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108501
SHAUGHNESSEY NO

REVIEW NO. _____

EEB REVIEW

DATE: IN 10-12-89 OUT 2/14/90

FILE OR REG. NO. 108501

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 8-15-89

DATE RECEIVED BY HED 10-11-89

RD REQUESTED COMPLETION DATE 11-21-89

EEB ESTIMATED COMPLETION DATE 11-21-89

RD ACTION CODE/TYPE OF REVIEW 661

TYPE PRODUCT(S) Herbicide

DATA ACCESSION NO(S) _____

PRODUCT MANAGER, NO. 74

PRODUCT NAME(S) Prowl

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Registrant response concerning previous EEB review of rice protocol and review of revised protocol

SHAUGHNESSEY NO.	CHEMICAL	% A.I.
_____	<u>Pendimetholin</u>	<u>42.3%</u>
_____	<u>Propanil</u>	<u>43.5%</u>
_____	_____	_____

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MEMORANDUM

SUBJECT: Prowl (Pendimethalin) Herbicide for Rice Use
Response to Registrant's Letter of August 15, 1989
(SN #108501)

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division

TO: R. Taylor PM 74
Fungicide-Herbicide Branch
Registration Division

The Ecological Effects Branch (EEB) has reviewed American Cyanamid Company's letter (and field monitoring protocol submission) of August 15, 1989 addressing a number of concerns regarding the reregistration of Prowl herbicide. As stated in our last action on this chemical (monitoring protocol review - 2/8/89), EEB is addressing only the requirements in Section 72-7 of the 1985 Registration Standard; the Environmental Fate and Ground Water Branch should address 164-2 requirements. The registrant, while agreeing to conduct additional monitoring studies, continues to insist that the studies done for 164-2 (MRID # 099889) are sufficient to negate ecological concern for rice uses of Prowl herbicide. EEB has previously responded that data in MRID #099889 is unacceptable and that a field monitoring study is still necessary. The former data are unacceptable for numerous reasons including no study site description, no description of proportion of floodwater level to treated soil area and no inclusion of receiving water residues (see attachment - Touart 1985).

The registrant continues to question EEB's interpretation of a 1977 core fish life-cycle study (MRID # 037940). We maintain exposure to a Prowl concentration of 10 ppb may cause adverse effects in a finfish and do not agree with American Cyanamide that "no adverse effects" result from exposure to 43 ppb and greater. The following explanation taken from the EEB review of the fish life cycle study (Windberg, L. A., 1978) best explains our rationale. The submitter may choose to repeat the fish life-cycle assay if they believe our interpretation (of 10 ppb concern level) is based on unreliable data.

CONCURRENCES

SYMBOL	H-7507C	H-7507C	H-7507C				
SURNAME	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>				
DATE	2/8/90	2/13/90	2/14/90				

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"The investigator's interpretation of the egg production and hatchability data for fathead minnows continuously exposed to Prowl for a complete life cycle (Table 8) were questionable. The investigator concluded that there were no adverse effects on spawning of test fish at treatment concentrations of Prowl which were tested (i.e., \leq 43 ppb). This conclusion was reached although the total number of eggs, eggs per spawn, and eggs per female exposed to 9.8 ppb were lower than those observed in all other treatments. These differences were ignored by the investigator because higher egg numbers were obtained from fish exposed to higher Prowl concentrations (22 ppb and 43 ppb). Yet there was no evidence offered to explain the reduced egg production observed at 9.8 ppb. Egg production by females in the 43 ppb treatment also appeared to be substantially lower than the control groups (Table 8). Although the mean number of eggs per spawn was similar between the 43 ppb treatment and the solvent-control group, the mean number of eggs per female was significantly lower ($P=0.04$, unpaired t - test) for the 43 ppb group (638 eggs per female) than among the solvent-control group (1273 eggs per female). The inconsistent results on spawning of test fish may be attributable to a relatively small number of females (3 to 7) used per treatment (Table 7) instead of 11-12 females per treatment as recommended in EPA protocol.

The investigator also reported that the mean percentages of eggs hatched from fish exposed to the 43 ppb and 22 ppb Prowl treatments were not significantly different from means of the controls and other treatments (Table 8). However, this reviewer checked the statistical comparisons and found evidence that hatchability data from both of the above treatments were significantly lower than the solvent-control group. Individual unpaired t - tests using the arc sin $\sqrt{\text{percentage}}$ transformation showed significantly lower percentages of eggs hatched for the 43 ppb treatment ($P < 0.01$) and for replicate = A of the 22 ppb treatment ($P = .048$). A second individual comparison using Chi-square tests (2 x 2 contingency table) showed significantly lower percentages of eggs hatched ($P < 0.01$) for both the 43 ppb and 22 ppb treatments. Therefore, the investigator should check his statistical analyses to confirm his initial conclusions." (Windberg, L.A. 1978).

Cyanamid has also requested information used in the EEC calculation (received by EEB from EAB on March 11, 1981) which resulted in an estimated concentration of 7 ppb in a bayou. An explanation of this EEC developed by J. C. Reinert of the former Environmental Fate Branch is attached. Further questions regarding the derivation of this estimate should be directed to the present Environmental Fate and Groundwater Branch.

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Included in this submission is a revised protocol for a field residue monitoring study in rice. EEB has previously reviewed (2/8/89) and made comments on a field study protocol submitted by Cyanamid (see attached). This protocol was rejected because it was for a pond study rather than a field monitoring study as required. The revised protocol is indeed designed for a monitoring study, yet it is presented in such summary form as not to supply sufficient information to determine its usefulness and does not qualify as a complete protocol. Before EEB can comment further or approve this protocol, the following concerns must be addressed.

- 1) The "objective" should be more specific, i.e., "to determine exposure duration by measuring concentrations at key intervals and to determine confidence limits on these measurements".
- 2) Site specific information must be submitted for review before the study is initiated. The proposed protocol describes the site only as "Arkansas" (the attached letter states Texas, Mississippi (2 sites) and Arkansas). These 4 geographic locations are satisfactory, however, there should be 3 to 5 "sites" or spray areas per geographic location. All sites (with boundaries, acreage, sampling stations, etc) must be located on an original USGS topographic 7.5 minute series map. Total spray area (location and site) must be described in relation to surrounding natural waters. There should be at least one control site at each geographic location.
- 3) Statistical methods must be defined before proceeding with the study in order to be certain that the sampling design, i.e.; number of sites, samples, etc. will yield a statistically valid study.
- 4) There must be a number of sampling stations per site; the number and locations depending on specifics of the site. Sample stations must not be located at "mixing" areas, such as the junction of gates, etc. Samples must not be composited throughout the entire bayou or pond.
- 5) Water sampling should occur within 2 to 3 hours following applications, two sample times in the first 24 hours after application and release of flood water, then once per day on Days 2 to 7 and Days 14, 21, 30, 45 and 60. Provision must be made for increased sampling within 24 hours after each major rainfall event (i.e., over 1 inch of rain). Sampling should not cease after Day 7. The number of sample stations and

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replicate samples (at least duplicate) taken must be sufficient for the statistical design employed.

- 6) Soil and/or sediment samples must be taken from the bayou and fields the same days water samples are taken and must be collected such that the top 1 cm can be analyzed separately. Soil sediment samples should not be composited.
- 7) Analytic methods employed must be submitted for review. Samples sent to the analytical laboratory must be coded to ensure unbiased results. Samples spiked in the field should be included as analytical controls. All collection/sample device materials must be calibrated for absorption of test material. Absorption greater than one percent is unacceptable.
- 8) The physical-chemical parameters (i.e, pH, temp, rainfall, etc.) of test site water must be measured at each sampling station on every sampling occasion. The soil/sediment properties must also be described.
- 9) Two drift cards should be used per station. Drift card stations should be located on all sides of the treated area as well as in the field and bayou for all sites. The total number will depend on the specific site. Drift cards must not be composited.
- 10) Data must be submitted to show that application of Prowl 4E in combination with Stan M4 will not mask or interfere with the detection or dispersion of Prowl 4E. This should include at least one field control site where Prowl 4E alone and in combination is applied.

EEB would welcome a meeting with the registrant, as requested after the above items have been addressed and results submitted. To have a meeting prior to this would be of little benefit to the registrant or the Agency.

EEB has previously recommended (Aug 1989) in the "List A Project Inventory Summary" (FIFRA '88) that the rice use of pendimethalin be cancelled because of failure to submit a field study.

Questions/Comments - Otto Gutenson - 558-3449

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