

US EPA ARCHIVE DOCUMENT

2-8-89

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234841
RECORD NO.

108501
SHAUGHNESSEY NO.

50
REVIEW NO.

EEB REVIEW

DATE: IN 11-18-88 OUT 2/8/89

FILE OR REG. NO 241-245

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 9-12-86

DATE RECEIVED BY EFED 11-18-88

RD REQUESTED COMPLETION DATE 1-18-89

EEB ESTIMATED COMPLETION DATE 1-18-89

RD ACTION CODE/TYPE OF REVIEW 665

TYPE PRODUCT(S) : I, D, H, F, N, R, S Herbicide

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. R. Taylor (25)

PRODUCT NAME(S) Prowl (Pendimethalin)

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Proposed protocol to combine aquatic field study (72-7) and aquatic dissipation study (162-4) for rice use in response to RS

SHAUGHNESSEY NO. 108501 CHEMICAL, & FORMULATION Pendimethalin % A.I. _____



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

MEMORANDUM

SUBJECT: Prowl Field Study Proposed Protocol SN# 108501 OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FROM: Jim Akerman *H.T. Cowen* 2/2/89
Ecological Effects Branch
Environmental Fate and Effects Branch (TS-769C)

TO: R. Taylor/F. Walters PM 25
Fungicide - Herbicide Branch
Registration Division (TS-769C)

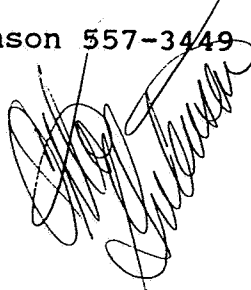
The Ecological Effects Branch (EEB) has reviewed the protocol for combined Guideline Studies 72-7 and 164-2 for the rice use of Prowl herbicide submitted to the Agency by the American Cyanamid Company on September 15, 1986. EEB received the protocol for review on November 18, 1988. The Environmental Fate and Ground Water Branch should comment on 164-2 requirements; our discussion will be limited to requirements of 72-7. This protocol was submitted as a result of requirements limited to requirements of the Registration Standard for Pendamethalin for a residue monitoring study. EEB is concerned the residues in receiving water could exceed those which impair finfish reproduction (10 ppb). To negate these concerns an aquatic residue monitoring study addressing both drift exposure and drainage into nearby waters was required to support the rice use.

The submitted protocol (9/15/86) is inappropriate and unacceptable to answer the concerns of the Registration Standard and EEB. The Standard required a monitoring study in order to establish the presence or lack of presence of Prowl in waters adjacent to rice use site (from drainage or drift). The objectives stated in the subject protocol (develop baseline data, examine diversity and productivity of pond inhabitants and develop a profile of the surrounding agricultural land) do not address this question. If an appropriately designed monitoring study demonstrates pesticide contamination of adjacent waters, then a mesocosm study may be required (rather than a one pond-one control pond field study) to determine effects on biota.

The registrant should at this time depart from the submitted "field study protocol" and design a residue monitoring protocol (as required by the registration standard) to quantify the amount of pesticide leaving the rice field either from drift or drainage. The monitoring protocol should include, but not be limited to, the following parameters:

1. The monitoring program should attempt to observe and make measurements from "normal use practice" but not interfere with or alter normal use. Artificial or designed "test plots" are not acceptable.
2. At least five sites or fields per geographic region (depending on the number of regions) in which rice is grown should be selected for sampling in order to obtain a variety of drainage situations (either fresh or estuarine waters).
3. Sampling shall be done 1) in field, 2) at points of drainage exit and 3) of adjacent waters and include water column and soil/sediment. Design should address both drift at time of aerial application and drainage runoff at appropriate time intervals.
4. Sampling stations must be described on USGS topographic 7.5 minute series maps.
5. Analytical methodology used to measure residues must be described. Detection limit must be at least as low as the lowest chronic LC50 from test data.
6. Samples should be taken before, during and following applications of the pesticide and should include control sites.
7. Sampling should be done at regular intervals for a long enough period to account for such things as seasonal and use variations. The first 96 hours of sampling after application and/or flushing are critical as these average concentrations detected in the field may be used for loading amounts in a mesocosm study, if such assay is indicated.
8. Devices are required at each site to record continuous temperature and rainfall profiles.
9. Any proposed monitoring protocol should be reviewed by EPA before the program is initiated.

Questions/Comments--Otto Gutenson 557-3449



OFFICE OF PESTICIDE PROGRAMS DATA REVIEW RECORD

ATTACHMENT 1

Confidential Business Information-Does Not Contain National Security Information(E.O. 12065)
 This form is to be used for individual studies and for submission of pesticide applications

1. PRODUCT NAME <u>Pendimethalin</u>					
2. IDENTIFYING NUMBER <u>241-245</u>	3. RECORD NUMBER	4. ACTION CODE <u>665</u>	5. MRID/ACCESSION NUMBER <u>204841</u>	6. STUDY GUIDELINE OR NARRATIVE <u>Protocol</u>	
7. REFERENCE NUMBER	8. DATE RECEIVED (EPA) <u>10/14/82</u>	9. PRODUCT/REVIEW MANAGER/DCI <u>Taylor/KWalker</u>	10. PM/RM TEAM NUMBER <u>25</u>	11. DATE SENT TO (HED/EFED/RD/BEAD) <u>4/16/82</u>	
12. PROJECTED RETURN DATE <u>1/18/89</u>	13. DATE RETURNED TO (RD/SRRD)	INSTRUCTIONS: <u>Protocol to combine aquatic residue study and aquatic sediment study & request to reevaluate effect on fish and acceptance of data</u>			

(THIS SECTION APPLIES TO REVIEW OF STUDIES ONLY)

14. CHECK APPLICABLE BOX:

15. NUMBER OF INDIVIDUAL STUDIES SUBMITTED

- ADVERSE 6(a)(2) DATA (405)
- SPECIAL REVIEW DATA (870)
- GENERIC DATA (660) (REREGISTRATION)
- PRODUCT SPECIFIC DATA (655) (REREGISTRATION)

16. HAVE ANY OF THE ABOVE STUDIES (in whole or in part) BEEN PREVIOUSLY SUBMITTED FOR REVIEW? (circle: yes or no) IF YES, PLEASE IDENTIFY THE STUDY(IES):

17. RELATED ACTIONS:

18. TO	TYPE OF REVIEW	19. REVIEWS ALSO SENT TO	20. DATA REVIEW CRITERIA
HED	SCIENCE ANALYSIS & COORD.	— SAC — PC	A. Policy Note #31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18 C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
	TOXICOLOGY/HFA	— TOX/HFA — PL	
	TOXICOLOGY/IR	— TOX/IR —	
	DIETARY EXPOSURE	— DEB — EA	
	NON-DIETARY EXPOSURE	— NDE — AC	
EF	<input checked="" type="checkbox"/> ECOLOGICAL EFFECTS	— EEB — BA	
SRRD	ENVIRONMENTAL FATE & GROUND H2O	— EFGWB	
	SPECIAL REVIEW		
	REREGISTRATION		
RD	GENERIC CHEMICAL SUPPORT	— SR	
	INSECTICIDE-RODENTICIDE	— RER	
	FUNGICIDE-HERBICIDE	— GSC	
	ANTIMICROBIAL		
	PRODUCT CHEMISTRY	— IR	
2AD	PRECAUTIONARY LABELING	— FH	
	ECONOMIC ANALYSIS	— AM	
	ANALYTICAL CHEMISTRY		
	BIOLOGICAL ANALYSIS		

CONFIDENTIAL STATEMENT OF FORMULA (TRADE SECRETS) LABEL ATTACHED

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

Include original + two (2) copies with each submission

Pendimethalin ecological effects review

Page _____ is not included in this copy.

Pages 5 through 25 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients
 - Identity of product impurities
 - Description of the product manufacturing process
 - Description of product quality control procedures
 - Identity of the source of product ingredients
 - Sales or other commercial/financial information
 - A draft product label
 - The product confidential statement of formula
 - Information about a pending registration action
 - FIFRA registration data
 - The document is a duplicate of page(s) _____
 - The document is not responsive to the request
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
