Dermatest Pty Ltd

Photoxicity Study Report

Client: Marinova Pty Ltd

Our Ref: Phot0110

Measured Intensity: 4.8 J/cm2

Contact: Vicki Gardiner

Exposure Time: 15 min

Marinova Cream with Maritech Bright

Results:

Date:	Subject Number		Control 24 hr	Control 48 hr	Control 7 Day	Sample 24 hr	Sample 48 hr	Sample 7 Day
11/1/2010	photo 1	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
11/1/2010	photo 2	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
11/1/2010	photo 3	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
11/1/2010	photo 11	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
12/1/2010	photo 12	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
12/1/2010	photo 5	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
13/1/2010	photo 13	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
13/1/2010	photo 14	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
14/1/2010	photo 4	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
14/1/2010	photo 15	L	0	0	0	0	0	0
		R	0	0	0	0	0	0

Adverse Experiences No adverse events were recorded.

Comments:

Clinical Manager ---------- Holly Huang Feng

Study Director ---------- John A. Staton

Dermatest Pty Ltd

Photoxicity Study Report

Client: Marinova Pty Ltd

Our Ref: Phot0110

Marinova Cream with Maritech Bright

1. STUDY OBJECTIVE
To determine the phototoxicity potential of topically applied product under occlusion to the skin of human panellists

2. SAMPLE DESCRIPTION
A sample marked Marinova Cream with Maritech Bright was received from Marinova Pty Ltd and allocated a reference number Phot0110.

3. TEST MATERIAL HANDLING
The record of the sample was entered into a log identifying the lot number, sample description, batch number, sponsc date received and tests requested. Samples are retained for a period of two years beyond final report generation.

4. STANDARD FOR INCLUSION OF A PANELLIST IN THE STUDY
4.1 Individuals 18 years of age or older.
4.2 Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretic of the investigator.
4.3 Individuals who have completed a preliminary medical history evaluation.
4.4 Individuals who have read, understood and signed an informed consent document relating to the specific study to which they are subscribing.
4.5 Individuals free of any topical or oral medication for at least 3 months prior to commencement of the study.

5. STANDARD FOR EXCLUSION FROM THE STUDY
5.1 Individuals who are under doctor's care.
5.2 Individuals taking medication which in the opinion of the investigator would mask or interfere with the results.
5.3 Individuals with chronic skin allergies
5.4 Individuals with suntan or sunburn
5.5 Individuals with abnormal reaction to the sun
5.6 Pregnant or lactating females.

6. INFORMED CONSENT
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 authorisation to proceed and acknowledgc 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 only on the premises of Dermatest Pty Ltd and during normal office hours.

7. PANEL COMPOSITION
Health individuals over the age of 18 years will be recruited for this study. The panel consisted of fair-skin individuals with types I, II, or III defined as follows:

Type 1	Always burns easily, never tans (sensitive).
Type 11	Always burns easily, tans minimally (sensitive).
Type 111	Burns moderately, tans gradually (light brown – normal).

8. INSTITUTIONAL ETHICS COMMITTEE (IEC).

The IEC of Dermatest Pty Ltd, consists of 5 or more individuals, chosen in accordance with IHC Guidelines for Good Clinical Practice. The list of IEC members is kept on file at Dermatest Pty Ltd, and is available for inspection on the premises during normal office hours.

9. SOLAR SIMULATION

A bank of 6 40W fluorescent bulbs (NEC T10 Black Light FL20SBL- 24) with a continuous long-wave UV-A spectrum ranging between 320 and 400nm (peak 365nm) were used. Prior to initiation of screening, the intensity of the light source was determined, using a Solar Light PM 2100 Radiometer.

10 PROCEDURE

10.1 The inner left arm was designated as the control (non-irradiated) site and the inner right arm as the test site. On the initial day of the study, the test sites were wiped clean with alcohol and tape stripped with hypo-allergenic tape 3 times to remove several layers of cornified epithelium.

Hydrophilic ointment USP served as the negative control (irradiated and non-irradiated) in order to indicate lack of excessive sensitivity to topically applied products under the skin surface conditions.

10.2 CONTROL (NON-IRRADIATED) ARM

1mL or 0.1g of test materials was placed onto a 2cmx2cm Parke-David Readi Bandage occlusive patch or the equivalent, was then applied to the non-irradiated control site (left arm) and allowed to remain in place for 24 hours.

10.3 IRRADIATED ARM

Test materials was applied to the right arm directly onto the skin. The site was irradiated with non-erythemogenic ultraviolet (UV-A) irradiation at a distance of 10cm from the source and receiving a UV-A light dosage of 4.4mW/cm2. The test site was covered with a Parke-Davis Readi Bandage occlusive patch containing additional test materials (0.1mL or 0.1g) for a period of 24 hours.

10.4 All patches were removed 22-26 hrs after placement.

11. EVALUATION OF RESPONSE

Immediately following and at approximately twenty-four, forty-eight hours and one week post removal all sites were scored as follows:

0 = no evidence of any effect
? = query
+1 = minimal, faint, uniform or spotty erythema
1 = pink uniform erythema covering most or all of the contact site
2 = pink-red erythema visibly uniform in entire contact site
3 = bright red erythema with or without petechiae or papules
4 = Deep red erythema with or without vesiculation or weeping.

12. ADVERSE EXPERIENCES

An adverse experience is defined as any medical event, intercurrent illness or injury related to study participation. All adverse experiences, the severity of which and relation to test products or procedures, will be documented and reported to the sponsor. All adverse experiences will be followed to satisfactory resolution.

13. STUDY DISCONTINUATION

Criteria for the discontinuation of a subject during the study will include the following.

1. Significant protocol violation
2. Serious adverse experience
3. At the request of the subject.
4. If a negative respones occurs to the positive irritation control.
5. At the investigator's discretion where any unmanageable factor may interfere significantly with the protocol or interpretation of results.

14. REPORT
Results of dermal responses are attached in tabular form.

15. REJECTION CRITERIA
Panelist's results were rejected and the panellist replaced if:
15.1 The responses on the control site were unclear. This was an indication that the test subject is unresponsive, or that the sites were not correctly prepared.

16. INDIVIDUAL PANELLIST RESULTS
These are set out in the attached report.
Adverse responses are also reported where these were experienced.

17. COLOUR DISCRIMINATION TEST
All technical employees of Dermatest Pty Ltd are required to take and pass a visual colour discrimination examinatior using the Farnsworth-Munsell 100 Hue Test.This test determines a persons ability to discern colour against a blank background.

18. ARCHIVING
All original samples, raw data sheets, technicians notebooks, correspondence files and copies of final reports and remaining specimens are maintained on premises of Dermatest Pty Ltd in limited access storage files.
A duplicate disk copy of final reports is archives separately off site.

19. REFERENCES
Dermatest Prtocol DESOP 078 V. 1.0.

Dermatest Pty Ltd

Photoxicity Study Report

Client: Marinova Pty Ltd

Our Ref: Phot0609

Maritech Reverse Cream

1. STUDY OBJECTIVE
To determine the phototoxicity potential of topically applied product under occlusion to the skin of human panellists

2. SAMPLE DESCRIPTION
A sample marked Maritech Reverse Cream was received from Marinova Pty Ltd and allocated a reference number Phot0609.

3. TEST MATERIAL HANDLING
The record of the sample was entered into a log identifying the lot number, sample description, batch number, sponsc date received and tests requested. Samples are retained for a period of two years beyond final report generation.

4. STANDARD FOR INCLUSION OF A PANELLIST IN THE STUDY
4.1 Individuals 18 years of age or older.
4.2 Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretic of the investigator.
4.3 Individuals who have completed a preliminary medical history evaluation.
4.4 Individuals who have read, understood and signed an informed consent document relating to the specific study to which they are subscribing.
4.5 Individuals free of any topical or oral medication for at least 3 months prior to commencement of the study.

5. STANDARD FOR EXCLUSION FROM THE STUDY
5.1 Individuals who are under doctor's care.
5.2 Individuals taking medication which in the opinion of the investigator would mask or interfere with the results.
5.3 Individuals with chronic skin allergies
5.4 Individuals with suntan or sunburn
5.5 Individuals with abnormal reaction to the sun
5.6 Pregnant or lactating females.

6. INFORMED CONSENT
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 authorisation to proceed and acknowledg 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 only on the premises of Dermatest Pty Ltd and during normal office hours.

7. PANEL COMPOSITION
Health individuals over the age of 18 years will be recruited for this study. The panel consisted of fair-skin individuals with types I, II, or III defined as follows:

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9. SOLAR SIMULATION

A bank of 6 40W fluorescent bulbs (NEC T10 Black Light FL20SBL- 24) with a continuous long-wave UV-A spectrum ranging between 320 and 400nm (peak 365nm) were used. Prior to initiation of screening, the intensity of the light source was determined, using a Solar Light PM 2100 Radiometer.

10 PROCEDURE

10.1 The inner left arm was designated as the control (non-irradiated) site and the inner right arm as the test site. On the initial day of the study, the test sites were wiped clean with alcohol and tape stripped with hypo-allergenic tape 3 times to remove several layers of cornified epithelium.

Hydrophilic ointment USP served as the negative control (irradiated and non-irradiated) in order to indicate lack of excessive sensitivity to topically applied products under the skin surface conditions.

10.2 CONTROL (NON-IRRADIATED) ARM

1mL or 0.1g of test materials was placed onto a 2cmx2cm Parke-David Readi Bandage occlusive patch or the equivalent, was then applied to the non-irradiated control site (left arm) and allowed to remain in place for 24 hours.

10.3 IRRADIATED ARM

Test materials was applied to the right arm directly onto the skin. The site was irradiated with non-erythemogenic ultraviolet (UV-A) irradiation at a distance of 10cm from the source and receiving a UV-A light dosage of 4.4mW/cm2. The test site was covered with a Parke-Davis Readi Bandage occlusive patch containing additional test materials (0.1mL or 0.1g) for a period of 24 hours.

10.4 All patches were removed 22-26 hrs after placement.

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Dermatest Pty Ltd

Photoxicity Study Report

Client: Marinova Pty Ltd

Contact: Vicki Gardiner

Maritech Reverse Cream

Our Ref: Phot0609

Measured Intensity: 4.4 J/cm2

Exposure Time: 11 min

Results:

Date:	Subject Number		Control			Sample		
			24 hr	48 hr	7 Day	24 hr	48 hr	7 Day
17/8/2009	Phot1	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
17/8/2009	Phot2	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
17/8/2009	Phot3	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
19/8/2009	Phot4	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
24/8/2009	Phot5	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
24/8/2009	Phot6	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
24/8/2009	Phot7	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
24/8/2009	Phot8	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
25/8/2009	Phot9	L	0	0	0	0	0	0
		R	0	0	0	0	0	0
26/8/2009	Phot10	L	0	0	0	0	0	0
		R	0	0	0	0	0	0

Adverse Experiences No adverse events were recorded.

Comments:

Clinical Manager ---------- Holly Huang Feng

Study Director ---------- John A. Staton

Cantor Research Laboratories, Inc.

630 Route 303
Blauvelt, NY 10913
Tel: 845.727.4100
Fax: 845.727.4110
E-mail: shyla@cantorlabs.com

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

Date: April 13, 2009

CR Ref. No.: RIPT.G0223-E.SO.50.MAV

Sponsor: Marinova
249 Kennedy Drive
Cambridge Tas 7170
Australia

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 under semi-occlusive patch conditions.

3.0 Test Material:

3.1 Test Material Description:

On February 23, 2009, one test sample labeled Maritech Bright Batch VG200914 was received from Dermatest Pty Ltd and assigned CR Lab No. G0223-E.

3.2 Test Material Handling:

Upon arrival at Cantor Research Laboratories, Inc., the test material was assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and test(s) requested.

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

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:

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. Reference: CFR Title 21 Part 56, Subparts A, B, C, and D.

5.0 Panel Selection:

5.1 Standards for Inclusion in the Study:

- Individuals who are not currently under a doctor's care.
- Individuals free of any dermatological or systemic disorder which would have interfered with the results, at the discretion of the investigator.
- Individuals free of any acute or chronic disease that may have interfered with or increased the risk of study participation.
- Individuals who have completed a preliminary medical history form mandated by Cantor Research Laboratories, Inc., and are in general good health.
- Individuals, who have read, understood and signed an informed consent document relating to the specific type of study they are subscribing.
- Individuals who were able to cooperate with the investigator and research staff, willing to have the test materials applied according to the protocol, and complete the full course of the study.

5.2 Standards for Exclusion from the Study:

- Individuals under 18 years of age.
- Individuals who were under doctor's care.
- Individuals who were currently taking any medication (topical or systemic) that may have masked or interfered with the test results.
- Subjects with a history of any acute or chronic disease that may have interfered with or increased the risk of study participation.
- Individuals diagnosed with chronic skin allergies.
- Female volunteers who indicated that they were pregnant or nursing.

5.3 Recruitment:

Panel selection was 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:

Each panelist completed an extensive medical history form and was assigned a permanent identification number. An informed consent was obtained from each volunteer describing the 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. These forms are only available for inspection on the premises of Cantor Research Laboratories, Inc. Reference 21 CFR Ch. 1 Part 50, Subpart B.

5.5 Population Demographics:

Number of subjects enrolled		58
Number of subjects completing study		58
Age Range		20 – 65
Sex	Male	11
	Female	47
Race	Caucasian	33
	Hispanic	6
	Asian	1
	African American	18

6.0 Equipment:

- Patch Description: Parke-Davis Hypoallergenic Readi Bandages (20 x 20mm Webril affixed to the center of a 40 x 40mm adhesive bandage) or the equivalent, trimmed at right angles on opposite sides to the opening of the paper backing of patch, allowing air flow.
- 1ml volumetric syringe without a needle.

7.0 Procedure:

- Subjects are requested to bathe or wash as usual before arrival at the facility.
- Test material G0223-E was diluted 1:10 in distilled water. Dilutions were freshly prepared on each application day.
- 0.2ml of the diluted test material was dispensed onto the semi-occlusive, hypoallergenic patch.
- The patch was then applied directly to the skin of the infrascapular regions of the back, to the right or left of the midline and the subject was dismissed with instructions not to wet or expose the test area to direct sunlight.
- After 24 hours the patch was removed by the panelist at home.
- This procedure was 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 were then given a 10 - 14 day rest period after which a challenge or retest dose was 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 was made between the nine inductive responses and the retest dose.

8.0 Adverse Reactions:

Panelists were instructed to promptly report adverse effects to the investigator. The investigator would then determine the need for an interim examination and, if warranted, termination from the study. Any adverse effect(s), spontaneously expressed by the panelist or observed by the investigator or research staff, during or after the study were recorded on an Adverse Effect(s)/Intercurrent Event(s) Report.

9.0 Observations:

No adverse reactions of any kind were noted during the course of this study.

10.0 Results:

Please refer to attached Table.

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.: G0223-E; Client No.: Maritech Bright Batch VG200914) when tested under semi-occlusive conditions at 1:10 dilution in distilled water as described herein, may be considered as a **NON-PRIMARY IRRITANT** and a **NON-PRIMARY SENSITIZER** to the skin according to the reference.

Shyla Cantor, Ph.D.
Study Director

Mellodene Charles, A.A.S. Cert. EMT
Laboratory Manager

Natacha Pierre, B.S.
Technician

Michelle Peters, B.A.
Quality Assurance Supervisor

4/13/09
Date

TABLE
SUMMARY OF RESULTS
SEMI-OCCLUSIVE PATCH

CR Lab No.: G0223-E
Client No.: Maritech Bright Batch VG200914
Dilution: 1:10 in distilled water

No.	Subject ID	RACE	SEX	Response									Chall.	
				1	2	3	4	5	6	7	8	9	24 HR	48 HR
1	03-7116	H	F	0	0	0	0	0	0	0	0	0	0	0
2	03-6100	C	F	0	0	0	0	0	0	0	0	0	0	0
3	03-7585	AA	M	0	0	0	0	0	0	0	0	0	0	0
4	03-7586	AA	M	0	0	0	0	0	0	0	0	0	0	0
5	03-6299	C	F	0	0	0	0	0	0	0	0	0	0	0
6	03-7347	C	F	0	0	0	0	0	0	0	0	0	0	0
7	03-7142	AA	F	0	0	0	0	0	0	0	0	0	0	0
8	03-6176	AA	F	0	0	0	0	0	0	0	0	0	0	0
9	03-6163	AA	F	0	0	0	0	0	0	0	0	0	0	0
10	03-6098	AA	F	0	0	0	0	0	0	0	0	0	0	0
11	03-6933	AA	M	0	0	0	0	0	0	0	0	0	0	0
12	03-6565	C	F	0	0	0	0	0	0	0	0	0	0	0
13	03-7239	AA	F	0	0	0	0	0	0	0	0	0	0	0
14	03-7029	AA	F	0	0	0	0	0	0	0	0	0	0	0
15	03-6378	C	M	0	0	0	0	0	0	0	0	0	0	0
16	03-6034	C	F	0	0	0	0	0	0	0	0	0	0	0
17	03-7634	AA	M	0	0	0	0	0	0	0	0	0	0	0
18	03-7197	C	F	0	0	0	0	0	0	0	0	0	0	0
19	03-7381	H	F	0	0	0	0	0	0	0	0	0	0	0
20	03-6970	C	M	0	0	0	0	0	0	0	0	0	0	0
21	03-7576	C	F	0	0	0	0	0	0	0	0	0	0	0
22	03-6107	AA	F	0	0	0	0	0	0	0	0	0	0	0
23	03-7461	AA	F	0	0	0	0	0	0	0	0	0	0	0
24	03-7320	C	F	0	0	0	0	0	0	0	0	0	0	0
25	03-6438	C	F	0	0	0	0	0	0	0	0	0	0	0
26	03-7384	C	F	0	0	0	0	0	0	0	0	0	0	0
27	03-7567	C	F	0	0	0	0	0	0	0	0	0	0	0
28	03-7592	AA	F	0	0	0	0	0	0	0	0	0	0	0
29	03-7597	AA	F	0	0	0	0	0	0	0	0	0	0	0
30	03-7340	C	F	0	0	0	0	0	0	0	0	0	0	0
31	03-7251	C	F	0	0	0	0	0	0	0	0	0	0	0
32	03-7237	C	F	0	0	0	0	0	0	0	0	0	0	0

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

CR Lab No.: G0223-E
Client No.: Maritech Bright Batch VG200914
Dilution: 1:10 in distilled water

No.	Subject ID	RACE	SEX	Response									Chall.	
				1	2	3	4	5	6	7	8	9	24 HR	48 HR
33	03-7250	C	F	0	0	0	0	0	0	0	0	0	0	0
34	03-7063	C	F	0	0	0	0	0	0	0	0	0	0	0
35	03-7238	C	F	0	0	0	0	0	0	0	0	0	0	0
36	03-7342	H	F	0	0	0	0	0	0	0	0	0	0	0
37	03-7338	C	F	0	0	0	0	0	0	0	0	0	0	0
38	03-7339	H	M	0	0	0	0	0	0	0	0	0	0	0
39	03-7246	H	F	0	0	0	0	0	0	0	0	0	0	0
40	03-6479	A	F	0	0	0	0	0	0	0	0	0	0	0
41	03-7001	C	M	0	0	0	0	0	0	0	0	0	0	0
42	03-7493	C	M	0	0	0	0	0	0	0	0	0	0	0
43	03-7033	AA	F	0	0	0	0	0	0	0	0	0	0	0
44	03-7630	AA	F	0	0	0	0	0	0	0	0	0	0	0
45	03-7050	AA	F	0	0	0	0	0	0	0	0	0	0	0
46	03-7617	C	F	0	0	0	0	0	0	0	0	0	0	0
47	03-7359	C	M	0	0	0	0	0	0	0	0	0	0	0
48	03-7223	C	F	0	0	0	0	0	0	0	0	0	0	0
49	03-6718	C	F	0	0	0	0	0	0	0	0	0	0	0
50	03-6668	C	F	0	0	0	0	0	0	0	0	0	0	0
51	03-7262	C	F	0	0	0	0	0	0	0	0	0	0	0
52	03-7575	C	F	0	0	0	0	0	0	0	0	0	0	0
53	03-7641	H	F	0	0	0	0	0	0	0	0	0	0	0
54	03-7269	C	F	0	0	0	0	0	0	0	0	0	0	0
55	03-7079	C	F	0	0	0	0	0	0	0	0	0	0	0
56	03-6643	C	F	0	0	0	0	0	0	0	0	0	0	0
57	03-7486	C	F	0	0	0	0	0	0	0	0	0	0	0
58	03-6573	AA	M	0	0	0	0	0	0	0	0	0	0	0

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

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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

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.

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

Date: June 1, 2009

CR Ref. No.: RIPT.G0417-E.SO.50.MAV

Sponsor: Marinova
249 Kennedy Drive
Cambridge Tasmania 7170 Australia

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 under semi-occlusive patch conditions.

3.0 Test Material:

3.1 Test Material Description:

On April 17, 2009, one test sample labeled Maritech Reverse was received from Dermatest Pty Ltd and assigned CR Lab No. G0417-E.

3.2 Test Material Handling:

Upon arrival at Cantor Research Laboratories, Inc., the test material was assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and test(s) requested.

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

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:

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. Reference: CFR Title 21 Part 56, Subparts A, B, C, and D.

5.0 Panel Selection:

5.1 Standards for Inclusion in the Study:

- Individuals who are not currently under a doctor's care.
- Individuals free of any dermatological or systemic disorder which would have interfered with the results, at the discretion of the investigator.
- Individuals free of any acute or chronic disease that may have interfered with or increased the risk of study participation.
- Individuals who have completed a preliminary medical history form mandated by Cantor Research Laboratories, Inc., and are in general good health.
- Individuals, who have read, understood and signed an informed consent document relating to the specific type of study they are subscribing.
- Individuals who were able to cooperate with the investigator and research staff, willing to have the test materials applied according to the protocol, and complete the full course of the study.

5.2 Standards for Exclusion from the Study:

- Individuals under 18 years of age.
- Individuals who were under doctor's care.
- Individuals who were currently taking any medication (topical or systemic) that may have masked or interfered with the test results.
- Subjects with a history of any acute or chronic disease that may have interfered with or increased the risk of study participation.
- Individuals diagnosed with chronic skin allergies.
- Female volunteers who indicated that they were pregnant or nursing.

5.3 Recruitment:

Panel selection was 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:

Each panelist completed an extensive medical history form and was assigned a permanent identification number. An informed consent was obtained from each volunteer describing the 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. These forms are only available for inspection on the premises of Cantor Research Laboratories, Inc. Reference 21 CFR Ch. 1 Part 50, Subpart B.

5.5 Population Demographics:

Number of subjects enrolled		52
Number of subjects completing study		51
Age Range		21 – 67
Sex	Male	9
	Female	43
Race	Caucasian	31
	Hispanic	4
	Asian	2
	African American	15

6.0 Equipment:

- Patch Description: Parke-Davis Hypoallergenic Readi Bandages (20 x 20mm Webril affixed to the center of a 40 x 40mm adhesive bandage) or the equivalent, trimmed at right angles on opposite sides to the opening of the paper backing of patch, allowing air flow.
- 1ml volumetric syringe without a needle.

7.0 Procedure:

- Subjects are requested to bathe or wash as usual before arrival at the facility.
- Test material G0417-E was diluted at 1:10 in distilled water. Dilutions were freshly prepared on each application day.
- 0.2ml of the diluted test material was dispensed onto the semi-occlusive, hypoallergenic patch.
- The patch was then applied directly to the skin of the infrascapular regions of the back, to the right or left of the midline and the subject was dismissed with instructions not to wet or expose the test area to direct sunlight.
- After 24 hours the patch was removed by the panelist at home.
- This procedure was 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 were then given a 10 - 14 day rest period after which a challenge or retest dose was 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 was made between the nine inductive responses and the retest dose.

8.0 Adverse Reactions:

Panelists were instructed to promptly report adverse effects to the investigator. The investigator would then determine the need for an interim examination and, if warranted, termination from the study. Any adverse effect(s), spontaneously expressed by the panelist or observed by the investigator or research staff, during or after the study were recorded on an Adverse Effect(s)/Intercurrent Event(s) Report.

9.0 Observations:

No adverse reactions of any kind were noted during the course of this study.

10.0 Results:

Please refer to attached Table.

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.: G0417-E; Client No.: Maritech Reverse) when tested under semi-occlusive conditions at 1:10 in distilled water as described herein, may be considered as a **NON-PRIMARY IRRITANT** and a **NON-PRIMARY SENSITIZER** to the skin according to the reference.

Shyla Cantor, Ph.D.
Study Director

Mellodene Charles, A.A.S. Cert. EMT
Laboratory Manager

Natacha Pierre, B.S.
Technician

Michelle Peters, B.A.
Quality Assurance Supervisor

6/1/09
Date

TABLE
SUMMARY OF RESULTS
SEMI-OCCLUSIVE PATCH

CR Lab No.: G0417-E
Client No.: Maritech Reverse
Dilution: 1:10 in distilled water

No.	Subject ID	RACE	SEX	Response									Chall.	
				1	2	3	4	5	6	7	8	9	24 HR	48 HR
1	03-6970	C	M	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
3	03-6098	AA	F	0	0	0	0	0	0	0	0	0	0	0
4	03-6573	AA	M	0	0	0	0	0	0	0	0	0	0	0
5	03-6933	AA	M	0	0	0	0	0	0	0	0	0	0	0
6	03-6509	AA	F	0	0	0	0	0	0	0	0	0	0	0
7	03-6565	C	F	0	0	0	0	0	0	0	0	0	0	0
8	03-6163	AA	F	0	0	0	0	0	0	0	0	0	0	0
9	03-7029	AA	F	0	0	0	0	0	0	0	0	0	0	0
10	03-7461	AA	F	0	0	0	0	0	0	0	0	0	0	0
11	03-7237	C	F	0	0	0	0	0	0	0	0	0	0	0
12	03-7251	C	F	0	0	0	0	0	0	0	0	0	0	0
13	03-7693	AA	M	0	0	0	0	0	0	0	0	0	0	0
14	03-7050	AA	F	0	0	0	0	0	0	0	0	0	0	0
15	03-7634	AA	M	0	0	0	0	0	0	0	0	0	0	0
16	03-7239	AA	F	0	0	0	0	0	0	0	0	0	0	0
17	03-6256	C	F	0	0	0	0	0	0	0	0	0	0	0
18	03-7002	C	F	0	0	0	0	0	0	0	0	0	0	0
19	03-7744	H	F	0	0	0	0	0	0	0	0	0	0	0
20	03-7676	C	F	0	0	0	0	0	Dc	Dc	Dc	Dc	Dc	Dc
21	03-7238	C	F	0	0	0	0	0	0	0	0	0	0	0
22	03-6165	C	F	0	0	0	0	0	0	0	0	0	0	0
23	03-6805	A	M	0	0	0	0	0	0	0	0	0	0	0
24	03-7360	C	F	0	0	0	0	0	0	0	0	0	0	0
25	03-7079	C	F	0	0	0	0	0	0	0	0	0	0	0
26	03-7641	H	F	0	0	0	0	0	0	0	0	0	0	0
27	03-7343	C	F	0	0	0	0	0	0	0	0	0	0	0
28	03-6045	A	M	0	0	0	0	0	0	0	0	0	0	0
29	03-7080	C	F	0	0	0	0	0	0	0	0	0	0	0
30	03-7342	H	F	0	0	0	0	0	0	0	0	0	0	0
31	03-7338	C	F	0	0	0	0	0	0	0	0	0	0	0
32	03-7734	C	F	0	0	0	0	0	0	0	0	0	0	0

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

CR Lab No.: G0417-E
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No.	Subject ID	RACE	SEX	Response									Chall.	
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35	03-7534	C	F	0	0	0	0	0	0	0	0	0	0	0
36	03-7743	C	F	0	0	0	0	0	0	0	0	0	0	0
37	03-6643	C	F	0	0	0	0	0	0	0	0	0	0	0
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40	03-7063	C	F	0	0	0	0	0	0	0	0	0	0	0
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44	03-7592	AA	F	0	0	0	0	0	0	0	0	0	0	0
45	03-7197	C	F	0	0	0	0	0	0	0	0	0	0	0
46	03-6683	C	F	0	0	0	0	0	0	0	0	0	0	0
47	03-7644	C	F	0	0	0	0	0	0	0	0	0	0	0
48	03-6718	C	F	0	0	0	0	0	0	0	0	0	0	0
49	03-7250	C	F	0	0	0	0	0	0	0	0	0	0	0
50	03-6668	C	F	0	0	0	0	0	0	0	0	0	0	0
51	03-7246	H	F	0	0	0	0	0	0	0	0	0	0	0
52	03-7262	C	F	0	0	0	0	0	0	0	0	0	0	0

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