

12-20-85



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

006287

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration Number: 1471-140
Balam DF

FROM: Deloris F. Graham
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

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TO: Robert Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Applicant: Elanco Products Company
A Division of Eli Lilly and Company
740 South Alabama Street
Indianapolis, IN 46285

Active Ingredient:

N-butyl-N-ethyl- α, α, α -trifluoro-2,
6-dinitro-p-toluidine

60%

Inert Ingredients 40%

Background:

Submitted Acute Inhalation and Dermal Sensitization Studies to fulfill acute toxicity data requirements for this product. Studies conducted by Lilly Research Laboratories. Studies under Accession Numbers 250568 and 255938. Method of support not indicated.

Recommendation:

1. FHB/TSS finds these studies acceptable to support conditional registration of this product.

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Label:

2. Precautionary Statements should be amended to include "Harmful if inhaled. If inhaled remove victim to fresh air. Get medical attention."

Review:

1. Acute Inhalation Toxicity Study: Lilly Research Laboratories; Study R-H-06-83; March 1983; EPA Accession No. 250568.

Procedure:

Two groups consisting of 10 male and 10 female Fischer 344 rats were exposed nose only for 4 hours to one of the following analytical concentrations: 2.014 mg benfen activity/L or 2.583 mg benetin activity/L. Mass median diameter ranged from 7.44 to 13.30 micrometers. Observations made for 14 days post-exposure. Necropsy performed on all animals.

Results:

At 2.014 mg/L, 1:10 F died; at 2.583 mg/L, 1:10 F, and 2:10 M died. Toxic signs reported included hypoactivity, rales, dyspnea, dry nasal exudate, wheezing, weight loss, and poor grooming. Necropsy revealed pulmonary congestion and edema in one female that died at 2.014 mg/L concentration, pulmonary hemorrhage in one female, and dried nasal exudate with pulmonary emphysema in one male that died at 2.533 mg/L concentration. LC50 reported to be greater than 2.583 mg/L analytical concentration.

Study Classification:

Core Guideline Data

Toxicity Category:

III-CAUTION

2. Dermal Sensitization Study: Lilly Research Laboratories; Study G01184; September 1984, EPA Accession No. 255938.

Procedure:

Two groups consisting of 12 guinea pigs each were treated with one of the following substances: Balan DF (test material) or 0.1% dinitrochlorobenzene (DNCB, positive control). Two groups

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consisting of six guinea pigs were treated with one of the two previously stated substances but only at challenge dose and several as irritation controls. During the induction each animal of the test group received 50 mg application of the test material three times a week for 3 weeks and the animals of the positive control group received 0.2 mL of a 0.1% DNCR in 70% ethanol in the same manner as test group. Ten days after final induction phase application challenge dose was applied to each group with appropriate substance. Observations made at 24 hours after each induction phase application and at 24, 48, and 72 hours after challenge dose.

Results:

Slight to moderate erythema and/or very slight edema in 4 of 12 guinea pigs at 24 hours after final induction phase application. Nine of twelve guinea pigs showed very slight to slight erythema or edema at 24, 48, and 72 hours after challenge. However three of six guinea pigs in test material irritation control (only treated at challenge) also showed very slight to slight erythema at 48 and 72 hours after challenge dose. Thereby indicating the product as a slight irritant, but not a contact sensitizer.

Very slight to slight erythema developed in 12 of 12 guinea pigs at 24 hours after third application in DNCR group (positive control). Severe erythema and slight to moderate edema after final application in all of the treated guinea pigs. Slight to moderate erythema and edema noted in all animals at challenge dose. However, at challenge dose of six animals of irritation control group no irritation reported. Thereby indicating a positive sensitizing response.

Study Classification:

Core Guideline Data

Toxicity

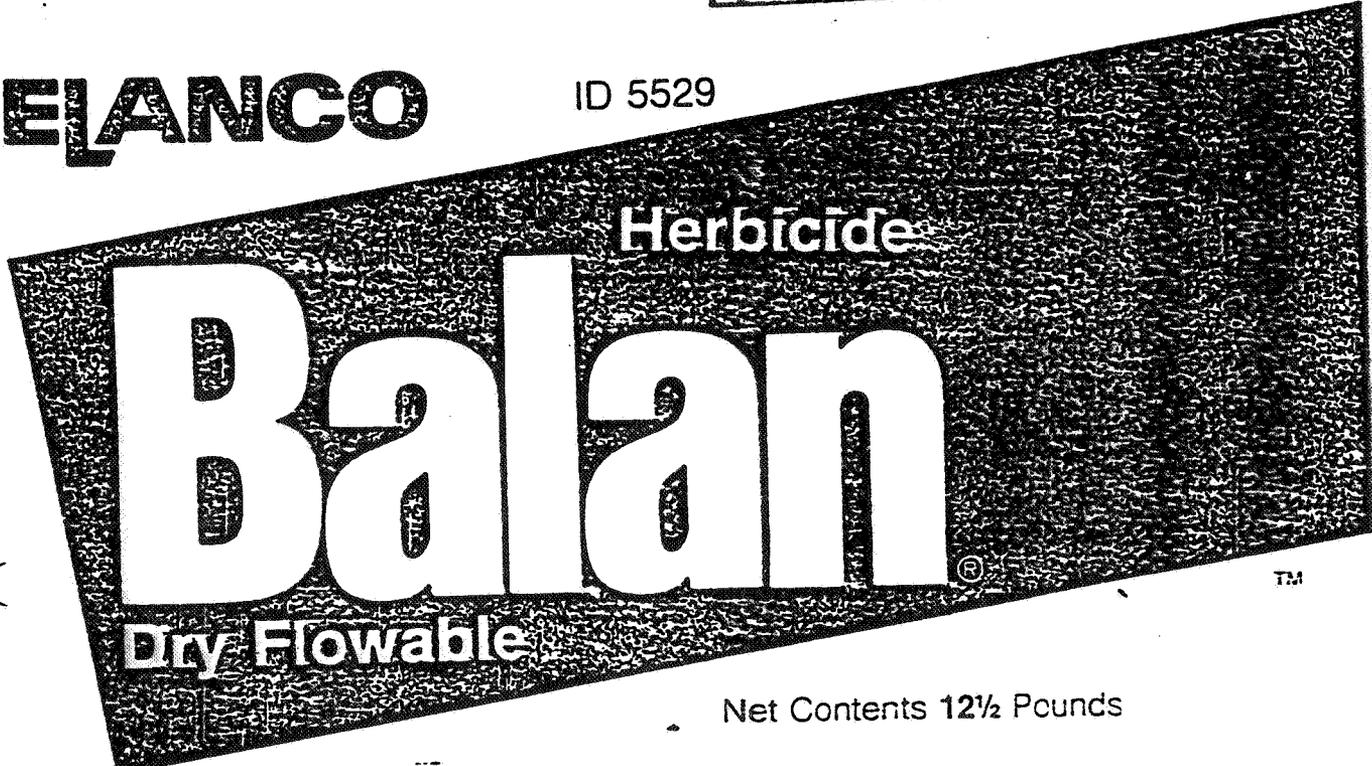
Nonsensitizing

ACCEPTED
FEB 22 1985
Under the Federal Insecticide, Fungicide, and Herbicide Act as amended, this pesticide is registered under EPA Reg. No. 1471-140

006287

ELANCO

ID 5529



Herbicide
Balan[®]
Dry Flowable

Net Contents 12½ Pounds

A selective herbicide for the preemergence control of annual grasses and broadleaf weeds

Active ingredient: N-butyl-7-ethyl- α , α -trifluoro-2,6-dinitro-p-toluidine 50%
Inert ingredients 40%
Contains 0.5 pounds active ingredient per pound
*BALAN[®]—the registered trademark for Elanco Products Company

Keep Out of Reach of Children.

CAUTION

See back of container for additional precautionary statements.

EPA Reg. No. 1471-140

EPA Est. 1471-IN-5

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STORAGE AND DISPOSAL

Storage: Store in original container only. Do not store in direct sunlight. Do not store at temperatures above 120°F. If stored above 120°, BALAN Dry Flowable could lose some of its dispersing properties, resulting in difficult application, poor weed control or crop injury. In case of leak or spill contain material and dispose as waste.

Pesticide Disposal: Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities by burning. If burned, stay out of smoke.

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Directions for Use

See attached literature for complete directions for use.

Read all directions carefully before applying.

It is a violation of Federal law to use this product in a manner inconsistent with the label.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Avoid contact with skin, eyes, or clothing. Harmful if swallowed.

First Aid: In case of contact, immediately flush eyes or skin with plenty of water. If swallowed drink large quantity of water and induce vomiting by placing finger in back of throat. Never give anything by mouth to unconscious person.

If accidentally swallowed, or if irritation persists, get medical attention.

Environmental Hazards

This product is toxic to fish. Do not contaminate any body of water by direct application, cleaning of equipment or disposal of wastes.

STORAGE AND DISPOSAL

Storage: Do not store in direct sunlight. Do not store at temperatures above 120°F. If stored above 120°F, BALAN Dry Flowable could lose some of its dispersing properties, resulting in difficult application, poor weed control or crop injury.

Container Disposal:

1. Empty container into spray tank
2. Refill container with water 1/5 to 1/4 full; shake and rinse thoroughly, pour into tank, drain.
3. Repeat rinsing and draining 3 times.
4. Do not reuse. Dispose of in a sanitary landfill, or by incineration if allowed by state and local authorities.

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Elanco Products Company • A Division of Eli Lilly and Company
Indianapolis, IN 46285, U.S.A.

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