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

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

**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

% < 2 um
I 26.1
II 34.3
III 28.5
IV 36.6

**Air Flow lpm**
10 lpm

Temperature range °F
76 - 86
76 - 84

Humidity Range %
52 - 76
52 - 84

**Mortality**
Males 0/5
Females 0/5
Combined 0/10

**Signs of Toxicity During Exposure**
Test material on muzzle
Decreased response to tapping on wall
in addition to above
Decreased locomotion
perineal staining

**Post exposure**
Days 1 - 14 Normal

**Necropsy Findings**
None

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Material</th>
<th>MRID No.</th>
<th>Results</th>
<th>TOX Cat</th>
<th>Core Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bacillus Thuringiensis subsp. kurstaki HD-263</td>
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</tbody>
</table>

Acute Dermal Limit test (Rabbits) Lot 4922
- 3/19/93
- E334

- LD_{50} > 2000 mg/kg
- III
- Minimum

Eye Irritation
- In Rabbits
- 1/8/93
- D320
- Clear by day 7
- III
- Minimum

Dermal irritation
- In Rabbits
- 3/12/93
- E334
- 427125-02
- PII 0.6
- IV
- Minimum