DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Reviewer: L. Markarian

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Product Manager: 18 MRID No.: 427125-01

Testing Laboratory: Cosmopolitan Safety

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Species: Rabbit, New Zealand White

Weight: 2.55 - 3.35

Source: Laboratory Colony

Test Material: BMP 123 (2X WP) Lot 4922

Quality Assurance (40 CFR §160.12):Included

Summary:

1. The estimated LD_{50} is > 2000 mg/kg

3. Tox. Category: III Classification: Core minimum

Procedure (Deviation From §81-2):

The test material was applied to the shaved dorsum of the animals on an area covering about 10 % of the body surface. A paste was made with the solid material and distilled water and applied to the skin. The required 5.1 to 6.7 g/rabbit was moistened with 9 ml of water. This is stated to be the minimum amount of wat 1 necessary to moisten the test material. The resultant paste was not runny. the sites were covered with gauze pad held in place with tape. The trunks of the animals were wrapped in plastic sheeting secured with masking tape. At 24 hrs the patches were removed and the sites wiped with moist paper towels. Observations were frequent on the day of administration and daily thereafter. Dermal reactions were recorded 1/2 hrs after the removal of the patches and on days 3, 7, and 14. Body weights were determined at initiation and weekly thereafter. Necropsy was perforced on all animals.

Results:

Reported Mcrtality

DOSAGE	(NUMBER KILLED/NUMBER TESTED)		
	Kales	Females	Combined
2000 mg/kg	0/5	0/5	0/10

Symptoms & Gross Necropsy Findings:

There was no mortality. No systemic signs of toxicity was observed. Dermal irritation was expressed as grade 1 erythema and grade 1 or 2 of edema. All irritation cleared by day 7. Necropsy revealed no gross pathology.