

US EPA ARCHIVE DOCUMENT



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11-29-89 008829 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:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
<u>Methamidophos (O,S-dimethyl phosphoram-</u> <u>idothioate)</u>	<u>40.0</u>
_____	_____
_____	_____
<u>Inert Ingredient(s):</u> . . . . .	<u>60.0</u>
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 Monitox 480 Concentrate).

These concerns refer to EPA # 3125-GTG, Monitox 480 Concentrate. MRID NOS. 410240-007-02

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<sub>50</sub> Core Minimum

Toxicity Category I

Acute dermal LD<sub>50</sub> Core Minimum

Toxicity Category II

Acute inhalation LC<sub>50</sub> 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.

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

Product Manager: (16) Reviewer: ~~M. Waller~~ <sup>Woodrow</sup>  
 MRID No.: 410240-00 Report Date: 11-28-89  
 Testing Laboratory: Tox. Dept., Miles, Inc. Report No. 963  
 Author(s): M.C. Porter, R.E. Craig, R.E. Hartnagle  
 Species: Guinea pigs  
 Sex: 30 Males Weight: 295-362g  
 Source: Hablen Sprague Dawley  
 Test Material: monitor-4LC (M-4), 40.2% A.I. liquid  
 Positive Control Material: 1-chloro-2,4-dinitrobenzene (DNCB)  
 Quality Assurance (40 CFR §160.12): adequate  
 Method: Modified Buchler

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. H<sub>2</sub>O.

Results: Induction:

<u>15 M-4 test animals</u>	
<u>5 M-4 control (naive) animals</u>	<u>30 animals</u>
<u>DNCB + control - 5 animals</u>	<u>Total.</u>
<u>DNCB + control (naive) animals 5</u>	

0.4ml of M-4 (test) applied under adhesive patch (2x2cm) Weibull 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 c-tape. 6hr exposures. Procedure repeated on 1, 7 & 14 days. Induction sites scored for erythema @ 24 & 48hrs after patch removal 0-3 score range. Animals tested 2 weeks prior to challenge.  
Challenge: Day prior to challenge, M-4 test and (naive) control animals clipped on dorsolateral

aspect of lumbar region, and left side of each m-4 test and control animal, and on both sides of each DNFB test and control animals. One day later (day 28), the appropriate test substance (m-4 test, or DNFB) was applied near left pelvic girdle on all treated & control animals and the DNFB vehicle (50% ethanol/dist. H<sub>2</sub>O) was similarly applied to right side of DNFB test and control animals. Animals scored for erythema @ 24 & 48 hours. Prior to scoring, sites washed in warm water and depilated.

### Results:

m-4 induction - no irritation/erythema

DNFB induction - 4/5 g.p. showed erythema after 2nd & 5/5 g.p. after 3rd induction

m-4 challenge - no irritation, no erythema

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

no response to m-4 for naive controls.

### Conclusions:

- 1) Miniton 415 (m-4) did not sensitize guinea pigs.
- 2) DNFB + control chemical did sensitize guinea pigs.