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

005117

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: June 22, 1983

Subject: EPA File Symbol 11273-UA
Telok Granular Herbicide

From: Deloris F. Graham DFG 6/27/83
FHB/TSS E 6/27/83

To: Richard Mountfort
Product Manager (23)

Applicant: Sandoz, Inc.
Crop Protection
480 Camino Del Rio South
Suite 204
San Diego, California

Active Ingredients:

Norflurazon: [4-chloro-5-(methylamino) -2-alpha, alpha, alpha-trifluro-m-tolyl-3-(2H)-pyridazinone]	4.0%
Simazine: [2-chloro-4,6-bis(ethylamino) -s-triazine]	2.0%
Sodium chlorate ($NaClO_3$)	39.1%
Sodium metaborate	51.8%
Inert Ingredients	3.1%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation, and Primary Dermal Irritation studies and Acute Inhalation Particle Size Analysis. Studies conducted by Sandoz, Inc. Data under accession number 250110. Combined Cite-All and Alternate Method of Support.

Recommendation:

(1) FHB/TSS finds these data acceptable to support conditional registration of this product. However, for future submissions please note:

(a) In the Acute Oral and Acute Dermal studies, individual necropsy reports must be submitted.

(2) The appropriate signal word is DANGER.

(3) The Acute Inhalation information submitted indicated that ~~we~~ 99.92% of the ~~minute~~ particles were greater than 2.38 mm indicating that the ~~many~~ majority of the particles are not in a respirable Range.

1/5

Label:
(1) Please see enclosed copy for appropriate storage and disposal statements.

Review

(1) Acute Oral Toxicity Study: Sandoz, Inc., Report No. T-3-8/24/82; August 24, 1982.

Procedure: Based on a preliminary study, 5 groups consisting of 10 male and 10 female rats received one of the following doses orally: 2850, 3225, 3675, 4140 and 4740 mg/kg. Observations made for 14 days after treatment.

Results: At 2850 mg/kg, 4/20 animals died; at 3225 mg/kg, 8/20 animals died; at 3675 mg/kg, 15/20 animals died; at 4140 mg/kg, 18/20 animals died; at 4740 mg/kg, 20/20 animals died. Clinical signs noted included decrease in locomotor activity, flattened body position, immobility, ataxia, loss of righting reflex, salivation, soiled fur, oral and anal discharge at death and labored breathing, also piloerection, diarrhea and lacrimation. LD_{50} for male and female combined was 3207 mg/kg, 95% confidence limits of 2972 to 3409 mg/kg.

Study Classification: Core Minimum Data. Individual necropsy reports must be submitted.

Toxicity Category: III - CAUTION

(2) Acute Dermal Toxicity Study: Sandoz, Inc.; Report No. T-6-12/15/82; December 15, 1982.

Procedure: Four male and four female New Zealand rabbits received 2 g/kg of the test material at abraded skin sites under occlusive wrap for 24 hour exposure. Observations made for 14 days posttreatment.

Results: No mortalities. Well defined erythema and slight edema noted. Eschar, scaliness and dryness also noted. LD_{50} greater than 2 g/kg.

Study Classification: Core Minimum Data: Individual necropsy reports must be submitted.

Toxicity Category: III - CAUTION

(3) Primary Skin Irritation Study: Sandoz, Inc.; Report No. T-2-8/24/82; August 24, 1982.

Procedure: Six New Zealand rabbits received 500 mg of the test material at abraded and intact skin sites per animal under occlusive wrap for 24 hour exposure. Observations were made at 24 and 72 hours and 8 and 15 days after treatment.

2

Results: At 24 hours, 6/6 had moderate to severe erythema and slight edema. At 72 hours, 6/6 had slight to well defined erythema and slight edema. Scaling also noted. Primary Irritation Score was 3.84. Severe erythema present at days 8 and 15 in 5/6 animals.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

(4) Eye Irritation Study: Sandoz, Inc.; Report No. T-1-8/24/82; August 24, 1982

Procedure: Nine New Zealand rabbits received 100 mg of the test material in one eye each. The treated eyes of three of the rabbits were washed 20-30 seconds after treatment. Observations were made at 24, 48 and 72 hours, 7, 14 and 21 days posttreatment.

At 7 days; 4/6 had corneal opacity (2/6 = 5, 1/6 = 20, 1/6 = 40); 6/6 had conjunctive redness (5/6 = 1, 1/6 = 2); 5/6 chemosis (2/6 = 1, 1/6 = 2, 2/6 = 3) and 3/6 discharge (3/6 = 2). Irritation had cleared in washed group.

Ulceration, pannus and epithelialization also present.

At 14 days, 3/6 had corneal opacity (2/6 = 5, 1/6 = 10); 5/6 conjunctive redness (5/6 = 1); 2/6 chemosis (2/6 = 1) and 4/6 discharge (2/6 = 1, 2/6 = 2).

At 21 days, 2/6 corneal opacity (2/6 = 5); 2/6 conjunctive redness (2/6 = 1).

Study Classification: Core Guideline Data.

Toxicity Category: I - DANGER

SODIUM METABORATE

RD 5117-93 Tox Review 005117

Page____ is not included in this copy.

Pages 4 through 5 are not included.

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.
