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

006170

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

OCT - 3 1986

MEMORANDUM

SUBJECT: EPA Registration No. 7969-60
Dazomet Technical

FROM: Deloris F. Graham DFG 10/10/86 E 10/10/86
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

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

APPLICANT: BASF Wyandotte Corporation
Agricultural Chemicals Group
100 Cherry Hill Road
Parsippany, NJ 07054

ACTIVE INGREDIENT:
240 Dazomet (tetrahydro-3,5-dimethyl
-2H-1,3,5-thiadiazine-2-thione) 99%
INERT INGREDIENTS: 1%

BACKGROUND:

Acute Oral, Acute Dermal, Acute Inhalation, Skin Irritation, Eye Irritation, and Dermal Sensitization Studies were conducted and submitted by BASF Wyandotte Corporation under Agency Code 400 (miscellaneous data). Studies under Accession No. 251666. Method of support not indicated.

RECOMMENDATION:

1. FHB/TSS finds the Acute Oral Study acceptable to support conditional registration of this product.

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2. However, the remaining studies are unacceptable for the following reasons.

   a. In the Acute Dermal Study, the product as formulated to be marketed, not a dilution, must be tested.

   b. In the Acute Inhalation Study, concentration tested, chamber conditions (temperature, humidity, etc.); LC_{50} for males and females individually must be submitted.

   c. In Skin Irritation Study at least six animals using formulated product must be tested.

   d. In the Eye Study at least six animals must be tested. Observations must be made 21 days post-treatment or until all irritation has subsided, whichever comes first.

   e. In the Skin Sensitization Study when using the epicutaneous method, applications should be made daily for 3 weeks or five times weekly for 4 weeks, using same test site. Observations are made at 24 hours after each application or at the end of each week.

LABEL:

Appropriate labeling cannot be determined at this time.

REVIEW:

(1) Acute Oral Toxicity Study: BASF Wyandotte; 80/46; December 10, 1980.

PROCEDURE:

Six groups consisting of 10 male and 10 female rats each received one of the following doses: 147, 215, 316, 464, 562, or 681 mg/kg. Observations made for 14 days posttreatment. Necropsy performed on all animals.

RESULTS:

At 215 mg/kg, 2/10 F died; at 316 mg/kg, 2/10 F died; at 464 mg/kg, 4/10 F died; at 562 mg/kg, 3/10 M and 9/10 F died; at 681 mg/kg, 9/10 M and 9/10 F died. Toxic signs reported included dyspnea, apathy, aggressivity, abnormal position, staggering, atonia, trembling, twitching, biting, spasm, feverish twitching, tonic convulsion, piloerection, erythema, exsiccosis, salivation, lacrimation, compulsive gnawing, paralysis,

shaking, and poor general state. Necropsy report revealed heart - dilatation on both sides, congestive hyperemia; top cardiac part of the stomach grown together with liver and peritoneum of some animals. LD_{50} for males 596 mg/kg. LD_{50} for females 415 mg/kg. LD_{50} for males and females combined reported to be 519 mg/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: II - WARNING.

(2) Acute Dermal Toxicity Study: BASF Wyandotte; 80/46; July 17, 1981.

PROCEDURE:

Four groups consisting of five male and five female rats with intact skin sites were treated with one of the following doses: 200, 400, 1000, or 2000 mg/kg as a 50 and 25% aqueous formulation. Observations made for 14 days posttreatment. Necropsy performed on all animals.

RESULTS:

No mortalities or abnormalities at necropsy reported. Toxic signs reported included dyspnea, apathy, poor general stata, staggering, spastic gait; after 24 hours, yellow substance residue; very slight, partly stained - necrotic erythema; slight to strong edema. LD_{50} reported to be greater than 2000 mg/kg of 50% aqueous formulation.

STUDY CLASSIFICATION:

Core Supplementary Data. Though the data are good for 50% formulation on which tested, it is not on formulation as intended to market.

(3) Acute Inhalation Toxicity Study: BASF Wyandotte; XVI/1; August 27, 1975.

PROCEDURE:

A group of 12 rats were exposed for 8 hours to an airstream saturated with basamid granular at 20 °C. Observations made for 7 days postexposure. Necropsy performed on all animals.

RESULTS:

No mortalities. No toxic signs or abnormalities at necropsy reported.

STUDY CLASSIFICATION:

Core Supplementary Data. See item 2b under Recommendations for details.

(4) Skin Irritation Study: BASF Wyandotte; XVI/1; August 27, 1975.

PROCEDURE:

Four rabbits were treated with 50% aqueous solution of test material for 1, 5, and 15 minutes and 20 hours using patch test. Observations made for 8 days.

RESULTS:

No irritation reported following short term exposures (1-15 minutes), but moderate inflammation following 20-hour exposure. At 8 days disturbances of tissue function at inflamed areas noted.

STUDY CLASSIFICATION:

Core Supplementary Data. See item 2c under Recommendations for details.

(5) Eye Irritation Study: BASF Wyandotte; XVI/1; August 27, 1975.

PROCEDURE:

A 50 mg dose of the compound was reported to have been placed in conjunctival sac of the rabbit's eye. Observations made at 1 and 24 hours and at 8 days posttreatment.

RESULTS:

Transient inflammation with erythema and slight edema reported in rabbit's eye.

STUDY CLASSIFICATION:

Core Supplementary Data. See item 2d under Recommendations for details.

(6) Skin Sensitization Study: BASF Wyandotte; XXI/131.

PROCEDURE:

Ten guinea pigs were painted in crisscross pattern three times with cotton pads soaked in 20% acetone solution of the product. Treatment was repeated on consecutive days for a

total of 10 paintings at first test site. After 12 days the second test site was painted in a manner similar to first site with 20 percent primary nonirritating acetone solution. Twenty days after second site paintings an intracutaneous injection with 0.05 ml of a 0.1% Basamid Granular solution (test material) was applied. Observations made 12 hours after second test site painting and 20 days later painting. An intracutaneous method described in Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics, 1955, p. 50 was chosen to confirm results of the previously stated epicutaneous method.

RESULTS:

The epicutaneous method reported produced ~~no irritation~~ throughout study. Intracutaneous application reported to have produced no irritation through seventh injection. However, from eight injection onward slight reddening around injection site noted. It was reported that after 18-day interval an intracutaneous injection produced no irritation.

STUDY CLASSIFICATION:

Core Supplementary Data. See item 2e under Recommendations for details.

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Pages _____ through _____ 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.