(UNDATED)

DATA EVALUATION RECORD

STUDY TYPE: ACUTE INHALATION TOXICITY TESTING (870.1300 formerly §81-3)

Product Manager: 23 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: GF-443; 21.9% XDE-638

SYNONYM: XDE-638 240 SC Formulation

CITATION: Landry, T.D. and Houtman, C.E. (2001) GF-443: acute liquid aerosol inhalation toxicity in Fischer 344 rats. Toxicology & Environmental Research and Consulting, The Dow Chemcial Company, Midland, Michigan. Laboratory Report Number 011173. December 21, 2001. MRID 45830819. Unpublished.

SPONSOR: Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268

EXECUTIVE SUMMARY: In an acute inhalation toxicity study, five young adult, Fischer 344 rats/sex (Weight: 203-212 g males; 127-133 g females; Source: Charles River, Inc., Raleigh, NC) were exposed by nose-only inhalation to GF-443 (Lot # E-828-59/TSN102739; 21.9% XDE-638; white opaque liquid) at 0.74 mg/L for a 4 hour period. Body weights were obtained prior to exposure and on days 2, 4, 8, 11 and 15. All animals were observed for clinical signs of toxicity and mortality during the exposure and for 14 days post exposure. Gross necropsies were performed on all animals.

Inhalation LC_{50} Males = > 0.74 mg/L (observed)
Inhalation LC_{50} Females = > 0.74 mg/L (observed)

GF-443 is classified as Toxicity Category III based on the observed LC_{50} value in the both sexes.

One female was found dead during the exposure. Its head was tucked between the forelimbs in the restraint tube. The other nine animals survived the exposure and the two-week observation period. Clinical signs noted were soiling of the haircoat during the exposure. Following the exposure, clinical signs included periocular, perineal and general body soiling. The animals appeared normal by day 3. All animals lost weight during the first few days of the study but all animals exceeded initial body weights by the end of the study. At necropsy on day 15, there were no visible lesions attributable to exposure noted in any of the surviving animals. In the animal that died, necropsy observations showed "no significant internal or external findings that would indicate cause of death. The absence of findings is consistent with suffocation as a cause of death." The gravimetric chamber concentration was 0.74 mg/L. The mass median aerodynamic diameter was 3.28 µm with a geometric standard deviation of 1.58.

(1)

This study is classified as Acceptable (870.1300) and satisfies the guideline requirement for an acute inhalation study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS:

Exposure Concentration mg/L (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
0.74	0/5	1/5	1/10

Chamber Atmosphere		
Gravimetric conc. mg/L	MMAD µm	GSD
0.74	3.28 [a]	1.58

[a] 91.3% of the particles were < 6 µm

Chamber Environment	
Chamber Volume	42 L
Airflow	30 LPM
Temperature	20-22 °C
Relative Humidity	72-79%

OBSERVATIONS: One female was found dead during the exposure. Its head was tucked between the forelimbs in the restraint tube. The other nine animals survived the exposure and the two-week observation period. Clinical signs noted were soiling of the haircoat during the exposure. Following the exposure, clinical signs included periocular, perineal and general body soiling. The animals appeared normal by day 3. All animals lost weight during the first few days of the study but all animals exceeded initial body weights by the end of the study.

GROSS NECROPSY: At necropsy on day 15, there were no visible lesions attributable to exposure noted in any of the surviving animals. In the animal that died, necropsy observations showed "no significant internal or external findings that would indicate cause of death. The absence of findings is consistent with suffocation as a cause of death."