**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.

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MEMORANDUM

SUBJECT: Prowl Field Study Proposed Protocol SN# 108501
FROM: Jim Akerman
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, 1986. 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
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**
   - Pyrametomid

2. **IDENTIFYING NUMBER**
   - 74-1-24.5

3. **RECORD NUMBER**
   - 065

4. **ACTION CODE**
   - 264841

5. **PRID/ACCESSION NUMBER**
   - Faktir

6. **STUDY GUIDELINE OR NARRATIVE**
   - Protocol to combine aquatic residue study and necropsy-edited study to account for dermal effect

7. **REFERENCE NUMBER**
   - 144188

8. **DATE RECEIVED (EPA)**
   - 10/14/93

9. **PRODUCT/REVIEW MANAGER/DCI**
   - Tad L. K. Waddell

10. **PM/RM TEAM NUMBER**
    - 25

11. **DATE SENT TO (HED/EFD/PR/READ/WHIP)**
    - 1/21/94

12. **PROJECTED RETURN DATE**
    - 7/15/94

13. **DATE RETURNED TO (RD/SRRD)**
    - 7/15/94

(This section applies to review of studies only)

14. **CHECK APPLICABLE BOX:**
   - ☐ ADVERSE 6(a)(2) DATA (405)
   - ☐ SPECIAL REVIEW DATA (870)
   - ☐ GENERIC DATA (Reregistration) (660)
   - ☐ PRODUCT SPECIFIC DATA (655) (Reregistration)

15. **NUMBER OF INDIVIDUAL STUDIES SUBMITTED**
    - 

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:**
   - ☐ 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
   - ☐ 2 = data of particular concern from registration standard
   - ☐ 3 = data necessary to determine tiered testing requirements

18. **TO TYPE OF REVIEW**

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<th>TYPE OF REVIEW</th>
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19. **LABEL ATTACHED**
   - ☐ 1 = data in support of continued use of List 1 inert

20. **DATA REVIEW CRITERIA**
   - A. Policy Note #31
   - B. Section 18
   - C. Inert Ingredients
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.