DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: 18
MRID No.: 426796-01
Testing Laboratory: Cosmopolitan Safety
Author(s): Geoffrey Robbins
Species: Rabbit, New Zealand White
Sex: 3 male and 3 female
Weight: M 2.0 - 2.1, F 2.0 - 2.2 K
Source: Laboratory Colony
Dosage: 0.1 g
Test Material: BMP 123(2X WP) Lot 4922
Quality Assurance (40 CFR §160.12): included

Summary:

1. Toxicity Category: III
2. Classification: Core minimum

Procedure (Deviations From §81-4):

Powdered test material was instilled in the conjunctival sacs of six pre-examined eyes. Observations were at 1, 24, 48, 72 hrs, and days 4, 7, 10, and 14. Hand held ophthalmoscope and/or slit lamp was used for evaluations. Corneal findings were confirmed with fluorescein.

Results:

<table>
<thead>
<tr>
<th>Observations</th>
<th>(number &quot;positive&quot;/number tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hour 1</td>
</tr>
<tr>
<td>Cornea Opacity</td>
<td>0/6</td>
</tr>
<tr>
<td>Iris</td>
<td>4/6</td>
</tr>
<tr>
<td>Conjunctivae</td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td>6/6*</td>
</tr>
<tr>
<td>Chemosis</td>
<td>6/6*</td>
</tr>
<tr>
<td>Discharge</td>
<td>0/6#</td>
</tr>
</tbody>
</table>

* grade 1 reaction, generally unremarkable
# Discharge reported, but not graded during scoring

Comments:
Blepharospasm is reported after the instillation of the test material in the eyes.