



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

MAR 18 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Primary Dermal Irritation 6(a)(2) Data Review for EPA
Regno. 279-3160, DP Barcode D234285

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

MJP
3/18/97

To: G. LaRocca, PM-13 / S. Willett
Registration Division

Applicant: FMC Corporation
APG Specialty Products
Princeton, NJ 08543

BACKGROUND

FMC Corporation has submitted a primary dermal irritation study under section 6(a)(2) of FIFRA. The study was performed with an alternate formulation (10/2/96 CSF) of Talstar 13% MUP Insecticide/ Miticide, EPA Regno. 279-3160. A primary dermal irritation study was previously performed with the basic formulation of this product (MRID# 437584-05). That study was assigned a category II classification by the Agency (2/27/96 PRS review). Talstar 13% MUP Insecticide/ Miticide contains bifenthrin (13%) as the sole active ingredient. The subject study was performed by FMC Corp. and has been assigned the MRID number 442262-01.



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RECOMMENDATION

1. Dermal Irritation; Category I / Self-validated

Based on the category I results, a complete review of this study was not performed. A category I classification is considered appropriate due to the presence of grade 4 erythema with severe eschar and moderate to severe fissuring in two animals at the 72 hour observation. These results indicate that significant injuries in depth were present in these animals at or beyond the indicated observation period.

Note To PM: Because the alternate formulation tested in this study requires different precautionary labeling from the basic formulation, it is not an acceptable alternate. An alternate formulation, by definition, may not have different precautionary labeling from the corresponding basic.

LABELING (Based on 10/2/96 alternate CSF)

1. The recommended signal word is "Danger."
2. The recommended precautionary statements are as follows

Corrosive. Causes skin burns. May be fatal if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Do not get on skin or on clothing. Avoid contact with eyes. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

3. The recommended first aid statements are as follows:

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.
May pose an aspiration pneumonia hazard.

4. The statement "Contains Petroleum Distillate" should appear in close proximity to the ingredient statement.

ACUTE TOX ONE-LINER

1. PC CODE: 128825
2. CURRENT DATE; 3/18/97
3. TEST MATERIAL: Bifenthrin 13%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
81-5, Rabbit, FMC Corp., A96-4548, 1/10/97	442262-01	Severe irritation and eschar at 72 hrs.	I	V

Core Grade Key:

- A = Acceptable
- S = Supplementary
- U = Unacceptable
- V = Self-validated

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ID #: 000279-03160 TALSTAR 13% MUP INSECTICIDE/MITICIDE

INGREDIENT LABELING:

Contains Petroleum Distillate.

SIGNAL WORD: DANGER**PRECAUTIONARY STATEMENTS:**

Corrosive. Causes skin burns. May be fatal if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Do not get on skin or on clothing. Avoid contact with eyes. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

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. If person is unconscious, do not give anything by mouth and do not induce vomiting.

OR

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, or if available by administering syrup of ipecac. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention. For Category III, add "if symptoms persist."

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

NOTE TO PHYSICIAN:

The proposed label should contain a Note to Physicians. Some suggested types of information include the following:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

More...

ID #: 000279-03160 TALSTAR 13% MUP INSECTICIDE/MITICIDE

NOTE TO PHYSICIAN (Cont.):

Probable mucosal damage may contraindicate the use of gastric lavage.

The proposed label should contain the following guidance:

May pose an aspiration pneumonia hazard.

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