Reviewer: Byron T. Backus, Ph.D. **Date: October 5, 2007**
Risk Manager (EPA): James Stone, RM Team 23

STUDY TYPE: Acute Inhalation Toxicity - Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: XDE-742 TGAI (Pyroxsulam; Purity: 98%; Batch No. E0952-52-01; a light tan solid (powder)

CITATION: Lowe, C. (2007) XDE-742 TGAI - Acute Inhalation Toxicity Study in Rats – Limit Test. PSL Study No. 21954. Unpublished study prepared by Eurofins | Product Safety Laboratories, Dayton, NJ 08810. 36 p. Study Completed: August 1, 2007. MRIDs 47236401 and 47237001 (duplicates of the same study).

Lowe, C. (2007) Study Profile Template (SPT) for XDE-742 TGAI: Acute Inhalation Toxicity Study in Rats – Limit Test. PSL Study No. 21954.SPT. Unpublished study prepared by Product Safety Laboratories, Dayton, NJ 08810. 7 p. August 1, 2007. MRID 47236402.

SPONSOR: The Dow Chemical Company, Midland, MI 48674 (for Dow AgroSciences LLC, Indianapolis, IN 46268).

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 47237001 and 47236402) five young adult Fischer 344 rats/sex (age: 9 weeks; weight: 211-224 g males; 156-169 g females; source: Harlan, Indianapolis, IN) were exposed nose only via the inhalation route to XDE-742 TGAI (Lot #E0952-52-01, TSN103826; 98.0% pyroxsulam, a light tan solid) for 4 hours. The time weighted average concentration of the test material (gravimetrically determined) was 5.12 mg/L; the mean mass aerodynamic diameter was 3.6 µm and the GSD was 1.87. Following exposure, rats were observed for 14 days.

All the rats survived. Some (5/5 males and 1/5 females) had slight weight losses (1-6 g) on day 1, but all showed weight gains in the period from day 0 to 7 and again from day 7 to 14. All rats appeared normal during exposure. Following exposure all rats appeared active and healthy, with no signs of toxicity or abnormal behaviour. No abnormalities were observed at gross necropsy.

LC_{50} Males	> 5.12 mg/L (0/5 died)
LC_{50} Females	> 5.12 mg/L (0/5 died)
LC_{50} Combined	> 5.12 mg/L (0/10 died)

XDE-742 TGAI (Lot #E0952-52-01, TSN103826, 98.0% pyroxsulam) has an LC_{50} > 5.12 mg/L and is in EPA Toxicity Category IV.

This acute inhalation study is classified as Acceptable. It does satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

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

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Gravimetric Conc. (mg/L)	MMAD µm	GSD	Mortality/Number Tested		
				Males	Females	Combined
15.52	5.12	3.6	1.87	0/5	0/5	0/10

Test Atmosphere / Chamber Description:

Chamber Volume:	**6.7 L**
Mean AirFlow:	**31.6 LPM**
Temperature:	**21-23°C**
Relative Humidity:	**47-50%**
Time to Equilibrium (T_{99}):	**1.0 min.**

Test Atmosphere Concentration: Gravimetric samples were collected from the breathing zone of the animals at six intervals during the exposure. The gravimetric concentration was determined by drawing a sample of the aerosol through a pre-weighed glass fiber filter. The change in weight of the filter (mg) was then determined and this value was divided by the volume of the chamber atmosphere sampled (L).

Particle Size Determination: Particle size was determined twice during the exposure using an eight-stage Andersen cascade impactor. The filter paper collection stages were weighed before and after sampling to determine the mass collected on each stage. The aerodynamic mass median diameter and geometric standard deviation were determined graphically using two-cycle logarithmic probit axes.

The mass median aerodynamic diameter and geometric standard deviation of the sampled particles were 3.6µm and 1.87, respectively. The percentage of particles ≤ 4.7 µm was 65%.

A. Mortality – None. All 10 (5M & 5F) rats survived the 14-day observation period.

B. Clinical observations - Some (5/5 males and 1/5 females) had slight weight losses (1-6 g) on day 1, but all showed weight gains in the period from day 0 to 7 and again from day 7 to 14. All rats appeared normal during exposure. Following exposure all rats appeared active and healthy, with no signs of toxicity or abnormal behaviour.

C. Gross Necropsy - No gross abnormalities were noted.

D. Reviewer's Conclusions: This reviewer agrees with the study author that the LC_{50} > 5.12 mg/L. The test material is in EPA Toxicity Category IV in terms of its inhalation toxicity.

E. <u>Deficiencies</u>: None.