

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

**Date:** April 3, 2008  
**CR Ref. No.:** RIPT.F0220-C1.OP.50.BGP  
**Sponsor:** BGP  
2118 Wilshire Blvd., #766  
Santa Monica, California 90403

**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 open patch conditions.

**3.0 Test Material:**

**3.1 Test Material Description:**

On February 20, 2008 one test sample labeled Micro Mist, Formula No. PA-08-032V was received from TCI Laboratories, Inc. and assigned CR Lab No. F0220-C1.

**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.....	20 – 64
Sex.....	Male..... 9
	Female..... 43
Race.....	Caucasian..... 31
	Hispanic..... 3
	Asian..... 4
	African American..... 14

**6.0 Equipment:**

- Acculine Surgical Marking Pen (Accu-Line Products, Inc.).
- 1ml volumetric syringe without a needle.

**7.0 Procedure:**

- Subjects are requested to bathe or wash as usual before arrival at the facility.
- 0.2 ml of the test material was dispensed directly onto a designated area of the panelist's back and allowed to air dry.
- This procedure was repeated until a series of nine consecutive open patch applications 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:**

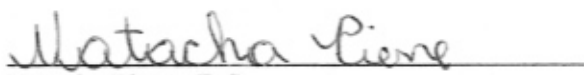
All raw data sheets, technician's notebooks, correspondence files, and copies of final reports are maintained on premises of Cantor Research Laboratories, Inc., in limited access storage files marked "Archive" for five years after completion of the study. A duplicate disk copy of final reports is separately archived in a bank safe deposit vault.

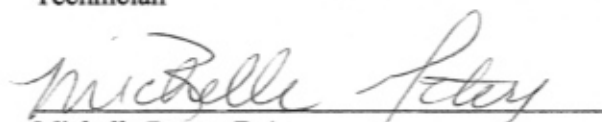
**12.0 Conclusions:**

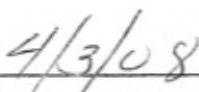
The test material (CR Lab No.: F0220-C1; Client No.: Micro Mist, Formula No. PA-08-032V) when tested under open patch conditions as described herein, may be considered as a **NON-PRIMARY IRRITANT** and a **NON-PRIMARY SENSITIZER** to the skin according to the reference.

  
Shyla Cantor, Ph.D.  
Study Director

  
Mellodene Charles, A.A.S. Cert. EMT  
Technician

  
Natacha Pierre, B.S.  
Technician

  
Michelle Peters, B.A.  
Quality Assurance Supervisor

  
Date

**TABLE**  
**SUMMARY OF RESULTS**  
**OPEN PATCH**

CR Lab No.: F0220-C1  
Client No.: Micro Mist, Formula No. PA-08-032V

No.	Subject ID	R A C E	S E X	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	03-6100	C	F	0	0	0	0	0	0	0	0	0	0	0
3	03-7335	C	F	0	0	0	0	0	0	0	0	0	0	0
4	03-7080	C	F	0	0	0	0	0	0	0	0	0	0	0
5	03-7001	C	M	0	0	0	0	0	0	0	0	0	0	0
6	03-7116	H	F	0	0	0	0	0	0	0	0	0	0	0
7	03-7360	C	F	0	0	0	0	0	0	0	0	0	0	0
8	03-7238	C	F	0	0	0	0	0	0	0	0	0	0	0
9	03-6679	C	M	0	0	0	0	0	0	0	0	0	0	0
10	03-6438	C	F	0	0	0	0	0	0	0	0	0	0	0
11	03-7079	C	F	0	0	0	0	0	0	0	0	0	0	0
12	03-7365	A	F	0	0	0	0	0	0	0	0	0	0	0
13	03-7342	H	F	0	0	0	0	0	0	0	0	0	0	0
14	03-7343	C	F	0	Dc	Dc	Dc	Dc	Dc	Dc	Dc	Dc	Dc	Dc
15	03-6034	C	F	0	0	0	0	0	0	0	0	0	0	0
16	03-6065	C	M	0	0	0	0	0	0	0	0	0	0	0
17	03-7338	C	F	0	0	0	0	0	0	0	0	0	0	0
18	03-6256	C	F	0	0	0	0	0	0	0	0	0	0	0
19	03-7246	H	F	0	0	0	0	0	0	0	0	0	0	0
20	03-7293	AA	F	0	0	0	0	0	0	0	0	0	0	0
21	03-6805	A	M	0	0	0	0	0	0	0	0	0	0	0
22	03-7366	AA	F	0	0	0	0	0	0	0	0	0	0	0
23	03-7367	AA	F	0	0	0	0	0	0	0	0	0	0	0
24	03-7208	C	F	0	0	0	0	0	0	0	0	0	0	0
25	03-6176	AA	F	0	0	0	0	0	0	0	0	0	0	0
26	03-6098	AA	F	0	0	0	0	0	0	0	0	0	0	0
27	03-6933	AA	M	0	0	0	0	0	0	0	0	0	0	0
28	03-7029	AA	F	0	0	0	0	0	0	0	0	0	0	0
29	03-6397	AA	F	0	0	0	0	0	0	0	0	0	0	0
30	03-6509	AA	F	0	0	0	0	0	0	0	0	0	0	0
31	03-6565	C	F	0	0	0	0	0	0	0	0	0	0	0
32	03-6854	AA	M	0	0	0	0	0	0	0	0	0	0	0

**TABLE (CONT'D)**  
**SUMMARY OF RESULTS**  
**OPEN PATCH**

**CR Lab No.:** F0220-C1  
**Client No.:** Micro Mist, Formula No. PA-08-032V

No.	Subject ID	R A C E	S E X	Response									Chall.	
				1	2	3	4	5	6	7	8	9	24 HR	48 HR
33	03-6919	AA	F	0	0	0	0	0	0	0	0	0	0	0
34	03-7239	AA	F	0	0	0	0	0	0	0	0	0	0	0
35	03-6163	AA	F	0	0	0	0	0	0	0	0	0	0	0
36	03-7078	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
38	03-7260	C	M	0	0	0	0	0	0	0	0	0	0	0
39	03-6052	A	F	0	0	0	0	0	0	0	0	0	0	0
40	03-7062	AA	F	0	0	0	0	0	0	0	0	0	0	0
41	03-7198	C	F	0	0	0	0	0	0	0	0	0	0	0
42	03-6076	C	F	0	0	0	0	0	0	0	0	0	0	0
43	03-7292	C	F	0	0	0	0	0	0	0	0	0	0	0
44	03-6003	C	F	0	0	0	0	0	0	0	0	0	0	0
45	03-6718	C	F	0	0	0	0	0	0	0	0	0	0	0
46	03-6770	C	F	0	0	0	0	0	0	0	0	0	0	0
47	03-6045	A	M	0	0	0	0	0	0	0	0	0	0	0
48	03-7250	C	F	0	0	0	0	0	0	0	0	0	0	0
49	03-6906	C	F	0	0	0	0	0	0	0	0	0	0	0
50	03-7269	C	F	0	0	0	0	0	0	0	0	0	0	0
51	03-7237	C	F	0	0	0	0	0	0	0	0	0	0	0
52	03-6039	C	F	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
- 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
- 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.

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

**Date:** April 3, 2008  
**CR Ref. No.:** RIPT.F0220-C3.SO.50.BGP  
**Sponsor:** BGP  
2118 Wilshire Blvd., #766  
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**1.0 Objective:**

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**3.0 Test Material:**

**3.1 Test Material Description:**

On February 20, 2008 one test sample labeled BGP Lotion, Formula No. PA-08-018B was received from TCI Laboratories, Inc. and assigned CR Lab No. F0220-C3.

**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.

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- 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.....		20 – 64
Sex.....	Male.....	9
	Female.....	43
Race.....	Caucasian.....	31
	Hispanic.....	3
	Asian.....	4
	African American.....	14

**6.0 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, 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.
- 0.2ml of the 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:

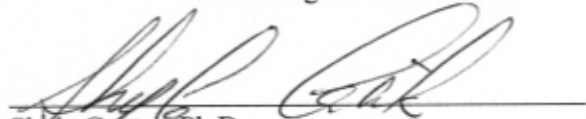
Please refer to attached Table.

#### 11.0 Archiving:

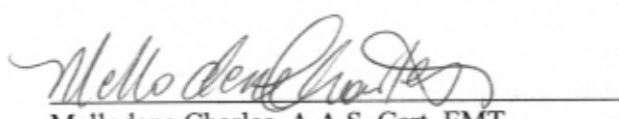
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#### 12.0 Conclusions:

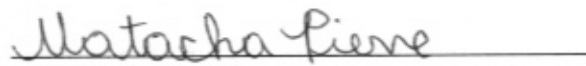
The test material (CR Lab No.: F0220-C3; Client No.: BGP Lotion, Formula No. PA-08-018B) when tested under semi-occlusive conditions as described herein, may be considered as a **NON-PRIMARY IRRITANT** and a **NON-PRIMARY SENSITIZER** to the skin according to the reference.



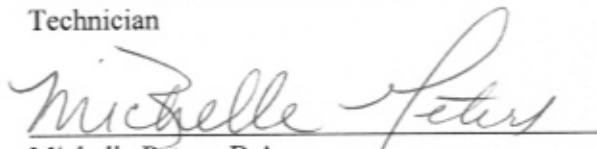
Shyla Cantor, Ph.D.  
Study Director



Mellodene Charles, A.A.S. Cert. EMT  
Technician



Natacha Pierre, B.S.  
Technician



Michelle Peters, B.A.  
Quality Assurance Supervisor

Date

4/3/08

**TABLE**  
**SUMMARY OF RESULTS**  
**SEMI-OCCLUSIVE PATCH**

CR Lab No.: F0220-C3

Client No.: BGP Lotion, Formula No. PA-08-018B

No.	Subject ID	R A C E	S E X	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	03-6100	C	F	0	0	0	0	0	0	0	0	0	0	0
3	03-7335	C	F	0	0	0	0	0	0	0	0	0	0	0
4	03-7080	C	F	0	0	0	0	0	0	0	0	0	0	0
5	03-7001	C	M	0	0	0	0	0	0	0	0	0	0	0
6	03-7116	H	F	0	0	0	0	0	0	0	0	0	0	0
7	03-7360	C	F	0	0	0	0	0	0	0	0	0	0	0
8	03-7238	C	F	0	0	0	0	0	0	0	0	0	0	0
9	03-6679	C	M	0	0	0	0	0	0	0	0	0	0	0
10	03-6438	C	F	0	0	0	0	0	0	0	0	0	0	0
11	03-7079	C	F	0	0	0	0	0	0	0	0	0	0	0
12	03-7365	A	F	0	0	0	0	0	0	0	0	0	0	0
13	03-7342	H	F	0	0	0	0	0	0	0	0	0	0	0
14	03-7343	C	F	0	Dc	Dc	Dc	Dc	Dc	Dc	Dc	Dc	Dc	Dc
15	03-6034	C	F	0	0	0	0	0	0	0	0	0	0	0
16	03-6065	C	M	0	0	0	0	0	0	0	0	0	0	0
17	03-7338	C	F	0	0	0	0	0	0	0	0	0	0	0
18	03-6256	C	F	0	0	0	0	0	0	0	0	0	0	0
19	03-7246	H	F	0	0	0	0	0	0	0	0	0	0	0
20	03-7293	AA	F	0	0	0	0	0	0	0	0	0	0	0
21	03-6805	A	M	0	0	0	0	0	0	0	0	0	0	0
22	03-7366	AA	F	0	0	0	0	0	0	0	0	0	0	0
23	03-7367	AA	F	0	0	0	0	0	0	0	0	0	0	0
24	03-7208	C	F	0	0	0	0	0	0	0	0	0	0	0
25	03-6176	AA	F	0	0	0	0	0	0	0	0	0	0	0
26	03-6098	AA	F	0	0	0	0	0	0	0	0	0	0	0
27	03-6933	AA	M	0	0	0	0	0	0	0	0	0	0	0
28	03-7029	AA	F	0	0	0	0	0	0	0	0	0	0	0
29	03-6397	AA	F	0	0	0	0	0	0	0	0	0	0	0
30	03-6509	AA	F	0	0	0	0	0	0	0	0	0	0	0
31	03-6565	C	F	0	0	0	0	0	0	0	0	0	0	0
32	03-6854	AA	M	0	0	0	0	0	0	0	0	0	0	0

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

**CR Lab No.:** F0220-C3

**Client No.:** BGP Lotion, Formula No. PA-08-018B

No.	Subject ID	R A C E	S E X	Response									Chall.	
				1	2	3	4	5	6	7	8	9	24 HR	48 HR
33	03-6919	AA	F	0	0	0	0	0	0	0	0	0	0	0
34	03-7239	AA	F	0	0	0	0	0	0	0	0	0	0	0
35	03-6163	AA	F	0	0	0	0	0	0	0	0	0	0	0
36	03-7078	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
38	03-7260	C	M	0	0	0	0	0	0	0	0	0	0	0
39	03-6052	A	F	0	0	0	0	0	0	0	0	0	0	0
40	03-7062	AA	F	0	0	0	0	0	0	0	0	0	0	0
41	03-7198	C	F	0	0	0	0	0	0	0	0	0	0	0
42	03-6076	C	F	0	0	0	0	0	0	0	0	0	0	0
43	03-7292	C	F	0	0	0	0	0	0	0	0	0	0	0
44	03-6003	C	F	0	0	0	0	0	0	0	0	0	0	0
45	03-6718	C	F	0	0	0	0	0	0	0	0	0	0	0
46	03-6770	C	F	0	0	0	0	0	0	0	0	0	0	0
47	03-6045	A	M	0	0	0	0	0	0	0	0	0	0	0
48	03-7250	C	F	0	0	0	0	0	0	0	0	0	0	0
49	03-6906	C	F	0	0	0	0	0	0	0	0	0	0	0
50	03-7269	C	F	0	0	0	0	0	0	0	0	0	0	0
51	03-7237	C	F	0	0	0	0	0	0	0	0	0	0	0
52	03-6039	C	F	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
- 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
- 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.

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

**Date:** April 3, 2008  
**CR Ref. No.:** RIPT.F0220-C2.O.50.BGP  
**Sponsor:** BGP  
2118 Wilshire Blvd., #766  
Santa Monica, California 90403

**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 occlusive patch conditions.

**3.0 Test Material:**

**3.1 Test Material Description:**

On February 20, 2008 one test sample labeled Nasal Spray, Formula No. PA-08-023B was received from TCI Laboratories, Inc. and assigned CR Lab No. F0220-C2.

**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.....		20 – 64
Sex.....	Male.....	9
	Female.....	43
Race.....	Caucasian.....	31
	Hispanic.....	3
	Asian.....	4
	African American.....	14

### 6.0 Equipment:

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

### 7.0 Procedure:

- Subjects are requested to bathe or wash as usual before arrival at the facility.
- 0.2ml of the test material was dispensed onto the 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.: F0220-C2; Client No.: Nasal Spray, Formula No. PA-08-023B) 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.



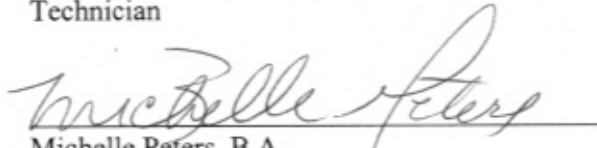
Shyla Cantor, Ph.D.  
Study Director



Mellodene Charles, A.A.S. Cert. EMT  
Technician



Natacha Pierre, B.S.  
Technician



Michelle Peters, B.A.  
Quality Assurance Supervisor

Date

4/3/08

**TABLE**  
**SUMMARY OF RESULTS**  
**OCCLUSIVE PATCH**

CR Lab No.: F0220-C2

Client No.: Nasal Spray, Formula No. PA-08-023B

No.	Subject ID	R A C E	S E X	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	03-6100	C	F	0	0	0	0	0	0	0	0	0	0	0
3	03-7335	C	F	0	0	0	0	0	0	0	0	0	0	0
4	03-7080	C	F	0	0	0	0	0	0	0	0	0	0	0
5	03-7001	C	M	0	0	0	0	0	0	0	0	0	0	0
6	03-7116	H	F	0	0	0	0	0	0	0	0	0	0	0
7	03-7360	C	F	0	0	0	0	0	0	0	0	0	0	0
8	03-7238	C	F	0	0	0	0	0	0	0	0	0	0	0
9	03-6679	C	M	0	0	0	0	0	0	0	0	0	0	0
10	03-6438	C	F	0	0	0	0	0	0	0	0	0	0	0
11	03-7079	C	F	0	0	0	0	0	0	0	0	0	0	0
12	03-7365	A	F	0	0	0	0	0	0	0	0	0	0	0
13	03-7342	H	F	0	0	0	0	0	0	0	0	0	0	0
14	03-7343	C	F	0	Dc	Dc	Dc	Dc	Dc	Dc	Dc	Dc	Dc	Dc
15	03-6034	C	F	0	0	0	0	0	0	0	0	0	0	0
16	03-6065	C	M	0	0	0	0	0	0	0	0	0	0	0
17	03-7338	C	F	0	0	0	0	0	0	0	0	0	0	0
18	03-6256	C	F	0	0	0	0	0	0	0	0	0	0	0
19	03-7246	H	F	0	0	0	0	0	0	0	0	0	0	0
20	03-7293	AA	F	0	0	0	0	0	0	0	0	0	0	0
21	03-6805	A	M	0	0	0	0	0	0	0	0	0	0	0
22	03-7366	AA	F	0	0	0	0	0	0	0	0	0	0	0
23	03-7367	AA	F	0	0	0	0	0	0	0	0	0	0	0
24	03-7208	C	F	0	0	0	0	0	0	0	0	0	0	0
25	03-6176	AA	F	0	0	0	0	0	0	0	0	0	0	0
26	03-6098	AA	F	0	0	0	0	0	0	0	0	0	0	0
27	03-6933	AA	M	0	0	0	0	0	0	0	0	0	0	0
28	03-7029	AA	F	0	0	0	0	0	0	0	0	0	0	0
29	03-6397	AA	F	0	0	0	0	0	0	0	0	0	0	0
30	03-6509	AA	F	0	0	0	0	0	0	0	0	0	0	0
31	03-6565	C	F	0	0	0	0	0	0	0	0	0	0	0
32	03-6854	AA	M	0	0	0	0	0	0	0	0	0	0	0

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

CR Lab No.: F0220-C2

Client No.: Nasal Spray, Formula No. PA-08-023B

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46	03-6770	C	F	0	0	0	0	0	0	0	0	0	0	0
47	03-6045	A	M	0	0	0	0	0	0	0	0	0	0	0
48	03-7250	C	F	0	0	0	0	0	0	0	0	0	0	0
49	03-6906	C	F	0	0	0	0	0	0	0	0	0	0	0
50	03-7269	C	F	0	0	0	0	0	0	0	0	0	0	0
51	03-7237	C	F	0	0	0	0	0	0	0	0	0	0	0
52	03-6039	C	F	0	0	0	0	0	0	0	0	0	0	0

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- 0 - No evidence of any effect
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