

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

Product Manager:18
 MRID No.: 418266-05
 Testing Laboratory:Cosmopolitan Safety
 Author(s):Geoffrey Robbins
 Species:Rabbit, NewZealand White
 Sex: 4 M and 2 F
 Weight:2.0 - 3.5 K
 Source:Not specified

Reviewer: L. Markarian
 Report Date:3/23/88
 Report No.:D1824

Dosage:0.1 g

Test Material:BMP Technical Powder 110,000 IU/mg, Lot 28, Powder
 Quality Assurance (40 CFR §160.12):Included

Summary:

1. Toxicity Category: **2**

2. Classification:supplementary

Procedure (Deviations From §81-4):

The test material was instilled in the conjunctival sacs of six pre examined eyes. Observations were at 1, 24, 48, and 72 hrs and on days 7 and 10 according to a scale similar to Draize. On this scale the laboratory states that grade 1 opacity is unremarkable. There is no evaluation of discharge. Although staining was positive in 5/6 eyes at 24 hrs the laboratory reports no opacity, and in the one eye where opacity is observed it seems to be in the area that did not stain. At 48 hrs no staining was done, and 4/5 eyes that had stained at 24 hrs were evaluated as negative for opacity. Yet at 72 hrs two of these still showed positive stain. They were still reported as negative for opacity. At 7 days no staining was observed in any eye, and the laboratory has claimed that the eyes had cleared. Grade 1 redness(4/6) and grade 1 chemosis (1/6) were present on day 7. All eyes are reported negative on day 10.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	10	21
Cornea Opacity	0/6	5/6	1/6?	3/6	-	0/6	0/6	
Iris	4/6	3/6	2/6	2/6	-	0/6	0/6	
Conjunctivae								
Redness	6/6*	6/6*	6/6*	6/6*	-	4/6*	0/6	
Chemosis	5/6	4/6	4/6*	3/6*	-	1/6*	0/6	
Discharge	-	-	-	-	-	-	-	

* Grade 1 reaction, unremarkable ? Questionable observation