

**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
Completion Date: April 19, 2010
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. LC₅₀ (mg/L) 4-hr exposure:** >2.15 mg/L in male and female rats
- 2. The estimated 4-hr acute inhalation LC₅₀ 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 |

¹Percent 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 |

¹Total 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.