

US EPA ARCHIVE DOCUMENT

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (' 81-6, 870.2600)

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Reviewer: Chris Jiang
Study Completion Date: April 22, 2003
Amended Report: February, 16, 2005
Report No.: 03-231

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Quality Assurance (40 CFR ' 160.12): A statement of GLP compliance was included.

Test Material: PXTS, lot 1685-30-1, black solid
Positive Control Material: 1-chloro-2,4-nitrobenzene (DNCB)
Vehicles: Ethanol and acetone

Species: Male Hartley albino guinea pigs (CRL:(HA) BR)
Weight: 371 to 431 g on day 1
Age: Six weeks on day of dosing

Source: Charles River Laboratories, Wilmington, MA

Method: Modified Buehler method

Summary:

- 1. This Product is not a dermal sensitizer.**
- 2. Classification:** Acceptable

Procedure (Deviation From ' 81-6): Excursions of relative humidity outside of the range specified by the protocol occurred during the study, but these **deviations were considered to have no adverse effects on the outcome of the study.**

The depilatory didn't remove hair cleanly enough to score the test sites of the animals so the depilatory had to be reapplied (causing moderate to severe skin irritation).

With the Sponsor=s approval, all guinea pigs were rechallenged.

Procedure: The animals used in the experiment were either induced with nothing, 0.3 g of neat test material, or 0.3 mL of 0.3% DNCB in ethanol. All induction materials were dispensed onto the pad of a Hill Top Chamber which was applied to the upper left quadrant of the shaved back of each animal once per week for a period of three weeks. The midsection of each animal was wrapped with an elastic adhesive bandage to keep the Hill Top Chamber in place. After six hours, all wrapping materials were removed and the test sites of all treated animals were wiped with Tricaprylin-moistened gauze. Two weeks after the third induction, the animals were either challenged with 0.3 g of neat test material or 0.05 % (w/v) DNCB/acetone solution that was dispensed onto the pad of a

Hill Top Chamber which was applied to the right quadrant of the shaved back of each animal. In all cases, the chambers were applied for six hours and then removed from the application sites which were subsequently wiped with Tricaprylin-moistened gauze. The test sites were evaluated at 24 and at 48 hours after the first induction and the challenge doses according to the Magnusson and Kligman Grading Scale.

Results: None of the test animals showed erythema after any of the inductions, after challenge, or after rechallenge.

The positive control showed appropriate results.