

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager:18  
MRID No.:426796-01  
Testing Laboratory:Cosmopolitan Safety  
Author(s):Geoffrey Robbins  
Species:Rabbit, New Zealand White  
Sex:3 male and 3 female  
Weight:M 2.0 - 2.1, F 2.0 - 2.2 K  
Source:Laboratory Colony

Reviewer: L. Markarian  
Report Date:1/8/93  
Report No.:D3320

Dosage:o.1 g  
Test Material:BMP 123(2X WP) Lot 4922  
Quality Assurance (40 CFR §160.12):included

Summary:

1. Toxicity Category:III
2. Classification:Core minimum

Procedure (Deviations From §81-4):

Powdered test material was instilled in the conjunctival sacs of six pre examined eyes. observations were at 1, 24, 48, 72 hrs, and days 4, 7, 10, and 14. Hand held ophthalmoscope and/or slit lamp was used for evaluations. Corneal findings were confirmed with fluorescein.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	10	14
Cornea Opacity	0/6	1/6	0/6	0/6	0/6	0/6	0/6	0/6
Iris	4/6	3/6	0/6	0/6	0/6	0/6	0/6	0/6
Conjunctivae								
Redness	6/6*	3/6	1/6	6/6*	6/6*	5/6*	3/6*	0/6
Chemosis	6/6*	6/6*	6/6*	6/6*	5/6*	1/6*	3/6*	0/6
Discharge	0/6#	3/6#	2/6#	2/6#	0/6#	0/6#	0/6#	0/6#

\* grade 1 reaction, generally unremarkable

# Discharge reported, but not graded during scoring

Comments:

Blepharospasm is reported after the instillation of the test material in the eyes.

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