EPA Reviewer: Anna Lowit, Ph.D. **Signature:** _____
Reregistration Branch 2, Health Effects Division (7509C) **Date** _____
EPA Secondary Reviewer: Judy Facey, Ph.D. **Signature:** _____
Reregistration Branch 2, Health Effects Division (7509C) **Date** _____

Template version 11/01

TXR#: 0051394

DATA EVALUATION RECORD

Updated Executive Summary to Previous TXR # 003991

STUDY TYPE: 30-Day Dermal Toxicity - rat; OPPTS 870.3250 (rodent) [§82-3]; OECD 411.

PC CODE: 068103 **DP BARCODE:** D284267
SUBMISSION NO.: S618557

TEST MATERIAL (PURITY): MITC (purity not given)

SYNONYMS: Methyl isothiocyanate

CITATION: Tsubura, Y.; Watanabe, F.; Shimomura, H.; et al. (1983) One-month Toxicological Study of MITC in Rats by Dermal Application. Prepared by Nara Medical College, Dept. 2 of Pathology, Japan, submitted by Nor-Am Agricultural Products, Inc., Naperville, IL; CDL: 251810-H, Nov 28, 1983. MRID 00132815. Unpublished.

SPONSOR: Nor-Am Agricultural Products

EXECUTIVE SUMMARY:

In a 30-day dermal toxicity study (MRID 00132815, MITC (% ai, and lot no. not provided) was dissolved in benzol and applied to a 4x4 cm area of skin of 10 Sprague Dawley rats/sex/dose at 0, 0, 120, 240, or 480 mg/kg/day during a 30-day period. Exposure duration (ie, number of hours per day or days/week) is not given in the study. (However, MITC is expected to volatilze quickly).

No changes in urinalysis was noted. Two animals died during the study: one each in the control and low dose groups. A large abscess in the lung was attributed as the cause of death in each case.

At termination, body weight and body weight gain were decreased in all dose groups(-60% to -70% in males and -20% in females). Although no changes in water consumption were noted, decreased food consumption was noted in all treatment groups.

Dermal ulceration was obsereved in all treatment groups within two weeks. The degree ofulceration was dose related and accompanied by severe cornification and necrosis of the exposed area.

The systemic LOAEL is 120 mg/kg/day, based on decreased body weight gain and food intake. The NOAEL was not established (< 120 mg/kg/day).

This 30-day dermal toxicity study in the rat is **unacceptable-guideline** and does **not** satisfy the guideline requirement for a subchronic dermal toxicity study (OPPTS 870.3250 ; OECD 411) in rat. This study has numerous deficiencies and can not be upgraded; a NOAEL was not identified.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were not provided.

DATA FOR ENTRY INTO ISIS

Subchronic Dermal (90 day) Study - rodents (870.3250)

PC code	MRID	Study	Species	Duration	Route	Admin	Dose range mg/kg/day	Doses mg/kg/day	NOAEL mg/kg/day	LOAEL mg/kg/day	Target organ	Comments
068103	00132815	subchronic	rat	30 days	dermal	dermal	120-480	0, 120, 240, 480	Not established	120	body weight decreased	Systemic
068103	00132815	subchronic	rat	30 days	dermal	dermal	120-480	0, 120, 240, 480	Not established	120	Skin–necrosis	Dermal