



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

008536

SEP 3 1991

OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

**MEMORANDUM**

**SUBJECT:** Zinc Omadine; Review of an Acute Inhalation Toxicity Study.

EPA ID# 1258-840  
Case No. 029309

Project No. 1-1108  
Tox. Chem. No. 923

**FROM:** John E. Whalan, D.A.B.T., Toxicologist  
Section 1, Toxicology Branch I  
Health Effects Division (H7509C)

*John E. Whalan*  
8-13-91

**TO:** John Lee (PM Team # 31)  
Registration Division (H7505C)

**THRU:** Roger L. Gardner, Section Head  
Section 1, Toxicology Branch I  
Health Effects Division (H7509C)

*Roger L. Gardner* *KB*  
8-30-91 8/30/91

Olin Corporation has submitted an Acute Inhalation Study of zinc omadine in accordance with FIFRA Section 6(a)(2). This study satisfied data requirement 81-3 for an Acute Inhalation Toxicity study, and met the criteria for Toxicity Category II.



Reviewed by: John E. Whalan *JW 8-30-91* GUIDELINE: 81-3  
Section I, Tox. Branch I (IRS) (H7509C)  
Secondary reviewer: Roger L. Gardner *Roger Gardner 8-30-91*  
Section I, Tox. Branch I (IRS) (H7509C)

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DATA EVALUATION REPORT

**STUDY TYPE:** Acute Inhalation Toxicity in Rats

**MRID NO:** 417764-01

**TOX. CHEM. NO.:** 923

**TEST MATERIAL:** Zinc Omadine FPS (48% a.i.)

**SYNONYMS:** Zinc Omadine

**STUDY NUMBER(S):** 397-050

**SUBMITTED BY:** Olin Corporation

**TESTING FACILITY:** International Research and Development Corporation

**TITLE OF REPORT:** Acute Inhalation Toxicity Evaluation in Rats

**AUTHOR(S):** C. E. Ulrich

**REPORT ISSUED:** January 2, 1991

**CONCLUSIONS:** The LC<sub>50</sub> for the combined sexes was 0.14 (0.1-0.2) mg/l. Male and female LC<sub>50</sub>'s were not calculated. Clinical signs included prostration, gasping, labored breathing, rales, nasal discharge, lacrimation, trembling, hunched posture, suspended weight gain, and death. Gross observation revealed congestion of the respiratory tract, and test material accumulation in the trachea and esophagus (presumably from licking the fur).

**STUDY CLASSIFICATION:** This study is **Acceptable**, and satisfies data requirement 81-3 for an Acute Inhalation Toxicity study; **Toxicity Category II**. The analytical information reveals as much as 2-fold variability in chamber concentration for some groups. Particle size distribution was only reported for one group (Group III). Probit analysis was not calculated for males or females, but rather for combined sexes only. It was peculiar that of only two deaths during exposure, one was a female in the lowest concentration group. There was no discussion of this in the report (i.e. no mention of possibly being an accidental death. This study received Quality Assurance review.

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**PROTOCOL:** Male and female Sprague-Dawley rats were received over a period of 6 weeks. Their ages at the time of exposure ranged from 50 to 70 days. The rats were individually housed throughout the study. They were assigned to six groups of 5 males and 5 females. Food and water were available ad libitum, except during exposure.

Each group was dynamically exposed (whole body) to an aerosol of the test article for 4 hours in a 160 liter glass and stainless steel chamber. Distilled/deionized water was used to dilute the test article.

A pneumatic atomizer was used to generate the aerosols. In order to generate sufficient test article for the two highest exposure groups (Groups I and II) the test article was generated directly into the chamber. The test article atmosphere for the other groups was generated into an atomization chamber prior to the exposure chamber. Particle size distribution was measured with an Anderson® 8-stage cascade impactor.

The rats were not observed for clinical signs during exposure, but they were examined upon removal from the chambers, and daily thereafter. Body weights were measured prior to exposure, on days 7 (or 8) and 14, and at the time of interim death. Surviving rats were sacrificed on day 14. All rats were necropsied, and their major thoracic and abdominal organs were examined.

**RESULTS:** The following table summarizes the nature of the chamber atmospheres:

Group*	Nominal Conc. (mg/l)	Analytical Conc. (mg/l)	MMAD (gsd) ( $\mu$ m)	<1 $\mu$ m
I	65	1.5	5.3 (1.94)	NA
II	37	1.4	5.1 (2.02)	NA
III	3.0	0.82	4.0 (1.81)	11%
IV	2.1	0.16	3.2 (1.72)	NA
VI	1.0	0.14	2.8 (1.81)	NA
VIII	0.37	0.054	3.0 (1.74)	NA

\* There were no Groups V or VII.

These data show that particle size increased with chamber concentration. The mortality pattern was as follows (all groups had 5 animals/sex):

Anal. Conc. (mg/l)	Exposure		Post-Exp.		Day 1		Day 2		Day 3		Total	
	♂	♀	♂	♀	♂	♀	♂	♀	♂	♀	♂	♀
1.5			1		4	4			1		5	5
1.4	1				4	4			1		5	5
0.82			2		3	3		2			5	5
0.16					4	2	1				5	2
0.14					2	1					2	1
0.054		1									0	1

The  $LC_{50}$  for the combined sexes was calculated to be 0.14 mg/l with 95% confidence limits of 0.1 to 0.2 mg/l. There was no attempt to perform a probit analysis for males or females alone.

Clinical signs noted upon removal from the chambers included prostration, gasping, labored breathing, rales, nasal discharge, lacrimation, trembling, hunched posture, and death. Labored breathing and the death of one female were observed in the lowest concentration. Body weight gain in the three lowest concentration groups (IV, VI, and VIII; the only ones with survivors) was suspended on day 7, but increased on day 14. Gross observation revealed congestion of the respiratory tract, and test material accumulation in the trachea and esophagus (presumably from licking the fur).