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

006097

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SEP - 6 1986

MEMORANDUM

SUBJECT: EPA File Symbol 10445-ON
Biochek 410

FROM: Deloris F. Graham 9/12/86
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

E 9/12/86

TO: Henry M. Jacoby, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Calgon Corporation
P.O. Box 1346
Pittsburgh, PA 15230

ACTIVE INGREDIENTS:
1,2-dibromo-2,4-dicyanobutane 19%
1,2-benzisothiazolin-3-one 6%
INERT INGREDIENTS: 75%

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Primary Dermal Irritation, and Eye Irritation Studies. Studies conducted by MB Research Laboratories, Inc. Data under Accession Number 262991. Method of support not indicated.

RECOMMENDATIONS:

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

2. Acute Inhalation and Dermal Sensitization Studies were not submitted and these studies must be submitted or data to support waiver.

3. The appropriate signal word is DANGER.

1/5

LABEL:

Additional precautionary labeling may be necessary upon submission of the two previously requested studies.

REVIEW:

(1) Acute Oral Toxicity Study: MB Research Laboratories, Inc.; Project No.: MB85-7700A; June 5, 1985.

PROCEDURE:

Four groups consisting of five male and five female rats each were dosed with one of the following doses orally: 1800, 2100, 2400, or 2700 mg/kg. Observations made twice daily for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

At 1800 mg/kg, 1/5 F died; at 2100 mg/kg 2/5 M and 2/5 F died; at 2400 mg/kg, 1/5 M and 3/5 F died; at 2700 mg/kg, 3/5 M and 4/5 F died. Toxic signs reported included piloerection, lethargy, ptosis, flaccid muscle tone, ataxia, prostration, wetness of the anogenital area, rales, brown staining of body areas, and hind limb paralysis, bloated abdomen, chromorhinorrhea, emaciation, and diarrhea. Necropsy report revealed abnormalities of the lungs, liver, and gastrointestinal tract; as well as yellow staining of body fat, brown staining of the anogenital area and nose/mouth area; adhesions in peritoneal cavity in animals that died during study. Survivor animals reportedly normal at necropsy. LD_{50} for males reported to be 2600 mg/kg with confidence limits between 2210 and 3058 mg/kg. LD_{50} for females reported to be 2200 mg/kg with confidence limits between 1905 and 2540 mg/kg. LD_{50} for males and females combined reported to be 2500 mg/kg with confidence limits between 2112 and 2841 mg/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(2) Acute Dermal Toxicity Study: MB Research Laboratories, Inc.; Project No. MB85-7700B; June 5, 1985.

PROCEDURE:

Five male and four female rabbits received 5.0 g/kg of the test material under occlusive wrap for 24-hour exposure period. Observations made twice daily for 14 days posttreatment. Necropsy performed on all animals.

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RESULTS:

No mortalities reported. Toxic signs reported included diarrhea, few feces, bloated abdomen, moderate to severe dermal irritation. Necropsy report revealed abnormalities of the treated skin, peritoneal cavity and intestines; emaciation; in all but 1/9 animals. LD_{50} reported to be greater than 5.0 g/kg.

STUDY CLASSIFICATION:

Core Minimum Data. At least five animals per sex per dose must be used.

TOXICITY CATEGORY: IV - CAUTION.

(3) Primary Dermal Irritation Study: MB Research Laboratories, Inc.; Project No. MB85-7700C; June 5, 1985.

PROCEDURE:

Six rabbits with one intact test skin site each received 0.5 ml of the test material under occlusive wrap for 4-hour exposure period. Observations made for 8 days posttreatment.

RESULTS:

At 24 hours posttreatment, 6/6 rabbits had well-defined erythema (6/6 = 2) and edema (6/6 = 2). At 72 hours, 6/6 had slight to well-defined erythema (5/6 = 1, 1/6 = 2) and 3/6 slight edema (3/6 = 1). Yellowish-tan stain from test article also noted. Irritation persisted through day 8 in a few animals, with flaking, dry, and scaly skin at test site noted in one animal on day 8.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(4) Eye Irritation Study: MB Research Laboratories, Inc.; Project No. MB85-7700D; June 5, 1985.

PROCEDURE:

Six rabbits received 0.1 ml of the test material in one eye each. Observations made for 3 days posttreatment.

RESULTS:

At day 1, 5/6 animal had corneal opacity, approximate scores from 10 to 15, however, due to severe chemosis accurate calculation could not be made; 1/6 animals could not be

scored for opacity and 6/6 could not be scored for iris irritation due to severe chemosis. At day 1, 6/6 had moderate redness (6/6 = 3), severe chemosis (6/6 = 4) and slight to moderate discharge (4/6 = 2, 2/6 = 3). Irritation and opacity persisted through day 3 with increase in opacity scores ranging from 10 to 40.

STUDY CLASSIFICATION:

Core Minimum Data. Observations must be made for 21 days or until all irritation subsides, whichever comes first.

TOXICITY CATEGORY: I - DANGER.

Proxel scientific review

Page 5 is not included in this copy.

Pages _____ through _____ 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

XX 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.
