

US EPA ARCHIVE DOCUMENT



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

8-15-94

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM:

Subject: EPA Reg. No./File Symbol: 62719-225 / XRM-5222

From: Ian Blackwell, Biologist  
Precautionary Review Section  
Registration Support Branch  
Registration Division (H7505W)

*JDB 8/15/94*

To: Dennis Edwards, PM 19  
Insecticide-Rodenticide Branch  
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head  
Precautionary Review Section  
Registration Support Branch  
Registration Division (H7505W)

Applicant: DowElanco  
9002 Purdue Road  
Indianapolis, IN 46268-1189

FORMULATION FROM LABEL:

<u>Active Ingredient(s)::</u>	<u>% by wt.</u>
Chlorpyrifos	22.8
<u>Inert Ingredient(s):</u>	<u>77.2</u>
Total:	100.0%



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**BACKGROUND:** DowElanco has submitted an acute inhalation toxicity study to support "XRM\_5222". The study was conducted by The Toxicology Research Lab of The Dow Chemical Company. The MRID number is 427710-01.

The original acute inhalation toxicity study submitted for XRM-5222 (reg. no. 62719-225) was found to have several problems and, accordingly, was graded supplementary. The results of that 4/25/92 PRS review were:

acute oral toxicity	III	minimum
acute dermal toxicity	III	guideline
acute inhalation toxicity		supplementary
primary eye irritation	III	guideline
primary skin irritation	III	minimum
dermal sensitization	not a sensitizer	guideline

**RECOMMENDATIONS:**

The acute inhalation toxicity study is classified core-minimum data, but is acceptable to support the product. The study deficiency is that two test animals died at the limit test concentration and no other concentrations were conducted. The lab stated that no other testing was conducted because of guidelines found in the "Interim Policy for Particle Size and Limit Concentration Issues in Inhalation Toxicology". However, the lab should be made aware that a 6/23/93 (admittedly dated after the study was conducted) memo states that the death of 2/5 animals per sex will disqualify a limit test. Limit tests conducted in this manner will not be accepted by PRS in the future. Please refer the lab to 6/26/93 Elizabeth Doyle and John C. Redden memo included with this review.


The acute toxicity profile for reg. no. 62719-225 is currently:

acute oral toxicity	III	minimum
acute dermal toxicity	III	guideline
acute inhalation toxicity	IV	minimum
primary eye irritation	III	guideline
primary skin irritation	III	minimum
dermal sensitization	not a sensitizer	guideline

**LABELING:**

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

"Harmful if swallowed or absorbed through skin. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling."



The submitted label contains statements recommending the use of eye protection, protective clothing and chemical resistant gloves when handling this product. The label also recommends that individuals avoid breathing vapors or spray mist of this product. Based on the results of the acute toxicity studies and the Chlorpyrifos Registration Standard, PRS cannot determine a basis for these statements. It appears to PRS that these statements are not required; however, the registrant may retain them if desired.

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

**Product Manager:** 19  
**MRID No.:** 427710-01

**Reviewer:** I. Blackwell  
**Study Completion Date:** 4/22/93  
**Lab Project No.:** M-005222-005

**Testing Laboratory:** The Toxicology Research Laboratory, The Dow Chemical Company  
**Author:** G.J. Bradley and K.E. Stebbins

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** XRM-5222; EPA reg. no. 62719-225.  
**Concentration:** 5.07 mg/L (nose only exposure)

**Species:** Fischer 344 rat  
**Weight:** males = 249-281 g; females = 145-154 g  
**Sex:** 5 males + 5 females  
**Source:** Charles River Breeding Laboratories, Inc.

**Age:** ≈ 7 weeks

**Summary:**

1. **LC<sub>50</sub> (mg/ℓ):** Males > 5.07 mg/L  
Females > 5.07 mg/L  
Combined > 5.07 mg/L
2. **MMAD:** 2.19 μm
3. **Tox. Category:** IV                      **Classification:** core-minimum

**Procedure (Deviation From §81-3):**

■ Two females died at the limit test concentration, no other concentration was tested.

**Results:**                                      **Reported Mortality**

Exposure Concentration	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
5.07 mg/L	0/5	2/5	0/10

4

Chamber Atmosphere				
Dose Level	MMAD	GSD	particles < 6.1 $\mu\text{m}$	particles < 3.0 $\mu\text{m}$
5.07 mg/L	2.19 $\mu\text{m}$	2.17 $\mu\text{m}$	91.4	66.5%

Chamber Environment	
Airflow	30 lpm
Temperature	21 °C
Target Relative Humidity	22 $\pm$ 12%

**Clinical Observations:** Labored breathing, noisy breathing; soiled fur; redness at nares, chromodacryorrhea.

**Gross Necropsy Findings:** Gas in digestive tract, hemolysed blood, perineal soiling, mucoid exudate; hemolysed blood in stomach, erosions and/or ulcers in stomach.

5

6

ACUTE TOX ONE-LINER

1. PC CODE: 059101
2. CURRENT DATE: August 12, 1994
3. TEST MATERIAL: Chlorpyrifos ... 22.8%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
acute inhalation toxicity / rat / The Toxicology Research Lab, The Dow Chemical Company / M-005222-005 / 4-22-93	427710-01	LC <sub>50</sub> > 5.07 mg/L for both males and females.	IV	M

Core Grade Key:

- G = Guideline  
M = Minimum  
S = Supplementary
- 6