BioScreen® Testing Services, Inc.

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ANALYTICAL REPORT

Gloves In A Bottle, Inc.
Attn: Dan Mueller
P.O. Box 615
Montrose, CA 91021

Report Date:	12/01/98
Date Received:	10/20/98
Date Completed:	12/01/98
Project #:	38821
P.O. #:	N/A
Reference #:	N/A

SAMPLE DESCRIPTION:

ACCESSION #:	SAMPLE:	LOT#
38821	White Lotion	N/A

TEST PERFORMED:
Human Patch Test(50 SUBJECT)

RESULTS:

	ACC # 38821
Human Patch Test	No evidence of sensitization

*See attached report

Ranil M. Fernando, B.S.
Operations Manager

* Test conducted at an outside laboratory.
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Midwest Clinical Trials
11100 Ash Suite 200
Leawood, Kansas 66211
(913) 491-6311

A Study to Assess the Skin Sensitization Potential of One (1) Test Product When Applied Topically to the Skin of Healthy Human Subjects in a Shared Panel Assay

Date:	November 20, 1998
Midwest Ref. No.	m71098-21
BioScreen Acc. No.	38821
Midwest Protocol No.	m27
Sponsor:	BioScreen Testing Services, Inc. 3892 Del Amo Blvd. #707 Torrance, CA 90503

This report accurately reflects the data derived from the procedures and materials tested in this study. The conclusions are based on an interpretation of the data and have been reviewed by the Principal Investigator and Consulting Dermatologist.

Douglas M. Rope, M. D.
President and Principal Investigator

David L. Kaplan, M. D.
Consulting Dermatologist

SUMMARY

The sensitization potential of AMA Gloves In A bottle - White Lotion # 2, was assessed in accordance with a modified maximization test. Fifty-one (51) healthy subjects were enrolled and forty-nine (49) completed the study. No adverse reactions were reported.

Under the conditions employed in this study, no evidence of sensitization to the test product was observed.

INTRODUCTION

Allergic contact dermatitis, also known as sensitization or delayed hypersensitivity is a cell-mediated immunological phenomenon involving antigen recognition in the epidermis and subsequent sensitization of T-lymphocytes. In the Gell and Coombs system, it is classified as Type IV, analogous to tuberculin sensitivity.

A repeat insult patch test such as the maximization test[1] is the accepted method for evaluating topically applied agents for the possibility of causing delayed hypersensitivity reactions.

OBJECTIVE

To determine the skin sensitization potential of one (1) product under of a maximization test in fifty subjects.

PRODUCT DESCRIPTION

Product Description	Midwest Clinical Trials Identification (m71098+)	Patching Instructions
AMA Gloves In A Bottle - White Lotion # 2 (Received 10/21/98)	21	Occlusively as received

SUBJECT SELECTION

Criteria for Inclusion

A. Subjects will be over the age of eighteen years, or will have obtained parental consent.
B. Male or female subjects of any skin type or race provided there degree of skin pigmentation does not interfere with taking readings of skin reactions.
C. Subjects must be cooperative and have given written informed consent after having been advised of the risks and nature of the study.
D. Subjects must be in good health, free of any significant active skin pathology.

Criteria for Exclusion

A. History of known sensitivity to cosmetics in general and in particular to the types of products being tested.
B. Pregnancy or attempting same during study period.
C. Lactation.
D. Loss of more than five patches throughout the evaluation.
E. Use of medications within thirty (30) days of induction, e. g., corticosteroids, anti-histamines which may tend to attenuate responses.

All subjects execute an Informed Consent. Said Consent contains information regarding the purpose of the study and possible risks of participation. Additionally, subjects are given a list of materials being tested. Said list is a general description of the product types; it contains no information with respect to brand names, manufacturers, or distributors. All consents and initialed product lists are maintained with each participant's records.

CLINICAL SITE

Midwest Clinical Trials
11100 Ash Suite 200
Leawood, Kansas 66211-1764

STUDY PERSONNEL

Principal Investigator:

Douglas M. Rope, M. D.

Diplomate, American board of Internal Medicine

Consulting Dermatologist:

David L. Kaplan, M. D.

Diplomate, American Board of Dermatology

TEST MATERIALS

Study material are packaged and labeled by BioScreen Testing Services, Inc. (BioScreen). BioScreen will notify Midwest Clinical Trials of the test product description, code, and testing instructions no less than five (5) business days prior to the commencement of the study.

Occlusive application of product is by means of an 8 millimeter aluminum Finn Chamber® (Epitest Ltd. Oy, Paijala 54, SF-04300 HYRYLA, Finland) on Scanpor® Tape (Norgesplaster A/S, Norway). Approximate capacity of the chambers is 25 µl.

Semiocclusive application is via absorbent paper with fixation by paper tape such as 3M Micropore™ or Kendall Tenderskin™ is used for fixation after preparation with an adhesion enhancer such as Mastisol® (Ferndale Laboratories, Ferndale, MI).

PRODUCT ACCOUNTABILITY

Upon receipt, product is logged in, assigned a Midwest sample tracking number, and stored in a secure area. Within one month of final report transmittal, unless instructed otherwise, test product will be destroyed. No testing information will be used in any manner not authorized by the study sponsor.

STUDY DESIGN

A maximum of forty (40) test sites on the back and volar forearm are used. The latter is generally reserved for products whose primary use is expected to be by children of age below thirteen years. At least ¾ inch of separation must be maintained between the edges of test sites.

SPECIMEN PREPARATION AND CONTROLS

A. Non-alcohol-containing products

Product is applied occlusively as received. The initial application is generally in combination with sodium lauryl sulfate (SLS, Stepanol, Stepan Co., Northfield, IL) in a five and one half (5.5) per cent proportion. Subsequent applications consist solely of the test product.

A pilot study consisting of a single forty-eight hour occlusive application to ten subjects may be performed at the option of the principal investigator in order to determine the dilution of SLS most likely to product moderate erythema during induction without causing more severe reactions, such as vesiculation or ulceration.

B. Alcohol-based products

Products intended for use in intertriginous areas are applied occlusively. A quantity of product is placed in an open container to allow evaporation of volatile substances. An amount of distilled water double the amount of product originally evaporated is then mixed with the residue, and used as the test substance.

Products not intended for use in such areas are applied semiocclusively to adsorbent paper and affixed as described previously. Initial application is in combination with 5.5 per cent SLS.

C. Controls

The control for this trial is white petrolatum, U. S. P. The initial application thereof is in combination with SLS in a 5.5 per cent proportion as in item A above.

TESTING SCHEDULE

A. Induction Phase

Product is applied five (5) times. The duration of each exposure is 48 hours unless application is made on a Friday. In such case, said duration is 72 hours. A rest period of 48 hours (72 hours on weekends) without product exposure is given between each exposure

Alternatively, should the test product prove incompatible with SLS e.g. formation of precipitates, the initial application will be an aqueous solution of five (5) per cent SLS for 48 hours, followed by a 48 hour application of the test product. Alternating application of test product and 5 per cent SLS continues for the duration of the induction phase.

To the extent possible, reapplication is to the identical site each time. In the case of significant irritation, e. g., vesiculation the application site may be moved. Should a grade three or four reaction as described below be noted, application of the product is discontinued for the remainder of the induction phase. The product may, however, be reapplied at challenge.

B. Challenge Phase

All products are applied for the challenge phase unless strong evidence of product sensitization was obtained during induction (generally grade 3 reactions). A "rest period" of from seven to fourteen days is given at the end of induction, depending on the intensity of latter phase induction reactions (where present). Products are then applied as previously. Exposure time is 48 hours. Participants are encouraged to observe for the possibility of delayed reactions, including redness or persistent itching or irritation, e. g., onset up to 72 hours after application. Should this possibility be entertained, participants are checked additionally as needed and results recorded.

SCORING

The scoring scale, shown below, is based on that used by the International Contact Dermatitis Research Group[2]

0=no reaction (negative)
1=erythema and induration throughout at least ¾ of patch area
2=erythema, induration, and vesicles
3=erythema, induration, and bullae
X=site discontinued
T=tape or other reaction unrelated to test product (e. g., pressure, suction) requiring move to new site

Scoring will be conducted by persons experienced in reading patch test reactions with supervision by the principal investigator and consulting dermatologist. All scores will be recorded on an individual case response log for each participant. Corrections will be indicated by a single line overstrike with the initials of the person making the correction.

DATA PREPARATION AND STATISTICAL METHODS

Data is presented in tabular form as well as by verbal summary description. The data summary displays the total reactions by severity for each evaluation day. The total number of subjects evaluated at each visit will be shown, as well as a Mean Induction Value (cumulative scores for a given day/total number of subjects scored on that day) and Mean Reaction Value (cumulative scores for a given day/total number of subjects **showing reactions** on that day).

Additional response analysis is by the frequency index (FI) method described by Carabello as adapted for sensitization scoring in this test.[3] In this approach, each scoring grade is treated as a different and distinct threshold. The number of responses equal to or greater than a given score (FI#) will be totaled and divided by the total number of possible responses.

A chi-square analysis will be performed both on the FI and as well on the raw reaction data for the test product and control. Any conclusions will be based on a level of significance of .05 or less.

RESULTS AND DEMOGRAPHICS

This test began on October 26, 1998, and ended on November 20, 1998. Fifty-one healthy male and female subjects were enrolled in the study, and forty-nine completed the protocol. Three reactions to the test product were reported during day one and a single reaction was reported on day two of the induction phase. No other reactions were reported at any time during the induction or challenge phases. The number of reactions is significantly less than that in the control.

In conclusion, under the conditions of this test, no evidence of sensitization to the test product was present.

DEMOGRAPHICS

Males completing test	4
Females completing test	45
Total	49

Age Range	No. of Subjects	
18-27	3	6.1 %
28-37	14	28.5 %
38-47	8	16.4 %
48-57	8	16.4 %
58-67	11	22.5 %
68-77	4	8.1 %
78-87	1	2.0 %
Totals	49	100.0%

ARCHIVING

All original samples, raw data sheets, technicians' notes, correspondence, and copies of final reports are maintained at Midwest Clinical Trials. All records relating to the conduct of studies will be maintained by Midwest for a period of not less than three years from the date of completion of the study. Unless otherwise instructed, retention will be on floppy disk format using generally accepted techniques. Sheets bearing signatures will be maintained as facsimiles, the originals being submitted to the study sponsor.

Records may be made available to representatives of the United States Food and Drug Administration or to other competent reviewing bodies upon request. In such case, Midwest will attempt to give thirty days notice to the study sponsor by United States Certified Mail, return receipt requested, as well as by other means as possible. Midwest will attempt to give the date, time, and location of said review as well as the identity of reviewing personnel. Nothing in this document, however, should be construed as a guarantee of such notice.

Test panel and report approved by:

Douglas M. Rope, M. D.
Principal Investigator

David L. Kaplan, M. D.
Consulting Dermatologist

[1] Kligman, A. L., *Jour. Invest. Derm. 47:* 393,1966.
[2] Rietschel, R. L., Fowler, J. F., Ed., *Fisher's Contact Dermatitis (fourth ed.)*. Baltimore, Williams & Wilkins, 1995.
[3] Carabello, F. B., *J. Toxicol.-Cut. & Ocular Toxicol. 4(2):* 61-71, 1985.

Detail of Responses

Non-Surfactant Control Panel ID m7098								
Response	Induction Insults					Challenge Insult		
	1	2	3	4	5	48 Hr.	96 Hr.	Totals
Negative	31	49	49	49	49	48	49	324
1	18	0	0	0	0	0	0	18
2	0	0	0	0	0	1	0	1
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
AE	0	0	0	0	0	0	0	0
Total	49	49	49	49	49	49	49	343
MIV	0.37	0	0	0	0	0.04	0	0.06
MRV	1	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	2	#DIV/0!	1.05

Detail of Responses

Product ID m71098-21								
Response	Induction Insults					Challenge Insult		
	1	2	3	4	5	48 Hr.	96 Hr.	Totals
Negative	46	48	49	49	49	49	49	339
1	3	1	0	0	0	0	0	4
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
AE	0	0	0	0	0	0	0	0
Total	49	49	49	49	49	49	49	343
MIV	0.06	0.02	0	0	0	0	0	0.01
MRV	1	1	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	1