

US EPA ARCHIVE DOCUMENT



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

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MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.: 279-GRRI / Prevail 4.0
Termiticide

From: Ian Blackwell, Biologist *ILB*
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

To: George LaRocca, PM 13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

E 10/7/92

Applicant: FMC Corporation
Agricultural Chemical Group
2000 Market St.
Philadelphia, PA 19103

FORMULATION FROM LABEL:

<u>Active Ingredient(s)::</u>	<u>% by wt.</u>
Cypermethrin	43.2
<u>Inert Ingredient(s):</u>	<u>56.8</u>
Total:	100.0%

134

BACKGROUND: FMC Corporation has submitted a rebuttal to a RSB/PRS review of the inhalation study of Prevail 4.0 Termiticide (also known as FMC 30980 4EW and Ammo 4 EW). The previous inhalation study was graded supplementary because, at 0.222 mg/L, the particle concentration was too low to qualify as a limit test. In their response, the registrant explained that the particle concentration reached was the maximum attainable concentration that could be reached while maintaining an acceptable percent of respirable particles.

RECOMMENDATIONS:

1. The acute inhalation toxicity study is acceptable and is classified as core-guideline data. The lab was not able to attain concentrations that would qualify as a limit test, but conducted the study using the maximum attainable concentration that would allow respirable particles. The acute inhalation toxicity study is toxicity category II.

The toxicity profile for this product is now:

acute oral	II	guideline
acute dermal	III	guideline
acute inhalation	II	guideline
primary eye irritation	IV	guideline
primary dermal irritation	IV	guideline
dermal sensitization	non-sensitizer	minimum

LABELING:

1. The signal word is "WARNING".
2. The precautionary statements should state:

"May be fatal if swallowed or inhaled. Harmful if absorbed through skin. Do not breath vapor or spray mist. Avoid contact with skin, eyes or clothing. Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove and wash contaminated clothing before reuse."

3. The statements of practical treatment should be revised as follows:

"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. Do not induce vomiting in or give anything by mouth to an unconscious or convulsing person."

"If on skin: Wash with plenty of soap and water. Get medical attention."

009120

"If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

4. The "Note To Physician" should be placed on the same page as the statements of practical treatment.
5. The statement of practical treatment for ocular exposure is not required, based on the eye irritation study. However, the registrant may retain this statement if he desires to do so.

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DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: 13
MRID No.: 417865-03

Reviewer: I. Blackwell
Report Date: 6-29-90
Report No.: A89-3133

Testing Laboratory: FMC Corporation, Toxicology Lab
Author(s): Everett Mount

Quality Assurance (40 CFR §160.12): Included

Test Material: Ammo (Formulation EW)
Concentration: 0.22 mg/l gravimetric; 0.35 mg/l analytical
Species: Sprague-Dawley rat
Weight: 222 to 270 grams
Sex: 5 males + 5 females
Source: Taconic Farms

Summary:

1. LC_{50} (mg/kg): Males > 0.222 mg/l
Females > 0.222 mg/l
Combined > 0.222 mg/l
2. The estimated LC_{50} is greater than 0.222 mg/l
3. MMAD: 2.52 μ m (At second sampling, 43.6% of particles were below 2.6 μ m)
4. Tox. Category: II Classification: guideline

Procedure (Deviation From §81-3):

Concentration was too low for limit test.
The lab used the maximum attainable concentration that would allow respirable particles.

Results:

Reported Mortality

Exposure Concentration	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
0.222 gravimetric	0/5	0/5	0/10

Clinical Observations: During exposure: difficulty breathing, nasal discharge, oral discharge, lacrimation and squinting eyes. Post exposure clinical signs were: abdominogenital staining, ataxia, decreased locomotion, swollen cheeks, chromodacryorrhea, chromorhinorrhea, lacrimation, nasal and oral discharge, rales, walking on toes and tremors.

Gross Necropsy Findings: No gross lesions were found at necropsy.

4