

DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OPPTS 870.2500)

Product Manager: 33
MRID No.: 481955-06

Reviewer: Ian Blackwell
Completion Date: April 19, 2010
Study No.: 28650

Testing Laboratory: Eurofins | PSL, East Brunswick, 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: 0.5 mL (applied as received)

Species: 3 Rabbits; New Zealand, albino
Sex: Females. Females were nulliparous and non-pregnant.
Age: Young adult (specific age not provided)
Weight: Information not provided (and not required)
Source: Robinson Services, Inc., Clemmons, NC
Housing: Temperature Range: 19-22°C
Humidity Range: 30-70%
Photoperiod: 12-hour light/12-hour dark cycle

Acclimation: 13 days

Summary:

1. **Toxicity Category:** III (moderately irritating)
2. **Classification:** Acceptable

Procedure (Deviations from 870.2500):

- No procedure deviations were reported.
- The guidelines recommend that testing be performed using healthy adult animals. Testing was performed using young adult animals (specific age not provided).

Results:

All animals appeared active and healthy during the study. Apart from the dermal irritation noted below, there were no other signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

For the first 48 hours after patch removal, all three treated sites exhibited well-defined to moderate/severe erythema and very slight to moderate edema. Desquamation was noted at two dose sites between Days 7 and 14. Although the overall incidence and severity of irritation decreased gradually with time, dermal irritation persisted for one animal through Day 14 (study termination).

The Primary Dermal Irritation Index for Ygiene 206 was calculated to be 3.8. [Scores for observations made during the first 30-60 minutes, 24, 48, and 72 hours were used in this calculation.] Under the conditions of this study, Ygiene 206 is classified as moderately irritating to the skin.

Incidence of Irritation

Time after Patch Removal	Erythema	Edema
30-60 minutes	3 / 3	3 / 3
24 hours	3 / 3	3 / 3
48 hours	3 / 3	3 / 3
72 hours	3 / 3	2 / 3
Day 7	2 / 3	1 / 3
Day 10	1 / 3	1 / 3
Day 14	1 / 3	0 / 3

Individual Skin Irritation Scores

Animal No.	Sex	Erythema / Edema						
		Time After Patch Removal						
		30-60 min	24 hours	48 hours	72 hours	Day 7	Day 10	Day 14
3501	F	2 / 3	3 / 2	3 / 2	3 / 2	2 / 1 ¹	1 / 1 ¹	1 / 0 ¹
3502	F	2 / 3	2 / 1	2 / 1	1 / 0	0 / 0	0 / 0	0 / 0
3503	F	2 / 3	2 / 1	2 / 1	2 / 1	1 / 0 ¹	0 / 0 ¹	0 / 0
Total		6 / 9	7 / 4	7 / 4	6 / 3	3 / 1	1 / 1	1 / 0
Mean		2.0 / 3.0	2.3 / 1.3	2.3 / 1.3	2.0 / 1.0	1.0 / 0.3	0.3 / 0.3	0.3 / 0.0

¹Desquamation

Summary of Skin Irritation Scores¹

	Time After Patch Removal						
	Hours				Day		
	1	24	48	72	7	10	14
Erythema	2.0	2.3	2.3	2.0	1.0	0.3	0.3
Edema	3.0	1.3	1.3	1.0	0.3	0.3	0.0
TOTAL (PDI)²	5.0	3.6	3.6	3.0	1.3	0.6	0.3

¹Average values for three rabbits

²PDI = Average Erythema + Average Edema