

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager:18
MRID No.:427125-02
Testing Laboratory:Cosmopolitan Safety
Autho:(s):Geoffrey Robbins
Species:Rabbit, New Zealand White
Age:young adult
Sex:J M & 3 F
Weight:2.0 - 2.2 K

Reviewer: L. Markarian
Report Date:3/12/93
Report No.:E3334

Dosage:0.5 g
Test Material:BMP 123 (2X WP) Lot 4922
Quality Assurance (40 CFR §160.12):Included

Summary:

1. The Primary Irritation Index = 0.6
2. Toxicity Category:IV
3. Classification:Core minimum

Procedure (Deviations From §81-5):

Each aliquot of test material was mixed with 0.7 ml of water to make it into a paste before application. This paste was applied to the shaved skin of the rabbits. The site was covered with 6 cm² gauze pad, and the trunks were wrapped in perforated plastic sheeting. At 4 hrs the patches were removed and the sites wiped with moist paper towels. Evaluations were at 1, 24, 48, 72 hrs and on day 4 according to modified Draize scale.

Results:

No score greater than grade 1 erythema or edema was observed at any site, at any interval. All irritation subsided by day 4.

6401

Results:

	Test	Control
Chamber Concentration		
Gravimetric mg/L		
Average	3.19	-----
Range	3.11 - 3.32	
MMAD ± SGD um		
Average	2.3	
I	3.1± 4.2	
II	2.3± 5.2	
III	3.0± 6.0	
IV	2.2± 4.1	
% < 2um		
I	26.1	
II	34.3	
III	28.5	
IV	36.6	
Air Flow lpm	10 lpm	10 lpm
Temperature range °F	76 - 86	76 - 84
Humidity Range %	52 - 76	52 - 84
Mortality		
Males	0/5	0/5
Females	0/5	0/5
Combined	0/10	0/10
Signs of Toxicity		
During Exposure	Test material on muzzle	None
	Decreased response to tapping on wall	" "
Post exposure	in addition to above	
	Decreased locomotion	
	perineal staining	
Days 1 - 14	Normal	" "
Necropsy Findings	None	None

Results:

2

Tox chem No:006407 Bacillus Thuringiensis
Subsp.Kurstaki HD-263
006402 Bacillus Thuringiensis subsp. Kurstaki

Current Date: 04/07/93

Laboratory:Cosmopolitan safety Evaluation, Inc., P.O.Box 71, Lafayette, NJ 07848

S T U D Y M A T E R I A L M R I D N O R E S U L T S T O X C A T C O R E G R A D E

Acute Dermal BMP 123 (2X-WP) 427125-01 LD₅₀ > 2000 mg/kg III Minimum
Limit test(Rabbits) Lot 4922
B3334

3/19/93

Eye Irritation " " " 426796-01 Clear by day 7 III Minimum
in Rabbits
D3320
1/8/93

Dermal Irritation " " " 427125-02 PII 0.6 IV Minimum
in Rabbits
E334
3/12/93

3