US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

1. CHEMICAL: Metolachlor (108801)

2. FORMULATION: Technical

3. CITATION: Affiliated Medical Research, Incorporated (1974) Evaluation of CGA-24705 Technical (FL740408) as a Potential Skin Sensitizer in the Guinea Pig: Contract No. 120-2255-34. Received September 26, 1974 under 5G1533. (Unpublished report prepared for CIBA-GEIGY Corp., Greensboro, N.C.; CDL:112840-K)

4. TRADE SECRET CLAIM: Yes

5. REASON FOR REVIEW: Generic Standard for Metolachlor

6. REVEIWED BY: Carolyn Gregorio
Biochemist, Metabolic Effects Branch
Criteria and Evaluation Division

7. DATE OF REVIEW: January 23, 1978

8. TEST TYPE: Dermal Sensitization Study

A. Two groups of ten (5 males, 5 females) guinea pigs of the Hartley Strain received a total of 10 single closed patch applications (0.5 ml technical (Group I) and 0.5 ml chlorodinitrobenzene, 0.05% (w/v) in ethanol which served as positive control (Group II) to the shaved dorsal body surface. Six hours following the application, the animals were unwrapped and patches removed; on alternate days closed patches were applied for a total of 10 insult applications. Twenty-four hours following each application, the animals were evaluated for irritation.

Two weeks following the last (10th) insult application, the animals received a single challenge applications

B. Results: There were no signs of general or systemic toxicity. One male died (Group II) on the 19th day of the study form causes "unrelated to the study". Dermal reactions following 10 insult applications:

Group I showed mild dermal reactions (erythema 1.24 $\pm$ 0.107 Edema: 080 $\pm$ 0.093)

Group II showed mild dermal reactions (Erythema 1.39 $\pm$ 0.099; Edema: 0.85 $\pm$ 0.108)

At challenge, 14 days after the last application:

Group I: Sensitization (Erythema: 0.70 ± 0.153; Edema: 0.50 + 0.167)

Group II: Sensitization (Erythema: 1.11 ± 0.200; Edema: 0.56 ± 0.242)

The Test compound (Group I) and chlorodinitrobenzene (Group II) showed no difference in reaction at challenge when compared to reaction produced during the first ten application (Evaluation of the Data by Students "t" Test).

C. Discussion: Technical Metolachlor was tested [*Sachsse, K, (1973)] and found to be essentially non-irritative to the skin. Generally, a dermally non-irritating compound is injected intradermally in sensitization testing. When intradermal injection is impractical because the test compound is highly irritating or cannot be dissolved or suspended in a form allowing injection, topical patch application can be substituted.

D. Conclusion: With the absence of the expected positive reaction in the positive control, this study should be re-done using the intradermal injection method or the company should supply a scientific explanation for use of the method employed

This study does not satisfy requirments for dermal sensitization.

Sachsee, K (1973)

Skin Irritaiton in the rabbit after single application of technical CGA-24705: Project No. Siss 2979. Received Sept. 26, 1974 under 5G-1553. [Unpublished report prepared by CIBA-GEIGY Corp., Greensboro, N.C., CDL:(1280-I]