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**DERMAL SENSITIZATION STUDY OF
FORMALDEHYDE SOLUTION IN GUINEA PIGS**

FINAL REPORT

FILE COPY

**IITRI Project No. L8100
Study No. 288
Test Article No. 100**

Contractor:

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Life Sciences Research
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March 3, 1982

IIT RESEARCH INSTITUTE

IITRI

IITRI Project No. L8100

DERMAL SENSITIZATION STUDY OF
FORMALDEHYDE SOLUTION IN GUINEA PIGS
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Formaldehyde is a strong sensitizer and was employed to test the upper limit of the maximization test. One group of 10 male guinea pigs was treated and a group of 5 male guinea pigs was used as a control.

The following procedure as described by Magnusson and Kligman¹ was employed.

A. Induction Procedure:

1. Intradermal Injections: Two series of 3 injections (one on either side of the midline) were made within the boundaries of a 2 x 4 cm area on June 3, 1981. Each series consisted of the following:

Injection I:	0.1 ml of Freund's Complete Adjuvant (Difco Laboratories).
Injection II:	0.1 ml of the Test Article (Formaldehyde Solution, 37%, Sargent Welch, lot KTKH) (0.1%).
Injection III:	0.1 ml of Test Article emulsified in Freund's Complete Adjuvant (0.1%).

Control animals received no clipping or injections.

2. Topical Application: One week following the injections, the intradermal injection site was shaved. The following day (6/10/81) the test article at a non-irritating concentration (a Draize Score less than 2) was spread over a 2 x 4 cm patch of filter paper (Whatman no. 3) to saturation. Impermeable plastic tape (Blenderm^R, 3M Company) was applied to cover the filter paper. Elastic Adhesive Bandage (Elastoplast^R Beiersdorf, Inc.) was wound around the torso of the animal to secure the plastic adhesive tape and filter paper. The dressing was removed 48 hours after application.

Control animals received no clipping or dosing.

¹Magnuson, Bertil and Kligman, Albert M., Allergic Contact Dermatitis in the Guinea Pig, Charles C. Thomas Publisher, Springfield, IL. (1970) p. 102-123.

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- B. Challenge Procedure: Two weeks following topical application and 24 hours prior to dosing, hair was clipped from a 5 x 5 cm area on the flank of all animals, including controls. The following day (6/24/81) the test article at a subirritating concentration was spread over a 2 x 2 cm patch of filter paper to saturation and sealed to the flank for 24 hours under Blenderm and Elastoplast tape.
- C. Results: Neither edema nor erythema was observed (Appendix I). All guinea pigs were humanely killed on June 29, 1981.

This study was conducted to develop a method for determining dermal sensitization in guinea pigs. Therefore, failure to obtain positive scores resulted in the termination of the study. This summary was prepared to close the file.

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DERMAL SENSITIZATION

Study Number 288Test Article 100Score at 24 Hrs.

Animal Number	Date	Time	Erythema	Edema	Initials
441	6/29/81	11:35 AM	0	0	MR
442	6/29/81	11:35	0	0	MR
443	6/29/81	11:35	0	0	MR
444	6/29/81	11:35	0	0	MR
445	6/29/81	11:35	0	0	MR
446	6/29/81	11:35	0	0	MR
447	6/29/81	11:35	0	0	MR
448	6/29/81	11:35	0	0	MR
449	6/29/81	11:35	0	0	MR
450	6/29/81	11:35	0	0	MR

CONTROL

TREATED

Read and Understood By MC BeckaDate 6/29/81

DERMAL SENSITIZATION

Study Number 288Test Article 100Score at 24 Hrs.TREATED

Animal Number	Date	Time	Erythema	Edema	Initials
451	6/29/81	11:35 AM	0	0	MR
452	6/29/81	11:35 AM	0	0	MR
453	6/29/81	11:35 AM	0	0	MR
454	6/29/81	11:35 AM	0	0	MR
455	6/29/81	11:35 AM	0	0	MR

Read and Understood By Mr M BeckerDate 6/29/81