

# DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager:18  
MRID No.: 418266-07  
Testing Laboratory: Cosmopolitan Safety  
Author(s):Geoffrey Robbins  
Species:Guinea Pig, Hartley

Reviewer: L. Markarian  
Report Date:4/10/88  
Report No.:F1824

Weight:300 - 500 g  
Source:Camm Research Lab Animals, Wayne, NJ  
Test Material:BMP technical Powder 110,00 IU/mg Lot 28 powder  
Positive Control Material:p-phenylenediamine  
Quality Assurance (40 CFR §160.12): Included

Method:Modified Buehler

## Summary:

1. This Product is / is not a dermal sensitizer.
2. Classification:Supplementary

## Procedure (Deviation From §81-6):

There was no pre test screening for the definition of the induction and elicitation concentrations.

The application for induction and elicitation as a paste made of 500 mg of test material with 0.7 ml of saline ( 1:1.4 w/v), on the shaved right of the animals. The applications were under 20 X 20 mm Webril Cloth patch under plastic film. The trunks of the animals were wrapped in plastic wrap. Exposure was for 6 hrs. There were three inductions applied once a week for three weeks. Elicitation was two weeks after the last induction at the induction site and at a naive site. The animals were not restrained and there were no naive controls. Reference is given to a positive control test conducted with p-phenylenediamine; however, the results of the test and the time frame in which it was conducted is not included. Evaluations were at 24 and 48 hours after inductions and challenge according to Draize. The diameter of the reaction is also given.

## Results:

All reactions were grade 1 erythema according to Draize as follows:

	I N D U C T I O N			C H A L L E N G E	
	I	II	III	INDUCTION SITE	NAIVE SITE
24 HRS	7/10	8/10	5/10	8/10	7/10
48 HRS	4/10	5/10	5/10	8/10	4/10

The laboratory has concluded that the test material is not a sensitizer.

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