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

JUN 11 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA File Symbol 241-~~EIR~~ 243
Prowl MC-60 Herbicide

FROM: Mary L. Waller
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

mw E 6/26/86

TO: Robert J. Taylor, PM 25
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Registration Division (TS-767C)

APPLICANT: American Cyanamid Company
Agricultural Research Division
P.O. Box 400
Princeton, NJ 08540

ACTIVE INGREDIENT:
Pendimethalin (N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine . . . . . 60.0%
INERT INGREDIENTS: . . . . . 40.0%

BACKGROUND:

The registrant has submitted an acute inhalation toxicity study on 241-243 to support registration of 241-EIR (registered as 241-281 on February 24, 1986). This data has been submitted as requested in an earlier TSS review dated August 23, 1985. The study was conducted by Food and Drug Research Laboratories, Inc. The data Accession Number is 261353. The type of support was not indicated.

RECOMMENDATION:

FHB/TSS finds the data acceptable to support registration of the product tested (241-243). The data, however, cannot be used to support registration of 241-281 as the products differ substantially. The product label for 241-281 lists 60% active ingredient (ai) and the product label for 241-243 lists 42.3% ai. In addition, 241-243 contains four additional inert ingredients not contained in 241-281.

This difference was clearly addressed in the August 23, 1985 TSS review where it was stated that data on 241-243 could not be used to support registration of 241-281 as the products were substantially different. TSS also provided a copy of the testing guidelines for the registrants use. Therefore, as stated in the August 23, 1985 TSS review, TSS again states that the registrant must still submit an acute inhalation toxicity study on 241-281 or data to support a waiver.

REVIEW:

Acute Inhalation Toxicity Study: Food and Drug Research Laboratory, Inc.; FDRL Study No. 8143; January 17, 1985.

PROCEDURE:

Four groups of ten males and ten female Sprague-Dawley rats were exposed in a 128 L acrylic chamber to a liquid droplet aerosol of test material having a concentration of either 2.75, 3.01, 4.09, or 4.63 mg/L (average actual chamber concentration) for 4 hours. An additional group of 10 animals/sex were exposed to air only under similar conditions. Gravimetric concentrations were calculated twice/hour. Animals were observed for 14 days. Animals were weighed on day 1 (before exposure) and on day 8 and 15. All animals were necropsied.

RESULTS:

No deaths occurred at 2.75 mg/L. At 3.01 mg/L, 5/10 males and 3/10 females died. At 4.09 6/10 males and 6/10 females died. At 4.63 mg/L, 10/10 males and 10/10 females died. The $LC_{50}$ for males was reported to be 3.5 mg/L (3.1 to 3.9 mg/L, 95% confidence interval). The $LC_{50}$ for females was reported to be 3.6 mg/L (3.2 to 3.9 mg/L, 95% confidence interval).

Toxic symptoms observed were decreased activity, dark material around eyes or nose, involuntary spasms and/or tremors, labored breathing, nasal discharge, and salivation. All surviving animals appeared normal by day 4. Gross necropsy revealed red or bright red to dark red nasal passages, dark red liver with blanched areas, bright red lungs, yellow substance in trachea, granular appearance of kidneys, atrial dilation in heart.

STUDY CLASSIFICATION: Core Guideline Data.