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

009742

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Methylisothiocyanate (MITC)
Phase IV Data Response

Submission No. S421372
Submission No. S424582
Chem No. 068103
Tox Chem No. 573

FROM: Ray Landolt *9/10/92*
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and
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J.M. Korman 9/11/92

M. van Gemert 9/15/92

Registrant: Degussa Corporation (Pazianos Associates), letter of June 19, 1992

Action Requested: The registrant has provided information on the acute dermal (81-2) and inhalation (81-3) toxicity studies found deficient during the Phase IV Data Review.

Conclusion:

1. The acute dermal toxicity studies in the rat (Acc No. 264384) and rabbit (Acc No. 264385) are acceptable and support the registration of technical MITC.
2. The acute inhalation toxicity study (Acc No. 264386) is acceptable and support the registration of technical MITC.

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Consideration Given this Request

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The acute dermal and inhalation toxicity studies conducted with MITC were initially reviewed (DER 006165) May 5, 1987 and classified Core Guideline. Subsequently, during the Phase IV Data Review the acute studies listed in DER 006165 were subjected to the acceptance criteria of November 7, 1989. Data evaluation report 006165 was not adequate to evaluate the testing parameters of the acute dermal and inhalation toxicity studies. With reference to the MITC-Fume Manual, the technical material is crystalline at 68°F and a liquid at 94°F.

1. Acute dermal toxicity study - rabbits, RCC No. 50747 (Acc No. 264385)
Acute dermal toxicity study - rats, RCC No. 042658 (Acc.No. 264384)

The following data were requested: "concentration and volume applied" and "whether the (dermal) LD₅₀ value reported is relative to the MITC in PEG 400 or to the technical material".

The registrant has provided the following information for the rabbit dermal toxicity study.

"The test substance was applied undiluted, pure TGAI was used. Volumes/doses of 0.05 ml to 0.30 ml pure TGAI per kg body weight (50 mg/kg to 300 mg/kg were applied."

"The value of the LD₅₀ reported is relative to MITC technical material (TGAI)." MRID 423656-04

The registrant has provided the following information for the rat dermal toxicity study.

"For the animals of group 1 (60 mg/kg) a weight/volume dilution of 6 parts MITC (TGAI) and 94 parts PEG 400 (polyethylene glycol) was prepared. Volumes/doses of 1 ml of this dilution per kg body weight were applied."

"Similarly for animals of group 2 (120 mg/kg) a weight/volume dilution of 12 parts MITC (TGAI) and 88 parts PEG 400 was prepared. Volumes/doses of 1 ml of this dilution per kg body weight were applied."

"For animals of groups 3 and 4 (250 and 600 mg/kg) undiluted MITC (TGAI) was used. Volumes/doses of 0.25 ml and 0.60 ml pure TGAI per kg body weight were applied."

"The value of the LD₅₀ reported is relative to MITC technical material (TGAI)." MRID 424435-01

The registrant has addressed the concerns raised in the Phase IV Data Review. These dermal toxicity studies, conducted in the rat and rabbit, are acceptable and support the registration of the technical MITC.

Consideration Given this Request (con't)

2. Acute inhalation toxicity study No. RCC 042660 (Acc No. 264386)

The registrant has provided the following information on "how the vapor concentrations were generated".

"Pressurized air was passed through a fine filter, a pressure stabilizer, a volume governor and a volumeter and then through a special gas washing bottle fitted with a D1 fritted glass filter. MITC (TGAI) was maintained above the glass filter at a constant level. Temperature of MITC was held at 40°C (104°F) using a water bath. Temperature of air was 22°C (72°F).

After the air had passed the gas washing bottle, the air containing the volatilized MITC was blown through the 100 L polyvinylchloride nose-only chambers.

For monitoring the concentration of MITC in the air, a gas chromatography equipment was used". MRID 423656-05

The registrant has addressed the concerns raised in the Phase IV Data Review of the acute inhalation study conducted with the technical MITC. This study is acceptable and supports the registration of MITC.