50 HUMAN SUBJECT REPEAT INSULT PATCH TEST
SKIN IRRITATION/SENSITIZATION EVALUATION
(OCCLUSIVE PATCH)

Date: July 21, 2023

CR Ref. No.: RIPT.C0608-A.O.50.GLO

Sponsor: WEQUIK MYRADERM DermaShield-X™
P.O. Box 615
Montrose CA 91021

1.0 Objective: Consumer products or raw materials designed for consistent reapplication to areas of the skin may, under proper conditions, prove to be contact sensitizers or irritants in certain individuals. It is the intention of a Repeat Insult Patch Test (RIPT) to provide a basis for evaluation of this irritation/ sensitization potential if such exists.

2.0 Reference: The method is modified to test 50 panelists and not the 200 cited in the reference Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics, published by The Association of Food and Drug Officials of The United States. The method also employs nine inductive patchings and not the ten cited in the reference.

3.0 Test Material:
3.1 Test Material Description:

On June 8, 2023 one test sample labeled Lotion,DermaShield-X™ Product Code No. 7-1A was received from, and assigned CR Lab No. C0608-A.

3.2 Handling: Upon arrival at Cantor Research Laboratories, Inc., the test material is assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date and test requested.

Samples are retained for a period of three months beyond submission of final reports unless otherwise specified by the sponsor or, if sample is known to be in support of governmental applications, representative retained samples are kept two years beyond final report submission.

Sample disposition is conducted in compliance with appropriate federal, state and local ordinances.

3.3 Test Material Evaluation Prerequisite:

Prior to induction of a human test panel, animal toxicology, microbiology and other in-vivo or in-vitro performance spectra may be required to assess the feasibility of commencement as dictated by an Institutional Review Board (IRB) described in Section 4.0.

3.3.1 Sponsor purports that prior to sample submission to Cantor Research Laboratories, Inc. the following tests were conducted with no adverse results and that the test data are on file on their premises and have not been made available to Cantor Research Laboratories, Inc. personnel:

- CTFA Preservative Efficacy Test or equivalent
- 90 Day Accelerated Stability and Container Compatibility Study

4.0 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C, and D. The IRB of Cantor Research Laboratories, Inc., consists of five or more individuals, chosen from within the company for technical expertise and from the local community for lay interaction. The list of IRB members is kept on file at Cantor Research Laboratories, Inc., and is available for inspection during the hours of operation.

5.0 Panel Selection:

5.1 Standards for Inclusion in a Study:

- Individuals who are not currently under a doctor's care.
- Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the Investigator.
- Individuals free of any acute or chronic disease that might interfere with or increase the risk of study participation.
- Individuals who will complete a preliminary medical history form mandated by Cantor Research Laboratories, Inc., and are in general good health.

- Individuals who will read, understand and sign an informed consent document relating to the specific type of study they are subscribing. Consent forms are kept on file and are available for examination on the premises of Cantor Research Laboratories, Inc. only.
- Individuals able to cooperate with the Investigator and research staff, willing to have test materials applied according to the protocol, and complete the full course of the study.

5.2 Standards for Exclusion from a Study:

- Individuals under 18 years of age.
- Individuals who are under doctor's care.
- Individuals who are currently taking any medication (topical or systemic) that may mask or interfere with the test results.
- Subjects with a history of any acute or chronic disease that might interfere with or increase the risk of study participation.
- Individuals diagnosed with chronic skin allergies.
- Female volunteers who indicate that they are pregnant or nursing.

5.3 Recruitment: Panel selection is accomplished by advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media or any combination thereof.

5.4 Informed Consent and Medical History Forms:

An informed consent was obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Panelists signed and dated the informed consent document to indicate their authorization to proceed and acknowledge their understanding of the contents. Each subject was assigned a permanent identification number and completed an extensive medical history form. These forms along with the signed consent forms, are available for inspection on the premises of Cantor Research Laboratories, Inc. only. Reference 21 CFR Ch. 1 Part 50, Subpart B.

6.0 Population Demographics:

Number of subjects enrolled		56
Number of subjects completing study		55
Age Range		20 – 69
Sex	Male.	16
	Female.	40
Race	Caucasian	32
	Hispanic	13
	Asian	1
	African American	10

7.0 Equipment:

- Patch Description: Parke-Davis Hypoallergenic Readi Bandages (20 x 20 mm Webril affixed to the center of a 40 x 40 mm adhesive bandage) or the equivalent.
- 1 ml volumetric syringe without a needle.

8.0 Procedure:

- Subjects are requested to bathe or wash as usual before arrival at the facility.
- 0.2 ml or 0.2 g of the test material is dispensed onto the occlusive, hypoallergenic patch.
- The patch is then applied directly to the skin of the infrascapular regions of the back, to the right or left of the midline and the subject is dismissed with instructions not to wet or expose the test area to direct sunlight.
- After 24 hours the patch is removed by the panelist at home.
- This procedure is repeated until a series of nine consecutive 24 hour exposures have been made for every Monday, Wednesday and Friday for three consecutive weeks.
- In the event of an adverse reaction, the area of erythema and edema is measured. The edema is estimated by the evaluation of the skin with respect to the contour of the unaffected normal skin. Reactions are scored just before applications two through nine and the next test date following application nine. Clients are notified immediately in the case of adverse reaction and determination is made as to treatment program if necessary.
- Subjects are then given a 10 - 14 day rest period after which a challenge or retest dose is applied once to a previously unexposed test site. The retest dose is equivalent to any one of the original nine exposures. Reactions are scored 24 and 48 hours after application.
- Comparison is made between the nine inductive responses and the retest dose.

9.0	Results:	Please refer to attached Table.
10.0	Observations:	No adverse reactions of any kind were noted during the course of this study.
11.0	Archiving:	All raw data sheets, technician's notebooks, correspondence files, and copies of final reports are maintained on premises of Cantor Research Laboratories, Inc., in limited access storage files marked "Archive" for five years after completion of the study. A duplicate disk copy of final reports is separately archived in a bank safe deposit vault.
12.0	Conclusions:	The test material (CR Lab No.: C0608-A; Client No.: Lotion, Product Code No. 7-1A) when tested under occlusive conditions as described herein, may be considered as a **NON-PRIMARY IRRITANT** and a **NON-PRIMARY SENSITIZER** to the skin according to the reference.

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Date

TABLE
SUMMARY OF RESULTS
(OCCLUSIVE PATCH)

CR Lab. No.: C0608-A
Client No.: Lotion, Product Code No. 7-1A

No.	Subject ID	RACE	SEX	Response									Chall.		Score
				1	2	3	4	5	6	7	8	9	24 HR	48 HR	
1	03-6496	C	M	0	0	0	0	0	0	0	0	0	0	0	0.0
2	03-6176	AA	F	0	0	0	0	0	0	0	0	0	0	0	0.0
3	03-6071	H	F	0	0	0	0	0	0	0	0	0	0	0	0.0
4	03-6003	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
5	03-6065	C	M	0	0	0	0	0	0	0	0	0	0	0	0.0
6	03-6770	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
7	03-6045	H	M	0	0	0	0	0	0	0	0	0	0	0	0.0
8	03-6747	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
9	03-6643	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
10	03-6085	H	F	0	0	0	0	0	0	0	0	0	0	0	0.0
11	03-6450	C	F	0	0	0	0	Dc	Dc	Dc	Dc	Dc	Dc	Dc	NA
12	03-6610	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
13	03-6721	AA	F	0	0	0	0	0	0	0	0	0	0	0	0.0
14	03-6077	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
15	03-6028	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
16	03-6030	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
17	03-6638	C	M	0	0	0	0	0	0	0	0	0	0	0	0.0
18	03-6794	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
19	03-6153	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
20	03-6088	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
21	03-6391	AA	F	0	0	0	0	0	0	0	0	0	0	0	0.0
22	03-6098	AA	F	0	0	0	0	0	0	0	0	0	0	0	0.0
23	03-6565	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
24	03-6518	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
25	03-6479	A	F	0	0	0	0	0	0	0	0	0	0	0	0.0
26	03-6076	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
27	03-6081	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
28	03-6009	H	F	0	0	0	0	0	0	0	0	0	0	0	0.0
29	03-6080	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
30	03-6416	AA	F	0	0	0	0	0	0	0	0	0	0	0	0.0
31	03-6034	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
32	03-6161	H	F	0	0	0	0	0	0	0	0	0	0	0	0.0

TABLE (CONT'D)
SUMMARY OF RESULTS
(OCCLUSIVE PATCH)

CR Lab. No.: C0608-A
Client No.:DermaShield-X™
, Product Code No. 7-1A

No.	Subject ID	RACE	SEX	Response									Chall.		Score
				1	2	3	4	5	6	7	8	9	24 HR	48 HR	
33	03-6274	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
34	03-6148	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
35	03-6418	C	M	0	0	0	0	0	0	0	0	0	0	0	0.0
36	03-6173	H	F	0	0	0	0	0	0	0	0	0	0	0	0.0
37	03-6264	H	M	0	0	0	0	0	0	0	0	0	0	0	0.0
38	03-6298	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
39	03-6787	AA	F	0	0	0	0	0	0	0	0	0	0	0	0.0
40	03-6089	H	F	0	0	0	0	0	0	0	0	0	0	0	0.0
41	03-6492	C	M	0	0	0	0	0	0	0	0	0	0	0	0.0
42	03-6376	C	M	0	0	0	0	0	0	0	0	0	0	0	0.0
43	03-6174	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
44	03-6062	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
45	03-6314	AA	F	0	0	0	0	0	0	0	0	0	0	0	0.0
46	03-6501	AA	M	0	0	0	0	0	0	0	0	0	0	0	0.0
47	03-6255	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
48	03-6278	AA	F	0	0	0	0	0	0	0	0	0	0	0	0.0
49	03-6164	H	M	0	0	0	0	0	0	0	0	0	0	0	0.0
50	03-6672	C	M	0	0	0	0	0	0	0	0	0	0	0	0.0
51	03-6144	C	F	0	0	0	0	0	0	0	0	0	0	0	0.0
52	03-6281	H	M	0	0	0	0	0	0	0	0	0	0	0	0.0
53	03-6235	AA	M	0	0	0	0	0	0	0	0	0	0	0	0.0
54	03-6183	H	M	0	0	0	0	0	0	0	0	0	0	0	0.0
55	03-6162	H	M	0	0	0	0	0	0	0	0	0	0	0	0.0
56	03-6356	H	M	0	0	0	0	0	0	0	0	0	0	0	0.0

Evaluation Period:

This study was conducted from June 8, 2005 through July 15, 2005.

Scoring Scale and Definition of Symbols Shown in Table:

0 - No evidence of any effect

? - (Barely perceptible) minimal faint (light pink) uniform or spotty erythema

1 - (Mild) pink uniform erythema covering most of contact site

2 - (Moderate) pink\red erythema visibly uniform in entire contact area

3 - (Marked) bright red erythema with accompanying edema, petechiae or papules

4 - (Severe) deep red erythema with vesiculation or weeping with or without edema

D - Patch eliminated due to reaction

Dc - Discontinued due to absence of subject on application date

M - Patch applied to an adjacent site after strong test reaction

NA - Score is not calculated for subjects discontinued before challenge

S - Skin stained from pigment in product

T - Tan

NOTE: All technical employees of Cantor Research Laboratories, Inc. are required to take and pass a visual discrimination examination conducted by a Board Certified Ophthalmologist using the Farnsworth-Munsell 100 Hue Test as published; which determines a person's ability to discern color against a black background. This test was additionally modified to include a flesh tone background more nearly approaching actual use conditions, wherein erythematous skin is graded according to intensity.