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CASWELL FILE

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 3125-GTG
Monitor 480 Concentrate

FROM: William S. Woodrow WSW 11-28-89
Precautionary Review Section
Registration Support Branch E 11/29/89
Registration Division (H7505C)

TO: William Miller (PM 16)
Insecticide - rodenticide Branch
Registration Division (H7505C)

APPLICANT: Mobay Corporation
Agricultural Chemicals Division
P.O. Box 4913
Kansas City, Missouri 64120-0013

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Methamidophos (o,S-dimethyl phosphoramidothioate)	40.0
Inert Ingredient(s):	60.0
Total	100.0%

BACKGROUND:

Mobay Corporation responded to an EPA Aug 8, 1986 letter requesting:

a. Additional information for acute dermal toxicity study # 67995, and;

b. Submit a dermal sensitization study (using Monitor 480 Concentrate).

These concerns refer to EPA # 3125-GTG, Monitor 480 Concentrate. MRID NOS. 410240-002 -02

RECOMMENDATIONS:

1) The acute dermal study is hereby upgraded from Supplemental Data to Core Minimum Data, and is now fully acceptable to RSB/PRS (Accession # 261604, Lab. # 67995):

a. Adequate explanation for wide 95% CL for male rabbit LD50 value

b. Adequate clinical data provided.

c. Adequate gross pathology data provided.

2) The dermal sensitization study submitted by Mobay is acceptable to RSB/PRS.

3) The acute dermal study was graded Core Minimum Data since 4/5 animals were tested per sex, instead of 5/5.

4) A complete acute toxicity listing for Monitor 480 Concentrate (3125-GTG) is shown below:

Acute oral LD_{50} Core Minimum Toxicity Category I

Acute dermal LD_{50} Core Minimum Toxicity Category II

Acute inhalation LC_{50} Core Minimum Toxicity Category II

Eye irritation Core Minimum Toxicity Category IV

Skin irritation Core Minimum Toxicity Category IV

Dermal sensitization Core Minimum

5) No additional acute toxicity data is required.

LABELING:

1) The Danger signal word is appropriate.

2) Under Precautionary Statements, add "Remove contaminated clothing and wash before reuse".

3) The Statements of Practical Treatment are appropriate.

4) The Registrant is reminded that symbolic skull and crossbones are not adequate; the actual skull and crossbones warning symbol must appear on the product label.

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DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: (16)
MRID No.: 410240-00
Testing Laboratory: Tox. Dept., Miles, Inc.
Author(s): M.C. Porter, R.E. Cruise, R.E. Wartnagle
Species: Guinea pigs
Sex: 30 Males
Source: Harlen Sprague Dawley
Test Material: monitor-4 LC (M-4), 40.2% A.I., liquid
Positive Control Material: 1-chloro, 2,4 dinitrobenzene (DNCB)
Quality Assurance (40 CFR §160.12): adequate

Reviewer: ~~M. Waller~~ Woodrow
Report Date: 11-28-89
Report No. 963
Weight: 295-362g.

Method: Modified Buehler

Summary:
1. This product is / (is not a dermal sensitizer)
2. Classification: Guidelines

Procedure (Deviation From §81-6): A preliminary screen to determine non-irritating concentration: undiluted, 25%, 10% - Undiluted caused death. Used 10% solution for main study. DNCB applied as 0.05% solution in 50% ethanol/dist. H2O.

~~Results:~~ Induction:

15 M-4 test animals
5 M-4 control (naive) animals — 30 animals
DNCB + control - 5 animals — total.
DNCB + control (naive) animals 5

0.4ml of M-4 (test) applied under adhesive patch (2x2cm) Webril pad on adhesive backing to clipped left side of 15 M animals, near scapula. DNCB similarly applied to 5 + control animals. Patches secured by elastic adhesive bandages, secured ē tape. 6hr exposures. Procedure repeated on (0 days), 7 & 14 days. Induction sites scored for erythema @ 24 & 48hrs after patch removal 0-3 scale range. Animals rested 2 weeks prior to challenge.

Challenge: Day prior to challenge, M-4 test and (naive) control animals clipped on dorsolateral

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aspect of lumbar region, and left side of each M-4 test and control animal, and on both sides of each DNCB test and control animals. One day later (day 29), the appropriate test solution (M-4 test, or DNCB) was applied near left pelvic girdle on all treated + control animals and the DNCB vehicle (60% ethanol/dist-H2O) was similarly applied to right side of DNCB test and control animals. Animals scored for erythema @ 24 + 48 hours. Prior to scoring, sites washed c warm water and depilated.

Results:

M-4 induction – no irritation/erythema

DNCB induction – 4/5 G.pigs showed erythema after 2nd + 5/5 G.p. after 3rd induction.

M-4 Challenge – no irritation, no erythema

DNCB " – slight to severe for 4/5 of DNCB treated animals; no DNCB response to naive controls.

no response to M-4 for naive controls.

Conclusions:

1) Mixture 4 L.C. (M-4) did not sensitize Guinea pigs.

2) DNCB + control chemical did sensitize Guinea pigs