US ERA ARCHIVE DOCUMENT

# DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)

**Product Manager**: 33 MRID No.: 481955-03

**Reviewer**: CSC and Ian Blackwell **Completion Date**: April 19, 2010

**Study No.**: 28647

Testing Laboratory: Eurofins | PSL, Dayton, NJ

Author: Jennifer Durando, B.S.

**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

Dosage:

5,000 mg/kg (applied as received)

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: 219-239 grams; Females: 184-200 grams; at experimental

start

Source:

Ace Animals, Inc., Boyertown, PA

Housing:

Temperature Range: 20-23°C Humidity Range: 50-66%

Photoperiod:

12-hour light/12-hour dark cycle

**Acclimation**: 7 days

**Summary**:

1. Acute Dermal LD<sub>50</sub> (mg/kg):

Male and Female Rats: >5,000

mg/kg

2. The estimated acute dermal LD<sub>50</sub> is greater than 5,000 mg/kg in male and female rats.

3. Toxicity Category: IV

**Classification**: Acceptable

## Procedure (Deviations from 870.1200):

- No procedure deviations were reported.
- The guidelines state that body weight changes should be calculated and recorded when survival exceeds one day. Individual body weights of test animals were recorded; however, body weight changes were not reported.

#### Results:

**Reported Mortality** 

Dose Level	Number Dead / Number Tested		
(mg/kg)	Males	Females	Total
5,000	0/5	0/5	0 / 10

### **Observations:**

All animals survived exposure to the test substance and gained body weight during the study. Following application, three male animals and all of the female animals exhibited red urine and/or ano-genital staining, but recovered from these symptoms by Day 3, and, along with the other animals, appeared active and healthy for the remainder of the 14-day observation period. No dermal irritation was observed at any dose site.

## **Gross Necropsy Findings:**

No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.