for review in response to the pendimethalin 1985 Registration Standard. Although the Data Review Record instructions to reviewers indicate a protocol is to be reviewed, the registrant is resubmitting 164-2 data for review.

4.0 STUDY/DOCUMENT IDENTIFICATION:

1. Manuel, A. 1980. Analysis for residues of PROWL in soil and in water from PROWL treated rice fields, Oct 1980, Lab report No. CY17, MRID #41245601.

2. Letter dated 2 Apr 1990 from Barbara Gingher of American Cyanamid to SRRD requesting resubmitted data [Aquatic (sediment) Dissipation] be reviewed.

3. Letter dated 15 Aug 1989 from American Cyanamid to RD in response to a protocol review.

5.0 REVIEWED BY:

Herbert L. Manning, Ph.D.
Microbiologist, EFGWB/EFED

Signature: Herbert L Manning
Date:

6.0 APPROVED BY:

Henry Nelson, Ph.D., Acting Chief
Section 3, EFGWB/EFED

Signature: H Nelson
Date: 8/17/90

7.0 CONCLUSION:

7.1 The EFGWB concludes that we are unable to review the Aquatic (sediment) Dissipation study (164-2) at this time because we do not have certain information contained in other studies we have not reviewed. The studies were received by the OPP (Office of Pesticide Programs), but have not been reviewed by the EFGWB.

7.2 The studies the OPP has received and we have not reviewed are as follows:

161-2 Photodegradation in Water, MRID #00153763
161-3 Photodegradation on Soil, MRID #00153764
162-1 Aerobic Soil Metabolism, MRID #40185104
162-2 Anaerobic Soil Metabolism, MRID #40185105
162-3 Anaerobic Aquatic Metabolism, MRID #40813501
163-1 Leaching-Ads/Des MRID #00153765
163-2 Lab Volatility, MRID #00153766
165-4 Accumulation in Fish, MRID #00158235

8.0 RECOMMENDATIONS:

8.1 NOTE TO PM - In order to review the 164-2 data [Aquatic (sediment) Dissipation study; subject of letter of 2 Apr 1990 from American Cyanamid to Bert Baker of SRRD), we need to review the studies the OPP has received but has not sent to the EFGWB. Please send us hardcopies of the studies cited in Section 7.2 above.

9.0 BACKGROUND:

A. Introduction- See the attached letters from American Cyanamid.

B. Directions for Use- Not applicable.

10. DISCUSSION OF INDIVIDUAL STUDY:

The resubmitted study was not reviewed. See Section 7.0.

11. COMPLETION OF ONE-LINER: Not applicable.

12. CBI APPENDIX: Not applicable.

CYANAMID

NO 40 CFR 158 DATA ARE IN THIS SUBMISSION

American Cyanamid Company
Agricultural Research Division
P.O. Box 400
Princeton, NJ 08540
(609) 799-0400

April 2, 1990

Mr. Bert Baker
Special Review and Reregistration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall, Bldg. No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Pendimethalin Registration Standard (RS-187)
Rice Use Protocol Submitted August 15, 1989

Dear Mr. Baker:

American Cyanamid Company understands that EPA needs additional copies of a proposed protocol for monitoring a PROWL® herbicide treated rice field, which was originally submitted on August 15, 1989. This proposed protocol was sent in as an attachment to a cover letter which dealt with several study areas pertinent to rice use, namely Study 164-2 (Aquatic Sediment Dissipation - EFGWB), Studies 72-4 (Fish Life-Cycle - EEB) and 72-7 (Aquatic Monitoring of Rice Fields - EEB).

As requested, I am sending three (3) copies of the proposed protocol, along with the American Cyanamid Company cover letter.

We ask that EFGWB address the data pertinent to Guideline Number 164-2, submitted as Volume 3 on August 15, 1989 (MRID #41245601) and only the portion of the cover letter entitled, "Study 164-2". We ask that EEB address the other portions of the cover letter and the proposed protocol.

If you have any questions concerning this submission or need more copies of any portion of the August 15, 1989 submission, please call me at Extension 2234.

Respectfully submitted,

Barbara Gingher

Barbara Gingher
Product Registration Manager
U.S. Regulatory Affairs

BG:sd
Enc.

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CYANAMID NO 40 CFR 158 DATA ARE IN THIS VOLUME

VOLUME 1 - ADMINISTRATIVE MATERIAL

American Cyanamid Company
Agricultural Research Division
P.O. Box 400
Princeton, NJ 08540
(609) 799-0400

August 15, 1989

Mr. Robert Taylor
Product Manager (25)
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall, Bldg. No. 2, Room 266A
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Pendimethalin Registration Standard Studies 164-2 and 72-7 for Rice Use and Related Issues

Dear Mr. Taylor:

American Cyanamid Company is hereby responding to your letter dated May 10, 1989 (attached) which reviewed a proposed protocol submitted for Studies 164-2 and 72-7 required for rice use under the Pendimethalin Registration Standard.

We appreciate your comments on the proposed protocol, however, it appears that perhaps not all aspects of our submission (dated September 12, 1986, attached) received full consideration. We refer to page 2, paragraphs 5 and 6, which responds to an April 15, 1986 EPA letter. Specifically, we are concerned that apparently certain studies were not reexamined to determine acceptability as these bear upon the need for the studies referenced above.

In addition, on page 3, paragraph 2, of my September 12, 1986 letter, I requested all information used in the EEC calculation (received by EEB from EAB on March 11, 1981) which resulted in 7 ppb in a bayou. Despite additional requests, we have not yet received this. We again request the details of these calculations.

Study 164-2 (Aquatic Sediment Dissipation)

As mentioned above, and since it apparently was not addressed, we ask again that certain data be considered by EFGWB in fulfillment of the Study 164-2 requirement.

To facilitate the review process, we are resubmitting studies which analyze soil and water from rice fields treated with PROWL® herbicide as well as the analytical methods used (EPA ID #099889). This work studied rice fields in Louisiana and in Texas where PROWL 4E was applied at the highest labeled rate (1.0 lb ai/A). Confusion over the acceptability of these studies may have resulted from the fact that the soil and the water analyses were originally presented in separate reports in each case. Thus, we are now including a summary covering results for soil and for water at each location. This should alleviate any earlier confusion concerning the acceptability of this work for the Study 164-2 requirement.

4

The stated purpose of Study 164-2 is to examine dissipation and mobility of the pesticide under actual use conditions; soil and water should be analyzed to this end. In accordance with the results of experiments on anaerobic aquatic (EPA ID #255814 & 40813501) and aerobic soil (EPA ID #40185104) metabolism and photodegradation in water and on soil (both in EPA ID #260402), it is appropriate to analyze soil and water only for pendimethalin.

We wish to emphasize that these field studies involve application of formulated product at the highest labeled rate at two locations in the area where the product is used on rice. Thus, we believe that the studies now being resubmitted (EPA ID #099889) address the issues and provide adequate data for the Agency's purpose relative to Study 164-2.

Study 72-7 (Aquatic Monitoring of Rice Fields)

In regard to study 72-7, we understand that the Agency requires information on what level of pendimethalin (if any) may be present, due to drift or drainage, in waters adjacent to treated rice fields.

The two field studies in EPA ID #099889 which were conducted at the labeled use rate address the drainage question in the region where PROWL is used on rice. Please note that there is no PROWL use on water-seeded rice or on rice in California, as per the label.

These studies, conducted in Louisiana and Texas with ground application at 1.0 lb ai/A (the maximum labeled rice rate), show levels of <1 ppb and 1.3 ppb, respectively, in water from the treated field one day after flooding (limit of detection is 1 ppb); the 1.3 ppb value declined below 1 ppb at later sampling intervals. Hence, used according to the label, PROWL results in levels of about 1 ppb or less in rice field water; the level decreases with time. The 1 ppb limit of detection is more than two orders of magnitude lower than LC_{50} values; your May 10, 1989 letter requires that the detection limit be at least as low as the lowest chronic LC_{50}. Thus, these ground application data, analyzed at a level well below that which you require, represent a "worst case" for drainage exposure and are pertinent to EEB's concerns in this regard.

Despite the existence of these data, Cyanamid agrees to conduct additional studies to address possible drift exposure levels and provide more information on drainage water levels in aerially applied PROWL treated rice fields. We propose to conduct studies in the following states: one in Arkansas, two in Mississippi and one in Texas. A proposed protocol is attached for your review.

Study 72-4 (Fish Life-Cycle)

Turning now to the Agency's concern for finfish, we continue to question whether a 10 ppb level of pendimethalin adversely affects fish reproduction. Although the approximately 9.8 ppb level, in an acceptable fish life-cycle experiment (EPA ID #037940), showed a decrease in egg production, with reduced hatchability at 22 and 43 ppb (approximate concentration) as stated in the EEB Science Chapter, these observations are adequately addressed in the report and should not be cited as causing concern.

The fish-life cycle report specifically discusses the first point, stating that the total number of eggs/female in the 9.8 ppb group was lower than the number for any other group, but that this was not treatment related in view of the larger number of eggs/female in the 22 and 43 ppb groups. In fact, the 22 ppb group had the highest number of any group and was significantly higher than in the control aquaria. Thus, we believe that the report's conclusion is correct and that the 43 ppb (not the 10 ppb) value should be used for consideration or for calculation.

Concerning hatchability, eggs spawned by fish in the 22 and the 43 ppb groups had lower percentages of hatching than other groups. However, the report states that analysis of variance shows that the differences were not significant at the 95% confidence level (P=0.05). Thus, these values should not be discussed by EEB as reducing hatchability.

Finally, we wish to emphasize the point that all of these results are for eggs of fish subjected to PROWL continuously for 288 days, clearly well beyond the length of any inadvertent drift or drainage exposure from the rice use of this product.

Thus, the study shows that there are no adverse effects on the fish life-cycle at the highest dose tested, approximately 43 ppb, even in fish exposed to PROWL continually for almost 10 months. Hence, we do not believe that the correct value has been used in Agency considerations which apparently resulted in concern for finfish.

In view of the above points, we ask that the Agency reconsider the use of the 10 ppb number; 43 ppb is the appropriate value to use for discussion or calculation, with due note that the extended exposure period involved in the experiment would not be expected to occur from any labeled use.

In summary, we ask that a copy of this cover letter be sent to EFGWB and EEB and that the Agency review the following items:

1. Acceptability of resubmitted data for fulfillment of Study 164-2.
2. Acceptability of the proposed monitoring protocol for Study 72-7.
3. Calculations resulting in an EEC estimate of 7 ppb in a bayou.
4. Whether a 10 ppb level should cause concern for finfish reproduction.

After your review, we request that a meeting be arranged where Cyanamid personnel can discuss these points with yourself, EFGWB and EEB personnel. Further, we urgently request a copy of any information or review pertaining to the EEC estimate of 7 ppb in a bayou, so that we may review this before the meeting.

We look forward to your response and to resolving these issues surrounding the rice use of PROWL.

Respectfully submitted and requested,

AMERICAN CYANAMID COMPANY
Agricultural Research Division

Barbara Gingher

Barbara Gingher
Product Registration Manager
U.S. Regulatory Affairs

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