DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: (15)  
MRID No.: AC# 252113  
Testing Laboratory: Mark Sharp & Vohme Res. Lab.  
Author(s): L.R. Gordon, D.L. Bokelman  
Species: Guinea pig, Hartley  
Sex: Males  
Weight: 341-390 gm.  
Source: Film Still  
Test Material: MK-0936 (0.5% aqueous - Black Flag), 98% pure  
Positive Control Material: Dinitrochlorobenzene (DNCB)  
Quality Assurance (40 CFR §160.12): adequate  
Method: Guinea Pig Maximization Test (Magnusson & Kligman)

Summary:
1. This product is ______ (is not a dermal sensitizer)  
2. Classification: ______ (Guidelines)

Procedure (Deviation from §81-6): Material imbedded in 1.0-ga day 0 test mat; as a 0.5% conc. (5 mg/ml) in emulsified sesame oil & complete Freund's adjuvant. 5% DNCB (5 mg/ml) same way except for sesame oil. For epicutaneous app. (Day 7) test.

Results: mat as a 1.0% conc. (10 mg/gm) in tempered petrolatum applied coded in seawater. DNCB as 5% conc. (5 mg/gm) same procedure to include as for test mat. Challenged (epicutaneous) Test material same as day 7, except prepared as 0.5% conc. (5 mg/gm).

Protocol quoted from testers report:

<table>
<thead>
<tr>
<th>Compound Tested</th>
<th>Day 0 Intradermal % conc. in sesame oil &amp; adjuvant</th>
<th>Day 7 Topical % conc. in petrolatum</th>
<th>Day 21 Challenge (topical) % conc. in petrolatum</th>
<th>No. of Animals</th>
<th>Day 23 Sensitization Readings</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>MK-0936</td>
<td>0.5</td>
<td>1.0</td>
<td>0.5</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNCB**</td>
<td>5.0</td>
<td>5.0</td>
<td>5.0</td>
<td>10</td>
<td>+++</td>
<td></td>
</tr>
<tr>
<td>Controls</td>
<td>-</td>
<td>-</td>
<td>0.5*</td>
<td>5</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

*Challenged with MK-0936 (Test material)

**Dinitrochlorobenzene (positive control)

- = no reaction

+++ = strong reaction, marked redness and edema, may have necrotic foci.

Unquote:
Day 0 (i.v. injection) - 2 sites (0.1 ml/site).
Day 1 (Experimental) - spread literally on filter paper, applied to test site, covered & exclude openings for 48 hours.
Day 21 (Experimental) spread on 2 x 2 cm paper applied to left hind, covered & exclude during 24 hrs.
10 male - test material, 10 male - DNCB
5 male: negative control group.
Daily observation продолжался.
No deaths, body weight unaffected by treatment.

Results:
1) DNCB did not irritate guinea pig
2) Vehicle control was not irritant or log challenge dose, did not show a sensitizing reaction.
3) The test chemical 0.05% dinitrochlorobenzene (Black Flag) did not sensitize guinea pig.