12-10-86

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

006372

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

~~NOV 25 1986~~

MEMORANDUM

SUBJECT: EPA Experimental Use Permit File Symbol 100-EUP-II
Dual/Ignite 4EW

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

12-10-86 CS 12/10/86

TO: Richard F. Mountfort, PM 23
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Agricultural Division
Ciba-Geigy Corporation
P.O. Box 18300
Greensboro, NC 27419

ACTIVE INGREDIENTS:
Metochlor: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide 30.30%
Glufosinate-Ammonium: monoammonium 2-amino-4-(hydroxymethyl-phosphinyl)butanoate 13.45%
INERT INGREDIENTS: 56.25%

BACKGROUND:

The applicant has submitted an acute oral toxicity study, an acute dermal toxicity study, two acute inhalation toxicity studies, a primary eye irritation study, a primary skin irritation study, and a dermal sensitization study. The studies were conducted by Stillmeadow, Inc. The data Accession Number is 266020. The method of support was not indicated.

006372

1 of 11

RECOMMENDATION:

FHB/TSS finds all data, excluding the acute inhalation toxicity study (Project No. 3990-86); acceptable to support registration of 100-EUP-II. FHB finds the acute inhalation toxicity study (Project No. 3990-86) unacceptable to support registration. The Product Manager should inform the registrant that five animals/sex/dose are required under Agency testing Guidelines.

The signal word is "CAUTION."

LABELING: Proposed labeling is acceptable.

REVIEW:

(1) Acute Oral Toxicity Study: Stillmeadow, Inc.; Project No. 3697-85; August 22, 1985.

PROCEDURE:

Four groups of five male and five female Sprague-Dawley rats were administered a single dose of test material by oral intubation as follows: 4000, 4500, 4750, or 5020 mg/kg. Three additional groups of males were tested as follows: five males received 4600 mg/kg; ten males received 5500 mg/kg and five males received 6000 mg/kg. Animals were observed three times on day of dosing and at least once daily thereafter for 14 days. Body weights were recorded prior to dosing and at 7 and 14 days. Animals were necropsied at study conclusion.

RESULTS:

At 4000 mg/kg, 2/5 females died. At 4500 mg/kg, 3/5 females died. At 4600 mg/kg, 1/5 males died. At 4750 mg/kg, 2/5 males and 4/5 females died. At 5020 mg/kg, 3/5 males and 5/5 females died. At 5500 mg/kg, no deaths occurred. At 6000 mg/kg, 3/5 males died. The LD_{50} for males was reported to be 6545 mg/kg with 95% confidence limits of 4502 to 9514 mg/kg. The LD_{50} for females was reported to be 4210 mg/kg with 95% confidence limits of 3861 to 4590 mg/kg.

Toxic symptoms observed were decreased activity, alopecia, ataxia, body tremors, constricted pupils, chromodacryorrhea, convulsions, dilated pupils, diarrhea, emaciation, epistaxis, exophthalmos, head cocked to side, lacrimation, nasal discharge, piloerection, polyuria, ptosis, rolling to side, salivation, sensitive to touch, and swollen tongue. Gross necropsy revealed gastrointestinal tract distended with gas, discolored contents in the gastrointestinal tract, pronounced serosal blood vessels along gastrointestinal tract, testes retracted into abdominal cavity, and discolored contents in the urinary bladder.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(2) Acute Dermal Toxicity Study: Stillmeadow, Inc.; Project No. 3698-85; June 11, 1985.

PROCEDURE:

Five male and five female New Zealand White rabbits were clipped free of hair on the dorsal surface of the trunk and 24 hours later, each animal received 2010 mg/kg of test material applied to the shaven test site and kept under occlusive wrap for 24 hours. After exposure, the wrap was removed and the test site was gently washed with room temperature tap water. Animals were observed at least once daily for 14 days. Body weights were recorded prior to dosing and at 7 and 14 days. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred. The LD_{50} was reported to be > 2010 mg/kg. Toxic symptoms observed were small feces and diarrhea. No abnormalities were noted at gross necropsy.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(3) Acute Inhalation Toxicity Study: Stillmeadow, Inc.; Project No. 3702-85; September 4, 1985.

PROCEDURE:

Three groups of five male and five female Sprague-Dawley rats were exposed for 4 hours in a 200 L inhalation chamber to an aerosol generated from a 67% or 75% solution of test material in deionized water having an analytically measured concentration of 1.97, 2.29, or 2.67 mg/L. Animals were observed frequently on day of exposure and at least once daily thereafter for 14 days. Body weights were recorded prior to dosing and at 7 and 14 days. Animals were necropsied at study conclusion.

RESULTS:

At 1.97 mg/L, 1/5 males and 1/5 females died. At 2.29 mg/L, 3/5 males and 4/5 females died. At 2.67 mg/L, 3/5 males and 5/5 females died. The LC_{50} for males was reported to be 2.36 mg/L with 95% confidence limits of 1.92 to 2.90 mg/L. The LC_{50} for females was reported to be 2.12 mg/L with 95% confidence limits of 1.97 to 2.29 mg/L.

Toxic symptoms observed were decreased activity, ataxia, body tremors, chromodacryorrhea, constricted pupils, convulsions, diarrhea, dilated pupils, emaciation, exophthalmos, facial alopecia, intermittent shivering, lacrimation, loss of forelimb motor coordination, melanuria, muscle tremors, nasal discharge, piloerection, polyuria, ptosis, respiratory gurgle, salivation, sensitivity to touch and sound, and swollen neck. Gross necropsy revealed hematuria, discolored and edematous lungs, nodules on lungs, discolored contents in the gastrointestinal tract, gastrointestinal tract distended with gas or empty, testes atrophied, and testes drawn into abdominal cavity.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(4) Acute Inhalation Toxicity Study: Stillmeadow, Inc.; Project No. 3990-86; March 31, 1986.

PROCEDURE:

Two groups of twenty male Sprague-Dawley rats were exposed for 4 hours in a 200 L inhalation chamber to an aerosol as follows: one test group was exposed to an aerosol generated from 67% v/v suspension of test material in deionized water having an analytically measured concentration of 1.34 mg/L and another test group was exposed to an aerosol generated from undiluted test material having an analytically measured concentration of 2.82 mg/L. Animals were observed frequently on the day of exposure and at least once daily thereafter for 14 days. Body weights were recorded prior to dosing and at 7 and 14 days. Animals were necropsied at study conclusion.

RESULTS:

At 1.34 and 2.82 mg/L, 2/20 animals died at each exposure level. Toxic symptoms observed were decreased activity, agressiveness, ataxia, body tremors, chromodacryorrhea, constricted pupils, diarrhea, dilated pupils, emaciation, epistaxis, exophthalmos, gasping, salivation, lacrimation, loss of forelimb coordination, muscle tremors, nasal discharge, polyuria, piloerection, ptosis, respiratory gurgle, sensitivity to sound and touch, shivering, swollen face, and swollen neck. No abnormalities were noted at gross necropsy.

STUDY CLASSIFICATION:

Supplementary - See comments under Recommendation.

(5) Primary Eye Irritation Study: Stillmeadow, Inc.; Project No. 3699-85; June 7, 1985.

PROCEDURE:

Nine New Zealand White rabbits were examined using 0.2% fluorescein sodium ophthalmic solution and found to be free of ocular injury or irritation. Twenty-four hours later, each animal received 0.1 ml of test material which was placed in the conjunctival sac of the right eye of each animal. The eyelids were held shut for 1 second. The treated eyes of 3/9 animals were washed with deionized water for 30 seconds after treatment. The untreated left eye of each animal served as a control. Eye irritation was scored at 1, 24, 48, and 72 hours and at 4, 7, and 10 days. Eyes were examined at 24-hour observation period with 0.2% fluorescein sodium ophthalmic solution.

RESULTS:

Eye irritation in the unwashed group was scored as follows: at 24 hours, conjunctivae redness (1/6 = 2, 5/6 = 1), chemosis (6/6 = 1) and discharge (1/6 = 2, 4/6 = 1); at 7 days, conjuctivae redness (1/6 = 1); and at 10 days, all irritation had cleared. Fluorescein staining was negative at 24 hours.

Eye irritation in the washed group was scored as follows: at 24 hours, conjunctivae redness (2/3 = 2, 1/3 = 1), chemosis (1/3 = 2, 2/3 = 1) and discharge (1/3 = 2, 2/3 = 1); and at 7 days, all irritation had cleared. Fluorescein staining was negative at 24 hours.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(6) Primary Skin Irritation Study: Stillmeadow, Inc.; Project No. 3700-85; June 18, 1985.

PROCEDURE:

Six New Zealand White rabbits were clipped on the dorsal area of the trunk and approximately 24 hours later, each animal received 0.5 ml of test material which was applied to the clipped test site. Test sites were kept under occlusive wrap for 4 hours. After exposure, the wrap was removed and the test sites were washed to remove residual test material. Skin irritation was scored at 1, 24, 48, and 72 hours.

RESULTS:

At 1 hour, 3/6 animals exhibited very slight erythema and 2/6 animals exhibited very slight edema. At 24 and 48 hours, 1/6 animals exhibited very slight erythema. At 72 hours, all irritation cleared.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category IV - CAUTION.

(7) Dermal Sensitization Study: Stillmeadow, Inc.; Project No. 3701-85; July 13, 1985.

PROCEDURE:

Two groups of ten Hartley-Albino guinea pigs were clipped free of hair on the back of the trunk and treated on days 1, 3, 6, 8, 10, 13, 15, 17, 20, 22, and 36: the test group received 0.5 ml of test material and the positive control group received 0.5 ml of 0.05% w/v solution of 2,4-dinitrochlorobenzene in ethanol. Each treatment was applied to the clipped test site and kept under occlusive wrap for 6 hours. Animals were restrained during exposure. Animals were clipped when necessary approximately 24 hours prior to each treatment. Animals were treated at an additional test site on day 36.

RESULTS:

One animal in the test group died on day 6. The test group displayed no irritation following induction or challenge treatments. Five out of ten animals in the positive control group displayed very slight erythema after the third induction treatment. After the tenth induction treatment, 10/10 animals in the positive control group displayed erythema ranging from very slight to well-defined and 5/10 animals displayed very slight edema. The degree of irritation in the positive control group increased with subsequent treatments to moderate to severe erythema and moderate edema by day 36 challenge dose. The positive control group exhibited very slight erythema and very slight edema after challenge treatment at the new test site.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Nonsensitizer.

ACCEPTED 006372

for shipment and use of this product for experimental purposes under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, subject to attached comments.

Permit No. 100-EUP-88

Issued on

Dual®/Ignite® 4EW

Herbicide

SHAKE WELL BEFORE USING

A prepackaged mixture for evaluation of weed control in soybeans

FOR EXPERIMENTAL USE ONLY

Active Ingredients:	
Metolachlor: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide	30.30%
Glufosinate-Ammonium: monoammonium 2-amino-4-(hydroxymethyl-phosphinyl) butanoate	13.45%
Inert Ingredients:	56.25%
Total:	100.00%

Dual/Ignite 4EW contains 2.8 lbs. of the active ingredient metolachlor and 1.2 lbs. of the active ingredient glufosinate-ammonium for a total of 4.0 lbs. active ingredients per U.S. gallon.

Keep Out of Reach of Children.

CAUTION

See additional precautionary statements at end of label booklet.

See directions for use in booklet attached to jug.

Experimental Use Permit 100-EUP-
EPA Est. 100-

Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program and for use only at an application site of a cooperator and in accordance with the terms and conditions of the Experimental Use Permit.

006372

1

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

FAILURE TO FOLLOW THE DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN CROP INJURY, POOR WEED CONTROL, AND/OR ILLEGAL RESIDUES.

Do not apply this product in such a manner as to directly or through drift expose workers or other persons, except those knowingly involved in the application. The area being treated must be vacated by unprotected persons.

Reentry Statement

Do not enter treated areas without protective clothing until sprays have dried.

Because certain states may require restrictive reentry intervals for various crops treated with this product, consult your State Department of Agriculture for further information.

Written or oral warnings must be given to workers who are expected to be in a treated area or in an area about to be treated with this product. Oral warnings must be given which inform workers of areas or fields that may not be entered without specific protective clothing until sprays have dried, and appropriate actions to take in case of accidental exposure, as described under Precautionary Statements on this label. When oral warnings are given, warnings shall be given in a language customarily understood by workers. Oral warnings must be given if there is reason to believe that written warnings cannot be understood by workers. Written warnings must include the following information: "CAUTION. Area treated with Dual/Ignite 4EW on (date of application). Do not enter without appropriate protective clothing until sprays have dried. In case of accidental exposure, flush eyes or skin with plenty of water. Call a physician if irritation persists. Remove and wash contaminated clothing before reuse."

Table 3: Rates of Lorox, Lexone, Sencor, or Scepter to be Applied in Tank Mix Combination with Dual/Ignite 4EW

Soil texture	Broadcast rates per acre		
	Lorox L	Lexone 4L or* Sencor 4	Scepter
Coarse	0.5-0.75 qt.	0.25-0.375 qt.	0.67 pt.
Medium	0.5-1.0 qt.	0.375-0.5 qt.	0.67 pt.
Fine	1.0-1.5 qts.	0.5 qt.	0.67 pt.

*When using Sencor 50WP, Sencor DF or Lexone DF, use equivalent rates. 0.5 qt. of Sencor 4 or Lexone 4L equals one lb. of Sencor 50WP or 0.67 lb. of Sencor DF or Lexone DF.

Crop Rotation: Do not replant for at least 12 months following application.

Storage and Disposal

Store at temperatures above 32°F. If frozen, allow product to completely thaw in warm room (72°F) and shake before using.

Pesticide Disposal

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Improper disposal of unused pesticide, spray mixture, or rinsate is a violation of federal law. Pesticide, spray mixture or rinsate that cannot be used according to label instructions must be disposed of according to federal, state, or local procedures. For guidance in proper disposal methods, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office.

Container Disposal

Do not reuse empty container. Triple rinse, puncture and dispose of in a sanitary landfill or by incineration; or by open burning, if allowed by state and local authorities. If burned, keep out of smoke.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. In the event of a major spill, fire, or other emergency, call (919)292-7100 day or night.

Precautionary Statements

Hazards to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Harmful if swallowed, inhaled, or absorbed through skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Statement of Practical Treatment

If in eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin: Wash with plenty of soap and water. Get medical attention.

If inhaled: Remove victim to fresh air. Get medical attention.

Environmental Hazards

Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply where runoff is likely to

Continued ... 14

occur. Do not apply when weather conditions favor drift from treated areas.

Physical or Chemical Hazards

Mix, apply, and store spray solutions of this product only in stainless steel, aluminum, fiberglass, and polyethylene containers.

DO NOT MIX, APPLY, OR STORE THIS PRODUCT OR SPRAY SOLUTIONS OF THIS PRODUCT IN GALVANIZED OR UNLINED STEEL, WITH THE EXCEPTION OF STAINLESS STEEL CONTAINERS OR SPRAY TANKS. This product or spray solutions of this product may react with such containers or tanks to form a highly combustible gas mixture. This gas mixture could flash or explode if ignited by any type of open flame or spark, causing serious personal injury.

Dual®, trademark of CIBA-GEIGY Corporation for metolachlor. U.S. Patent 3,937,730.

Ignite™ trademark of Hoechst-Roussel Agri-Vet for glufosinate-ammonium.

Lexone® trademark of E.I. duPont de Nemours and Co. for metribuzin

Lorox® trademark of E. I. duPont de Nemours and Co. for linuron

Scepter® trademark of American Cyanamid for imazaquin

Sencor® trademark of the Parent Company of Farbenfabriken Bayer GmbH, Leverkusen for metribuzin

Unite® trademark of Hopkins Agricultural Chemical Company for compatibility agent HA-914

Agricultural Division
CIBA-GEIGY Corporation
Greensboro, NC 27419

DUAL/IGNITE October 27, 1986