HARRISON RESEARCH LABORATORIES, INC.

2497 Vauxhall Road • Union, NJ 07083
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AVINTIV
HRL Panel #15-381
Test Materials #1 - #4

PURPOSE: The purpose of this test was to evaluate the potential of the Test Materials to induce a primary skin irritation in humans.

IRB APPROVAL: Both the HRL Standard Protocol #375 and the Informed Consent were approved by the Clarus Institutional Review Board (CIRB) on January 24, 2015.

SPONSOR: AVINTIV
9335 Harris Corners Parkway
Charlotte, NC 28269
Per: Dustin Darnall

SPONSOR AUTHORIZATION: September 28, 2015

SAFETY ASSURANCE: September 28, 2015

PRINCIPAL INVESTIGATOR: Lynne B Harrison, PhD
CO-INVESTIGATORS: Deborah R Spey, MD, FAAD
Kimberly K Ruhl, MD, PhD, FAAD

TEST FACILITY: Harrison Research Laboratories, Inc. (HRL)
2497 Vauxhall Road
Union, New Jersey 07083

TEST MATERIALS:

TM #	PSRR #	Product Code
1	2015-062	74733, 60 gsm Microfiber Light – Blue Print
2	2015-069	74735, 60 gsm Microfiber Light – Yellow Print
3	2015-070	74734, 60 gsm Microfiber Light – Red Print
4	2015-071	74736, 60 gsm Microfiber Light – Green Print

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TEST MATERIALS: (continued) The Test Materials were received at HRL on September 29, 2015 with the following instructions: Cut test material into approximately 2 cm X 2 cm samples; test colored printed area side of the fabric against the skin. Wet with saline prior to application to skin; patch occlusively.

SUBJECTS: 28 subjects were inducted; 27 subjects completed the test. 01 subject discontinued.

TEST DATES: October 21, 2015 through October 23, 2015

METHOD: This test was conducted according to HRL Standard Protocol #375 and HRL Standard Operating Procedures (including any Sponsor alterations).

SCORING SYSTEM: See Table I.

RESULTS: See Table I. No adverse reactions nor adverse events were observed in any of the subjects.

TM #	PSRR #	Reactions (48 hr post-patching) 0	±	1	1E	2
1	2015-062	24	3			
2	2015-069	24	3			
3	2015-070	22	5			
4	2015-071	22	5			

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CONCLUSIONS:

TM #	PSRR #	CONCLUSION
1	2015-062	minimal dermal irritation
2	2015-069	minimal dermal irritation
3	2015-070	minimal dermal irritation
4	2015-071	minimal dermal irritation

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

SCORING CRITERIA

TALLY OF SCORES	REACTION	CONCLUSION
All	0	no dermal irritation
Approximately <10%	± / 1-level	negligible dermal irritation potential
Approximately 10% to 25%	± / 1-level	minimal dermal irritation potential
Approximately 25% to 50%	± / 1-level	moderate dermal irritation potential
Approximately 50% or more or 1 or more	± / 1-level edematous or 2-level	significant dermal irritation potential

Deborah R Spey, MD, FAAD
Co-Investigator (Dermatologist)

Debra Harrison, MA
Project Manager

Lynne B Harrison, PhD
Principal Investigator

Date: 10/28/15

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SUBJECTS: Each potential subject completed an HRL Subject History Form (HRL Form:SHF), including relevant medical history. (An updated 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 which would preclude topical application of the Test Materials. Upon enrollment, no subject reported using any medication that would interfere with the results. No known pregnant nor nursing women were used on this PDI. No minor subjects were used on this PDI.

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: A webril/adhesive patch (Kendall Healthcare Products Company Patch #4022), or equivalent, was used occlusively. An approximately 2 cm X 2 cm square of each Test Material was applied to each designated patch. Each subject was patched and instructed that the patches were to remain in place and dry.

As per HRL Standard Operating Procedures (SOP), the patches were applied on the back. The test sites were recorded on the anatomical diagram of each Data Form. The subjects returned to HRL approximately 48 hr post-patching and the Project Manager removed the patches. The test sites were read approximately 20 min after patch removal.

If the 48 hr readings had showed signs of significant irritancy in human subjects, these subjects would have been requested to return to HRL for additional readings.

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, 1986: p 26.

RESULTS: See Table I. No serious adverse events related to the Test Materials 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, the Co-Investigator. A total of 27 subjects completed the test; 9 male and 18 female. The subjects range in age from 19 to 73.

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 each 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: PRIMARY DERMAL IRRITATION TEST 48 Hr Readings

					48 Hr Readings Test Material			
Subj #	HRL #	Init	Age	Sex	1	2	3	4
1	42897	DG	50	F	0	0	0	0
2	44768	MC	71	M	0	0	0	0
3	30796	KO	63	M	±	0	±	±
4	20714	CD	73	M	0	0	0	0
5	43650	DC	47	M	0	0	±	±
6	35211	JR	52	F	0	0	0	0
7	21906	JF	67	F	±	±	±	±
8	39561	LD	42	F	0	0	0	0
9	43731	PM	35	F	0	0	0	0
10	44713	LG	42	F	0	0	0	0
11	42759	JF	53	F	0	0	0	0
12	39998	DB	59	F	0	0	0	0
13	43177	SE	19	F	0	0	0	0
14	44267	LK	50	F	0	±	0	±
15	41075	CC	66	F	0	0	±	±
16	41106	GM	66	M	0	0	0	0
17	44912	AM	33	F	0	0	0	0
18	42959	HJ	34	F	0	0	0	0
19	27611	RC	63	F	0	0	0	0
20	43264	JF	60	M	±	0	±	0
21	16846	LR	63	M	0	0	0	0
22	35828	LM	29	M	0	0	0	0
23	02431	CX	68	F	0	0	0	0
24	41821	LH	33	F		Discontinued		
25	44733	AS	30	F	0	±	0	0
26	38696	HT	39	M	0	0	0	0
27	36228	MV	58	F	0	0	0	0
28	03184	LD	71	F	0	0	0	0

SCORING SYSTEM*:

0	=	No visible reaction
±	=	Faint, minimal erythema
1	=	Erythema
2	=	Intense erythema
3	=	Intense erythema, induration, vesicles
4	=	Severe reaction with erythema, induration, vesicles, pustules (may be weeping)
E	=	Edema
DR	=	Dryness
P	=	Peeling
S	=	Staining
^	=	Hyperpigmentation / Hypopigmentation
-	=	No reading
TR	=	Tape Reaction

Test Materials

#1	PSRR# 2015-062
#2	PSRR# 2015-069
#3	PSRR# 2015-070
#4	PSRR# 2015-071

***This Scoring System is the modified International Contact Dermatitis Research Group System: Fisher, Alexander A., Contact Dermatitis, Lea & Febiger, Philadelphia, 1986: 26.**

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QUALITY ASSURANCE MEMORANDUM

This Final Report was reviewed for accuracy and conformity with both HRL Standard Protocol #375 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.

Michael Jascur

MICHAEL JASCUR
Quality Assurance

QUALITY ASSURANCE UNIT

Dated 10-28-15