DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

Product Manager: 33
MRID No.: 481955-05

Reviewer: CSC and Ian Blackwell
Completion Date: April 19, 2010
Study No.: 28649

Testing Laboratory: Eurofins | PSL, East Brunswick, 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
Dosage: 0.1 mL (instilled 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: 20-49%
Photoperiod: 12-hour light/12-hour dark cycle
Acclimation: 34 days

Summary:

1. **Toxicity Category**: I (severely irritating)

2. **Classification**: Acceptable

Procedure (Deviations from 870.2400):

- The laboratory reported the following protocol deviation: "The humidity was below the targeted lower limit for 2 days during the study. A portable humidifier was used to raise the humidity levels during this time."
- The guidelines recommend that testing be performed using healthy adult albino rabbits. Testing was performed using young adult albino rabbits (specific age not provided).

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

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

Within 24 hours of test substance instillation, all three treated eyes exhibited corneal opacity, iritis, and "positive" conjunctivitis. The overall incidence and severity of irritation decreased thereafter. Pannus was noted for one female animal between Days 10 and 21. Two animals were free of ocular irritation within 14 days. Ocular irritation persisted for the other animal through Day 21 (study termination). The Maximum Mean Total Score of Ygiene 206 is 34.7. Under the conditions of this study, Ygiene 206 is classified as severely irritating to the eye.

Incidence of Irritation

Time Post Instillation	No. of Animals Testing "Positive" / No. of Animals Tested			Severity – Mean Score
	Corneal Opacity	Iritis	Conjunctivae	
1 hour	3 / 3	3 / 3	3 / 3	27.7
24 hours	3 / 3	3 / 3	3 / 3	34.7
48 hours	3 / 3	3 / 3	3 / 3	33.3
72 hours	2 / 3	2 / 3	3 / 3	29.7
Day 4	2 / 3	2 / 3	3 / 3	29.7
Day 7	2 / 3	2 / 3	2 / 3	24.3
Day 10	2 / 3	2 / 3	2 / 3	22.3
Day 14	1 / 3	1 / 3	1 / 3	17.7
Day 17	1 / 3	1 / 3	1 / 3	9.3
Day 21	1 / 3	1 / 3	1 / 3	9.3

Individual Scores for Ocular Irritation

Observations	Rabbit No. 3401 (Female)									
	Hours After Treatment				Days After Treatment					
	1	24	48	72	4	7	10	14	17	21
I. Corneal Opacity	1	1[1]	1	2[1,2]	2	2[1]	2[1,3]	2[3]	1[1,3]	1[1,3]
II. Iritis	1	1	1	1	1	1	1	1	1	1
III. Conjunctivae										
A. Redness	2	3	3	3	3	3	3	3	2	2
B. Chemosis	2	2	2	2	2	2	2	2	1	1
C. Discharge	2	3	2	3	3	3	2	2	1	1
Observations	**Rabbit No. 3402 (Female)**									
	Hours After Treatment				Days After Treatment					
	1	24	48	72	4	7	10	14	17	21
I. Corneal Opacity	1	1[1]	1	0[1]	0	0	0	0	0	0
II. Iritis	1	1	1	0	0	0	0	0	0	0
III. Conjunctivae										
A. Redness	2	2	2	2	2	1	1	0	0	0
B. Chemosis	2	2	2	1	1	0	0	0	0	0
C. Discharge	2	3	2	1	1	1	0	0	0	0
Observations	**Rabbit No. 3403 (Female)**									
	Hours After Treatment				Days After Treatment					
	1	24	48	72	4	7	10	14	17	21

I. Corneal Opacity	1	1[1]	1	1[1]	1[1]	1[1]	1[1]	0[1]	0	0
II. Iritis	1	1	1	1	1	1	1	0	0	0
III. Conjunctivae										
A. Redness	2	2	2	2	2	2	2	1	0	0
B. Chemosis	2	2	2	1	1	1	0	0	0	0
C. Discharge	3	3	3	2	2	1	1	1	0	0

[1]2% ophthalmic fluorescein sodium used to evaluate the extent or verify the absence of corneal opacity.
[2]Fluorescein no longer staining opacity; white light source used to confirm opacity.
[3]Pannus