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

006313

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

FEB 6 1987

SUBJECT: EPA File Symbol 7969-TA
Storm 7969-76

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

TO: Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Basf Corp.
Chemical Division
100 Cherry Hill Road
Parsippany, NJ 07054

ACTIVE INGREDIENTS:
Sodium salt of bentazcn 28.9%
Sodium salt of acifluorfen 14.0%
INERT INGREDIENTS: 57.1%

BACKGROUND:

The applicant has submitted an acute oral, acute dermal, acute inhalation, primary skin irritation, and primary eye irritation study. The studies were conducted by Basf Aktiengesellschaft Department of Toxicology. The data Accession Number is 265969. The method of support is owner submission. The applicant has also requested a waiver of the dermal sensitization study by referencing the dermal sensitization study (Accession No. 26540[illegible]) on the active ingredient 7969-42.

RECOMMENDATION:

FHB/TSS finds the data acceptable to support registration. The signal word is "DANGER" based on the primary eye irritation study.

The registrant should be informed that when conducting future primary eye irritation studies, observations should be conducted for 21 days or until all eye irritation subsides, whichever comes first.

FHB/TSS cannot waive the dermal sensitization study at this time. A dermal sensitization study (Accession No. 265409) referenced to support this waiver was received by the Agency on October 20, 1986. These data have not been reviewed and have not even been forwarded to TSS for review. In addition, the most recently accepted label (dated January 1, 1986) on file in the jacket for the technical (7969-42) does not contain language indicating that 7969-42 is a sensitizer.

Therefore, TSS recommends that the PM team forward the dermal sensitization study on 7969-42 (Accession No. 265409) to TSS for review and at the same time, resubmit the request for a waiver of the dermal sensitization study for 7969-TA.

LABELING:

1. Add "irreversible" to the first sentence under the precautionary statements so that it reads as follows: "Causes irreversible eye damage."

2. Add the following sentence to the precautionary statements: "Wash thoroughly with soap and water after handling."

3. Revise Statement of Practical Treatment for oral exposure as follows: "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."

REVIEW:

(1) Acute Oral Toxicity Study: Basf Aktiengesellschaft Department of Toxicology; RZ Report No. 85/254; May 21, 1985.

PROCEDURE:

Four groups each consisting of five male and five female Wistar rats were administered by gavage a single oral dose of test material in water as follows: 825, 1210, 1780, or 2610 mg/kg.

Animals were observed several times on day of dosing, twice on workdays and at least once on holidays for 14 days. Animals were necropsied at study conclusion.

RESULTS:

At 825 mg/kg, no deaths occurred. At 1210 mg/kg, 3/5 females died. At 1780 mg/kg, 2/5 males and 5/5 females died. At 2620 mg/kg, 5/5 males and 5/5 females died. The combined LD_{50} was reported to be 1470 mg/kg with 95% confidence limits of 1240-1740 mg/kg.

Toxic symptoms observed were dyspnea, apathy, staggering, paresis, twitching, piloerection, exsiccosis, and general congestive hyperemia. No abnormalities were noted at gross necropsy.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(2) Acute Dermal Toxicity Study: Basf Aktiengesellschaft Department of Toxicology; RZ Report No. 85/255; May 15, 1985.

PROCEDURE:

Five male and five female Wistar rats each received 2000 mg/kg of test material which was applied to the clipped dorsal and dorsolateral parts of each animal's trunk. The test sites were covered with occlusive wrap for 24 hours. After exposure, the wrap was removed and the test sites were washed with water. Animals were observed frequently on day of dosing and at least once daily thereafter for 14 days. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred. The LD_{50} was reported to be > 2000 mg/kg. No toxic symptoms and no abnormalities at gross necropsy were noted.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(3) Primary Skin Irritation Study: Basf Aktiengesellschaft Department of Toxicology; RZ Report No. 85/169; April 19, 1985.

PROCEDURE:

Three male and three female white Vienna rabbits were clipped free of fur on the back and approximately 15 hours later, each animal received 0.5 ml of test material which was applied to a test patch that was placed on the test site. The test patch was covered with semiocclusive wrap for 4 hours. After exposure, the wrap was removed and the test site was washed with a 1:1 solution of lutrol and water. Skin irritation was scored at 4, 24, 48, and 72 hours.

RESULTS:

No irritation was observed at 24, 48, or 72 hours.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

(4) Primary Eye Irritation Study: Basf Aktiengesellschaft Department of Toxicology; RZ Report No. 85/170; April 23, 1985.

PROCEDURE:

Four male and two female white rabbits each received 0.1 ml of test material which was placed in the conjunctival sac of the right eye. Eye irritation was scored at 1, 24, 48, and 72 hours and at 8 days.

RESULTS:

Eye irritation was scored as follows: at 24 hours, corneal opacity (1/6 = 10, 5/6 = 5), conjunctivae redness (1/6 = 3, 5/6 = 2), conjunctivae swelling (2/6 = 2, 4/6 = 1); and at 8 days, corneal opacity (1/6 = 15, 2/6 = 10, 3/6 = 5), iris irritation (2/6 = 10, 2/6 = 5), conjunctivae redness (2/6 = 3, 1/6 = 2, 3/6 = 1) and conjunctivae swelling (1/6 = 2, 1/6 = 1).

At 8 days, animals exhibited small retractions in eyelids, marginal vascularization of the cornea, panmus, pupils contracted, suppuration, and detachment of cornea.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY:

I - DANGER. See comments under Recommendations.

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(5) Acute Inhalation Toxicity Study: Basf Aktiengesellschaft Department of Toxicology; RZ Report No. 86/037; May 28, 1985.

PROCEDURE:

Ten male and ten female Wistar rats were exposed for 4 hours in a nose only inhalation chamber to a mean analytically measured concentration of 5.53 mg/L of test material. Animals were weighed prior to testing and at 7 and 14 days. Animals were observed daily and necropsied on the 15th day.

RESULTS:

No deaths occurred. The LC_{50} for males and females was reported to be > 5.5 mg/L. No toxic symptoms or abnormalities at necropsy were noted.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

Acifluorfen

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