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.	CHEMICAL, & FORMULATION	% A.I.
108501	Pendimethalin	

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MEMORANDUM

SUBJECT: Prowl Field Study Proposed Protocol
SN# 108501

FROM: Jim Akerman   *H.T.Craven*   2/8/89
Ecological Effects Branch
Environmental Fate and Effects Branch (TS-769C)

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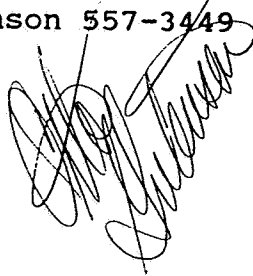Registration Division (TS-769C)

The Ecological Effects Branch (EEB) has reviewed the protocol for combined Guideline Studies 72-7 and 164-2 for the rice us3e 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 <u>monitoring</u> 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 mnay 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 <u>monitoring</u> 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:

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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

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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   Prowl Technical

CHEMICAL NAME   Pendimethalen

2. IDENTIFYING NUMBER	3. RECORD NUMBER	4. ACTION CODE	5. MRID/ACCESSION NUMBER	6. STUDY GUIDELINE OR NARRATIVE
241-245		665	204841	Protocol

7. REFERENCE NUMBER	8. DATE RECEIVED (EPA)	9. PRODUCT/REVIEW MANAGER/DCI	10. PM/RM TEAM NUMBER	11. DATE SENT TO (HED/EFED/RD/BEAD)
	10/14/88	Taylor/K Walter	25	11/1/88

12. PROJECTED RETURN DATE	13. DATE RETURNED TO (RD/SRRD)	INSTRUCTIONS:
1/18/89		Protocol to combine aquatic residue study and aquatic sediment study. Request to reconsider effort on analysis and acceptance of data.

(THIS SECTION APPLIES TO REVIEW OF STUDIES ONLY)

14. CHECK APPLICABLE BOX:

15. NUMBER OF INDIVIDUAL STUDIES SUBMITTED [   ]

☐ ADVERSE 6(a)(2) DATA   (405)   ☐ GENERIC DATA   (660)   ☐ PRODUCT SPECIFIC DATA (655)
☐ SPECIAL REVIEW DATA   (870)   (REREGISTRATION)   (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
		TOXICOLOGY/HFA	— TOX/HFA	— PL	☐ 1 = data which meet
		TOXICOLOGY/IR	— TOX/IR		6(a)(2) or meet
		DIETARY EXPOSURE	— DEB	— EA	3(c)(2)(B) flagging
		NON-DIETARY EXPOSURE	— NDE	— AC	criteria
EFED	✓	ECOLOGICAL EFFECTS		— BA	☐ 2 = data of particular
		ENVIRONMENTAL FATE & GROUND H2O	— EFB		concern from
SRRD		SPECIAL REVIEW	✓ EFGWB		registration
		REREGISTRATION			standard
		GENERIC CHEMICAL SUPPORT	— SR		☐ 3 = data necessary to
		INSECTICIDE-RODENTICIDE	— RER		determine tiered
RD		FUNGICIDE-HERBICIDE	— GSC		testing requirements
		ANTIMICROBIAL			B. Section 18
		PRODUCT CHEMISTRY	— IR		☐ 1 = data in support of
		PRECAUTIONARY LABELING	— FH		section 3 in lieu
BEAD		ECONOMIC ANALYSIS	— AM		of section 18
		ANALYTICAL CHEMISTRY			C. Inert Ingredients
		BIOLOGICAL ANALYSIS			☐ 1 = data in support of

☐ CONFIDENTIAL STATEMENT OF FORMULA (TRADE SECRETS)   ☐ LABEL ATTACHED

continued use of List 1 inert

White - Data Coordinator
Yellow - Data Review Section
Include original + two (2) copies with each submission
Green - Return with completed review
Pink - PM/RM/DCI

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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

_X_ 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.