HARRISON RESEARCH LABORATORIES, INC.

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Polymer Group, Inc.
HRL Panel #14-115
Test Material #13B: **PSRR# 2014-050, Product Code: 3735800, 71 gsm R/xxS 71 Orange**

PURPOSE:	To evaluate the potential of the Test Material, as a result of repeated applications, to induce dermal sensitization in human subjects.
IRB APPROVAL:	Both the HRL Standard Protocol #100 and the Informed Consent were approved by the Clarus Institutional Review Board (CIRB) on January 23, 2014. A Sponsor-signed Protocol is retained in HRL files.
SPONSOR:	Polymer Group, Inc. 9335 Harris Corners Parkway Charlotte, NC 28269 Per: C.L. DeMille
SPONSOR AUTHORIZATION:	September 22, 2014
SAFETY ASSURANCE:	September 22, 2014
PRINCIPAL INVESTIGATOR:	Lynne B Harrison, PhD
CO-INVESTIGATORS:	Deborah R Spey, MD, FAAD Kimberly K Ruhl, MD, PhD, FAAD Adriana Ros, DO, FAOCD
TEST FACILITY:	Harrison Research Laboratories, Inc. (HRL) 2497 Vauxhall Road Union, New Jersey 07083
TEST MATERIAL:	Test Material PSRR# 2014-050, Product Code: 3735800, 71 gsm R/xxS 71 Orange, an orange-colored fabric, was received on September 23, 2014, with the following instructions: Cut test material into 2 cm X 2 cm samples; test either side of the fabric against the skin. Wet with saline prior to application to skin; patch occlusively.

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SUBJECTS: The even-numbered subjects of this 200-subject panel were patched with this Test Material--115 subjects were enrolled; 104 subjects completed the test. One subject, #138 (HRL #12885), died prior to starting the Challenge Phase. Appropriate Adverse Event notification was sent to the Sponsor. Ten subjects discontinued due to personal reasons. No subject discontinued due to test material reaction.

METHOD: This test was conducted according to HRL Standard Protocol #100 and HRL Standard Operating Procedures (including any Sponsor alterations).

TEST DATES: September 24, 2014 through October 31, 2014.

SCORING SYSTEM: See Table I.

RESULTS: See Table I. During the Induction Phase and the Challenge, no reactions were exhibited.

CONCLUSION: In this Repeated Insult Patch Test, Test Material PSRR# 2014-050, Product Code: 3735800, 71 gsm R/xxS 71 Orange, did not induce dermal sensitization in human subjects.

QUALITY ASSURANCE (QA): The QA Unit performed an in-phase audit of this study.

Deborah R Spey, MD, FAAD	Debra Harrison, MA	Lynne B Harrison, PhD
Co-Investigator (Dermatologist)	Project Manager	Principal Investigator

Date: 11/5/14

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SUBJECTS: Each potential subject completed an HRL Subject History Form (HRL Form:SHF), including relevant medical history. (An updated Subject History Form is secured approximately every two years.) Each accepted subject was assigned a permanent HRL Identification Number. No subject was used if he or she exhibited any dermatological or other medical or physical condition that would preclude topical application of the Test Material. Upon enrollment, no subject reported using any medication that would interfere with the sensitization results. No known pregnant nor nursing women were used on this RIPT. No minor subjects were used on this RIPT.

An appropriate clearance period had elapsed since a subject was patched on a Repeated Insult Patch Test (RIPT) or a Photoallergy Test (PA) before being used in this RIPT.

Legally valid written IRB-approved Informed Consent, in conformity with: 21 CFR 50.25, Subtitle A, Protection of Human Subjects, was secured from each subject.

METHOD: Induction Phase: A webril/adhesive patch (Kendall Healthcare Products Company Patch #4022), or equivalent, was used occlusively. An approximately 2 cm X 2 cm square of the Test Material was applied to each patch. As per HRL Standard Operating Procedures (SOP) (HRL Form:SOP/RIPT), the left side of the back was usually the test area for the Induction Phase. The subject's skin was marked with gentian violet surgical marker at the left side of the test site. The test site was recorded on the anatomical diagram of each subject's individual Data Form. In addition, at that time, the prospective placement of the Challenge test site was also recorded on the anatomical diagram.

Each subject was instructed that the patch was to remain in place and kept dry for approximately 24 hours, at which time the patch was to be removed by the subject. An approximately 24-hour period, during which no test material was applied, followed the weekday patch removals; an approximately 48-hour period followed the weekend patch removals.

Each subject returned to HRL on the appropriate day. The test site was observed by the HRL technician, and the reaction scored and recorded (see **SCORING SYSTEM**, below). The identical test site was then repatched until nine (9) Induction patchings were completed.

In accordance with HRL SOP, if a subject was unable to make up a missed patching during the same week, the subject was either patched four days the following week or was patched at the end of the Induction Phase. Any absences and make-up days are noted by the dates on the individual Data Form.

A series of nine (9) Induction patchings was completed over a period of approximately three weeks.

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METHOD: (continued)

Rest Period: A Rest Period of approximately two weeks followed the last Induction patching; no test material was applied during the Rest Period. Subjects were instructed to notify HRL if they experienced any reaction during the Rest Period.

Challenge Phase: At the Challenge Phase, the original Induction test site was observed and each subject queried as to whether any reaction was experienced during the Rest Period. A webril/adhesive patch (Kendall Healthcare Products Company Patch #4022), or equivalent, was used occlusively. An approximately 2 cm X 2 cm square of the Test Material was applied to each patch. As per HRL RIPT SOP, the right side of the back was usually the virgin test site for the Challenge Phase.

As per HRL RIPT SOP, the Challenge patch was applied to the virgin site only. Each subject was again instructed to keep the patch on and dry.

Each subject reported to HRL approximately 24 hours later (Challenge Reading 1), at which time the patch was removed and the Challenge site scored and recorded by the HRL technician. The original test site was also observed. (See **RESULTS**, below.)

Each subject reported to HRL at approximately 48 hours (Challenge Reading 2), approximately 72 hours (Challenge Reading 3) and approximately 96 hours (Challenge Reading 4) post-patching for additional observations; reactions were scored and recorded.

SCORING SYSTEM: See Table I. The test sites were scored using the modified scoring scale of the International Contact Dermatitis Research Group System: Fisher, Alexander A., *Contact Dermatitis*, Lea & Febiger, Philadelphia, 2008: p 27.

RESULTS: See Table I. No serious adverse events related to the Test Material occurred during this test. Erythema, edema, dryness, staining, peeling and hyperpigmentation / hypopigmentation are possible, expected endpoints and not considered Adverse Reactions. This test was conducted under the supervision of a Board-Certified Dermatologist, a Co-Investigator. At Challenge Reading 3, the Dermatologist participated in the scoring of the subjects. A total of 104 subjects completed the test; 34 male and 70 female. The subjects range in age from 18 to 70.

RETENTION: All original Data Forms will be retained at HRL for a period of three years, or such other time as may be required by law. A laboratory retainer bottle of the Test Material shall be retained, in ambient conditions, for at least two years, or as required by law. Return or disposal of unused Test Material shall be as per the Sponsor's instructions—to be communicated within 30 days of receipt of this Final Report. HRL shall appropriately dispose of any Test Material after six months if no Sponsor instructions have been communicated.

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TABLE I: SUMMARY OF REACTIONS

TOTAL NUMBER OF SUBJECTS ENROLLED: 115
TOTAL NUMBER OF SUBJECTS COMPLETED: 104

Reaction	Induction Reading									Challenge Reading			
Grade	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**1**	**2**	**3**	**4**
0	113	111	111	111	110	110	110	109	107	104	104	104	104
±													
1													
1E													
2													
2E													
3E													
4E													
-													
N9R													
Total	113	111	111	111	110	110	110	109	107	104	104	104	104

SCORING SYSTEM:
0 = No visible reaction
± = Faint, minimal erythema
1 = Erythema
2 = Intense erythema, induration
3 = Intense erythema, induration, vesicles
4 = Severe reaction with erythema, induration, vesicles, pustules (may be weeping)
E = Edema
- = No reading
N9R = No 9th reading

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QUALITY ASSURANCE MEMORANDUM

This Final Report was reviewed for accuracy and conformity with both HRL Standard Protocol #100 and HRL Standard Operating Procedures (including any Sponsor alterations) and any written communication from the Sponsor.

Inspections were accomplished by a random sampling approach and reported to the Project Manager and the Principal Investigator immediately following their completion.

The raw data for this study are retained at Harrison Research Laboratories, Inc.

HARRISON RESEARCH LABORATORIES, INC.

Susan Lauck

SUSAN LAUCK
Quality Assurance Manager

QUALITY ASSURANCE UNIT

Dated: 11/5/14