



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

006241

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FEB 27 1987

MEMORANDUM

SUBJECT: EPA File Symbol 524-EUP-AI
Partner WDG

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

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4/5/87

E *4/8/87*

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

APPLICANT: Monsanto Company
1101 17th Street NW.
Washington, DC 20036

ACTIVE INGREDIENTS:

Alachlor [2-chloro-2'-[6'-diethyl-N-(methoxymethyl)acetanilide]	69.6%
Imazaquin 2-[4,5-dihydro-4-methyl-4-(1-methoxyethyl)-5-oxo-1H-imidazol-2-yl]-3-quinolinecarboxylic acid	4.4%
INERT INGREDIENTS	26.0%

BACKGROUND:

The applicant has submitted an acute oral, acute dermal, primary skin irritation, and primary eye irritation study. The studies were conducted by Bio/dynamics, Inc. The data are not accessible and the method of support was not provided. The applicant has submitted particle sizing data as a basis for why an acute inhalation toxicity study is not required. The applicant has also cited an EPA registration and data to fulfill the dermal sensitization data requirement.

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RECOMMENDATION:

FHB/TSS finds the data acceptable to support registration. The signal word is "CAUTION." FHB/TSS also finds that an acute inhalation toxicity study is not required based on the registrant's statement in a June 4, 1986 letter signed by Mr. Robert Street, of Monsanto that product specifications require that no more than 0.5% of the formulation have a particle size < 150 microns and that particle size of the product ranges between 200 and 400 microns.

Regarding the dermal sensitization study, data on 524-344 that were cited on the data matrix cannot be used to support 524-EUP-AI because the two products are not substantially similar. However, if the technical used in 524-EUP-AI is a sensitizer, then the applicant can reference these data and label 524-EUP-AI as a sensitizer. If the technical is not a sensitizer, then the applicant must submit a dermal sensitization study conducted on 524-EUP-AI.

LABELING:

The subheading "Storage & Disposal" and the information on storage and disposal should be placed under the heading "Directions for Use" either immediately following the misuse statement or at the end of the Directions for Use.

REVIEW:

- (1) Acute Oral Toxicity Study: Bio/dynamics, Inc.; Project No. 6694-86; August 18, 1986.

PROCEDURE:

Five male and five female Sprague-Dawley rats were each administered via oral intubation a single dose of 5000 mg/kg of test material in methocel. Animals were observed twice daily for 14 days. Body weights were measured prior to dosing and at 7 and 14 days. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred. The LD₅₀ was reported to be > 5000 mg/kg. Toxic symptoms observed were wet rales, urinary staining, hypoactivity, and decrease in food consumption. Gross necropsy revealed two females with reddened ovaries and one female with reddened uterus.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

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- (2) Acute Dermal Toxicity Study: Bio/dynamics, Inc.; Project No. 6695-86; August 18, 1986.

PROCEDURE:

Five male and five female New Zealand White rabbits each received 5000 mg/kg of test material moistened with 0.9% saline applied to the clipped intact skin of the dorsal area of the trunk of each animal. The test site was covered with occlusive wrap for 24 hours. Animals were observed twice daily for mortality and at least once daily for toxic symptoms for 14 days. Animals were weighed prior to dosing and at 7 and 14 days. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred. The LD₅₀ was reported to be > 5000 mg/kg. Toxic symptoms observed were soft stool and fecal staining clearing by day 4 and slight weight loss in some males reversing by day 7. Gross necropsy revealed discolored and red foci on lungs and one female exhibiting reddened and swollen uterus. However, these necropsy findings were reported to be normal physiological variation and similar to those observed in control animals in the laboratory.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

- (3) Primary Eye Irritation Study: Bio/dynamics, Inc.; Project No. 6697-86; August 18, 1986.

PROCEDURE:

Six female New Zealand White rabbits each received 0.1 cc of test material which was placed in one eye of each animal. The other eye served as a control. Irritation was scored at 1, 24, 48, and at 72 hours and at 7 days.

RESULTS:

Eye irritation was scored as follows: at 24 hours, corneal opacity (5/6 = 20), iris irritation (6/6 = 5), conjunctivae redness (1/6 = 2, 5/6 = 1), chemosis (4/6 = 2, 2/6 = 1), and discharge (2/6 = 1); and at 7 days, all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

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(4) Primary Dermal Irritation Study: Bio/dynamics, Inc.;
Project No. 6696-86; August 18, 1986.

PROCEDURE:

Six New Zealand White rabbits each received 0.5 g of test material/two test sites applied to the clipped intact skin on the back of each animal. Test sites were covered with occlusive wrap for 4 hours. After exposure, the test sites were wiped free of residual test material. Skin irritation was scored at 30 minutes and at 24, 48, and 72 hours after removal of wrap.

RESULTS:

At 24 hours, 3/6 animals displayed very slight erythema. All irritation had subsided by 72 hours.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

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Alachlor/
Imazaquin toxicology review

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Pages 5 through 6 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
 - ☐ FIFRA registration data
 - ☐ The document is a duplicate of page(s) _____
 - ☐ The document is not responsive to the request
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• 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.
