

Copies to:

E. I. du Pont de Nemours and Company
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Elkton Road, Newark, Delaware 19711

HASKELL LABORATORY REPORT NO. 55-80

Material Tested

Haskell No.
13,197

Other Codes

Study Initiated/
Completed
8/27-10/5/79

Material Submitted by

Chemicals, Dyes, and Pigments
Jackson Laboratory

PRIMARY SKIN IRRITATION AND SENSITIZATION TEST ON GUINEA PIGS

Procedure: A range-finding study was conducted with 3 male albino guinea pigs to test for skin irritation potential. This material was not a skin irritant as received.

The primary irritation test was conducted on 10 unexposed guinea pigs by applying and lightly rubbing in 0.05 ml of a 100% and 10% dispersion (vol/vol) of the test material in distilled water on shaved, intact shoulder skin.

The induction phase for sensitization was a series of 4 sacral intradermal injections of 0.1 ml of a 1.0% solution in saline, 1 each week beginning 2 days after the test for primary irritation.

After a 13-day rest period, the test animals were challenged for sensitization by applying and lightly rubbing in 0.05 ml of a 100% and a 10% dispersion (vol/vol) of test material in distilled water on shaved, intact shoulder skin. At the same time 9 unexposed guinea pigs (controls) of the same age received identical topical applications.

Results:

	Reactions on Intact Guinea Pig Skin			
	Test Animals		Control Animals	
	(10 Animals - In. Avg. Wt. = 369 g)		(10 Animals - In. Avg. Wt. = 387 g)	
	10 Animals Final Avg. Wt. = 618 g)		9** Animals Final Avg. Wt. = 693 g)	
Concentration in distilled water	As Received	10%	As Received	10%
Primary Irritation Test - 24 Hours	10 Neg.	10 Neg.		
- 48 Hours	10 Neg.	10 Neg.		
Challenge Test - 24 Hours	10 Neg.	10 Neg.	9 Neg.	9 Neg.
- 48 Hours	10 Neg.	10 Neg.	9 Neg.	9 Neg.

Sensitization Response Ratio***
at 100% (as received) Concentration 0/10

Summary: [REDACTED] produced no irritation when tested as received (100%) or as a 10% dispersion in distilled water. No sensitization was observed at challenge. No unusual dermatitis hazard is expected from handling this material if good industrial hygiene practices are employed.

- ** One control animal died 2 days after being put on test. (Non-compound related)
*** Sensitization is defined as a significant score increase at challenge over the response expected from the same amount applied initially or on the concurrent controls.

+ Range Finding Results:		Reactions on Intact Guinea Pig Skin	
	Test Material		
	% (vol/vol)		
	100 as received		
	50		3 neg.
	25		3 neg.
	5		3 neg.
			3 neg.

Report by:

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JEH:jrg

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