DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS 870.1300)
(NOSE-ONLY EXPOSURE)

Product Manager: 33
MRID No.: 481955-04

Reviewer: CSC and Ian Blackwell
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Study No.: 28648

Testing Laboratory: Eurofins | PSL, Dayton, NJ
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Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA).

Test Material: Ygiene 206, Batch #: 9001F1 / Colorless clear liquid

Species: 10 Rats; Sprague-Dawley derived, albino
Sex: 5 Males and 5 Females. Females were nulliparous and non-pregnant.
Age: Young adult (8-9 weeks old)
Weight: Males: 245-287 grams; Females: 183-216 grams; at experimental start
Source: Ace Animals, Inc., Boyertown, PA
Housing: Temperature Range: 19-22°C
Humidity Range: 41-59%
Photoperiod: 12-hour light/12-hour dark cycle
Acclimation: 7 days

Concentration:

Group	Gravimetric Exposure Concentration (mg/L)	Nominal Concentration (mg/L)
I	2.15	5.33

Summary:

1. **LC_{50} (mg/L) 4-hr exposure**: >2.15 mg/L in male and female rats

2. **The estimated 4-hr acute inhalation LC_{50} of Ygiene 206 is greater than 2.15 mg/L in male and female rats.**

3. **Average MMAD**: 1.4 µm at the 2.15 mg/L exposure level

4. **Toxicity Category**: IV **Classification**: Acceptable

Procedure (Deviations from 870.1300):

- The laboratory reported the following protocol amendment: "Gravimetric concentration will be determined by using 37 mm glass fiber filters (GF/B Whatman or equivalent) in filter holders attached by Tygon tubing to an electric vacuum pump."
- The guidelines state that the animals should be acclimated and heat stressed minimized. The laboratory did not indicate whether animals were acclimated to exposure conditions and heat stress minimized.
- The guidelines state that body weight changes should be calculated and recorded when survival exceeds 1 day. Individual body weights of test animals were recorded; however, body weight changes were not reported.

Results:

Reported Mortality

Exposure Concentration (mg/L)	Number Dead / Number Tested		
	Males	Females	Combined
2.15	0 / 5	0 / 5	0 / 10

Chamber Atmosphere

Exp. Conc. (mg/L)	Sample	MMAD (µm)	GSD (µm)	Cumulative % of Particles < Effective Cutoff Diameter (µm)[1]								
				0.0	0.4	0.7	1.1	2.1	3.3	4.7	5.8	9.0
2.15	1	1.4	2.77	0.0	6.0	21.3	44.8	66.1	78.1	87.4	91.8	97.3
	2	1.4	3.02	0.0	10.7	25.1	47.9	65.6	77.2	86.5	91.2	96.7

[1]Percent of particles smaller than corresponding effective cutoff diameter

Chamber Environment During Exposure

Exposure Level (mg/L)	2.15
Chamber Volume (L)	~6.7
Average Total Airflow Volume (Lpm)[1]	25.7
Air Changes Per Hour	~230
Mean Oxygen Content (%)	not reported
Temperature Range (°C)	21-23
Relative Humidity Range (%)	34-38

[1]Total air = compressed air + diluent air

Clinical Observations:

All animals survived exposure to the test atmosphere and gained body weight over the 14-day observation period. Following exposure, all animals appeared active and healthy over the entire 14-day observation period. No signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior were observed.