

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (870.2600)

Product Manager: 22
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Reviewer: Eugenia McAndrew
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Study No.: 8141

Testing Facility: Product Safety Labs
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Quality Assurance (40 CFR §160.12):Included

Test Material: GX-612/Equus DF; Lot #427-37; 85.94% Chlorothalonil; tan powder

Positive Control Material: 1-Chloro-2,4-Dinitrobenzene (DNCB)

Species: Guinea pig; Hartley albino

Age: Young adult

Weight: Males: 349-418 g; Females: 350-374 g

Source: Davidson's Mill Farm, South Brunswick, NJ

Method: Buehler

Conclusion:

1. **There is no indication that this product is a sensitizer.**
2. **Classification:** Acceptable

Procedure (Deviations from 870.2600): None

Procedure: Preliminary irritation testing was conducted to determine the correct concentrations for induction and challenge. For the induction, 0.4 g of an 80% w/w mixture of the test substance in distilled water was applied under occlusion to 20 test animals for a period of six hours once each week for three weeks. The animals rested for two weeks. For the challenge, 0.4 g of a 75% w/w mixture (HNIC) of the test substance in distilled water was applied to naive sites of each test animal and to 10 guinea pigs known as the naive group. Reactions were scored 24 and 48 hours after each induction application and after challenge.

Results: Very faint to moderate erythema (0.5-2) was observed at most test sites during the induction phase with severity of irritation increasing with each application. Following challenge, very faint erythema (0.5) was observed at 19/20 test sites at 24 and 48 hours. Similar results were observed with the naive control group with very faint erythema (0.5) at 9/10 test sites at 24 and 48 hours. A positive control study using DNCB was conducted within six months of the main study to validate the test system.

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