MEMORANDUM

DATE: MAR 26 1981


FROM: John Doherty
Toxicology Branch/HED (TS-769)

TO: Robert Taylor, PM #25
Registration Division (TS-767)

Action Requested:

The registrant is requesting a registration for the use of Prowl® herbicide on rice. The instructions for the product include making a tank mix with the herbicide propanil (Stam® M-4) and applying the mixture by aerial and/or ground application.

Remarks:

1. This product may be mislabelled (see J. Doherty memo dated March 23, 1979, concerning PP 9F2134 and EPA Reg. No. 241-243). The problems raised two years ago have not yet been resolved according to Toxicology Branch files. As a condition for allowing this registration, the registrant should be asked to agree (in writing) to conduct the appropriate acute toxicity studies to determine the proper signal word for this product.

2. Four acute studies with the tank mix of Prowl® and propanil have been submitted and reviewed. (See below):

   Because the tank mix is an eye irritant (Toxicity Category II), Prowl® (or the registered product of propanil) will have to have proper instructions on its label for using a product that produces eye irritation.

   The portion of the product label (for PROWL or Stam M-4) concerning the precautionary statements and the signal word were not sent to Toxicology Branch.

3. PP 2401 requesting a tolerance of pendimethalin (PROWL®) on rice has been approved by Toxicology Branch (see J. Doherty memo dated March 2, 1981).

Review of Studies

All studies were conducted by the American Cyanamid Company using test material identified. (Accession No. 099888) "Emulsifiable Concentrate Formulation of PROWL (178 grams ai/l) plus Propanil Herbicide (266 grams ai/l)."
1. Acute Oral LD50 - rats (male and female, 5 sex/dose group)
   Males - 1,056 (800-1393) mg/kg
   Females - 915 (no range) mg/kg
   Combined - 966 (841-1110) mg/kg
   Signs of intoxication = diuresis and prostration
   Core Supplementary, no necropsy.

2. Acute Dermal Study - rabbits (male only)

   A Single dose of 5200 mg/kg to five animals resulted in no deaths.
   No signs of intoxication reported, no necropsy performed. Core
   Supplementary.

3. Eye Irritation

   Six rabbits were dosed with 0.1 ml of tank mix solution and observed
   for 7 days. Corneal opacity developed which persisted for 72 hours
   but was not reported as being present at 7 days.

   Core Minimum (no wash was conducted). The tank mix should be handled
   as a toxicity category II (Warning) eye irritant.

4. Skin Irritation

   Six rabbits were subjected to a dermal application of 0.5 ml of the tank
   mix product for 24 hours. A primary irritation score of 0.38 was reported.
   Core Supplementary (Insufficient documentation of procedures and results).
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 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.