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48 HOUR PATCH TEST
SKIN IRRITATION EVALUATION
(Semi-Occlusive Patch)

AMA Ref. No.: MS14.48HR.N7063SO.50.HYM

Date: September 29, 2014

Sponsor: Hydromer, Inc.
35 Industrial Parkway
Branchburg, New Jersey 08876

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 irritants in certain individuals. It is the intention of a 48 Hour Patch Test to provide a basis for evaluation of this irritation potential if such exists.

2.0 Test Material:

2.1 Test Material Description:

On September 17, 2014 one test sample labeled Hydromer Foaming Antimicrobial Soap Lot # 2319-145, Batch/Formula # 2319-140LC was received from Hydromer, Inc. and assigned AMA Lab No. N-7063.

2.2 Handling:

Upon arrival at AMA 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 received and tests requested.

Samples are retained for a period of three months beyond submission of final report 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.

2.3 Test Material Evaluation Prerequisite:

Prior to induction of a human test panel, toxicology, microbiology 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 3.0.

Sponsor purports that prior to sample submission 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 AMA personnel:

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

3.0 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C, and D. The IRB of AMA 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 AMA Laboratories, Inc. and is available for inspection during the hours of operation.

4.0 Panel Selection:

4.1 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 AMA 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 AMA Laboratories, Inc. only.
- Individuals able to cooperate with the Investigator and research staff, be willing to have test materials applied according to the protocol, and complete the full course of the study.

4.2 Standards for Exclusion from a Study:

- Individuals under 18 years of age.
- Individuals who are currently under a 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 associated with study participation.
- Individuals diagnosed with chronic skin allergies.
- Female volunteers who indicate that they are pregnant or lactating.

4.3 Recruitment:

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

4.4 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 AMA Laboratories, Inc. only. Reference 21 CFR Ch. 1 Part 50, Subpart B.

The parties agree to comply with applicable state and federal privacy laws for the use and disclosure of a subject's personal health information by taking reasonable steps to protect the confidentiality of this information. This obligation shall survive the termination or expiration of this Agreement.

5.0 Population Demographics:

Number of subjects enrolled	50
Number of subjects completing study	50
Age Range	19-68
Sex	Male 7
	Female 43
Race	Caucasian 41
	Hispanic 8
	Asian 1

6.0 Equipment:

- Patch Description: Parke-Davis Hypoallergenic Readit Bandages 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.
- As per client request, the test material N-7063 was diluted to 10% in distilled water.
- 0.2 ml of the test material is dispensed onto the semi-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 48 hours the patch is removed at the facility, and test sites evaluated by trained laboratory personnel.
- 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 again 48 hours following the initial evaluation. Subjects are instructed to report any delayed reactions which might occur after the final reading.
- Clients are notified immediately in the case of an adverse reaction and a determination is made as to treatment program if necessary.

8.0 Results:

Please refer to attached Table.

9.0 Observations:

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

10.0 Archiving:

All original samples, raw data sheets, technician's notebooks, correspondence files and copies of final reports and remaining specimens are maintained on premises of AMA Laboratories, Inc. in limited access storage files marked "Archive". A duplicate disk copy of final reports is separately archived in a bank safe deposit vault.

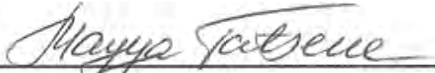
11.0 Security Label Disclosure:

To prevent loss of and protect intellectual property, original, certified documents issued by AMA Laboratories Inc. can be identified by a proprietary, tamper evident security hologram affixed to all Conclusion/Signature pages on final reports. Any attempt to remove the hologram will irreversibly damage the label and leave an immediate trace, thus invalidating the document.

Only reports containing the AMA LABS, INC. hologram intact will be recognized by AMA Laboratories Inc. as a certified original.

12.0 Conclusions:

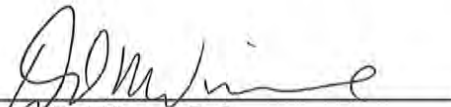
The test material (AMA Lab. No.: N-7063; Client No.: Hydromer Foaming Antimicrobial Soap Lot # 2319-145, Batch/Formula # 2319-140LC) when tested under 48 hour semi-occlusive patching conditions at a 10% dilution in distilled water as described herein, may be considered: a **NON-PRIMARY IRRITANT** to the skin.



Mayya Tatsene, M.D.
Study Director



Breanna Wanamaker, A.A. (Candidate)
Technician



David R. Winne, B.S.
Technical Director

9/29/14

Date



TABLE
SUMMARY OF RESULTS
(Semi-Occlusive Patch)

AMA Lab No.: N-7063
 Client No.: Hydromer Foaming Antimicrobial Soap Lot # 2319-145,
 Batch/Formula # 2319-140LC
 Dilution: 10% in distilled water

No.	SUBJECT ID	RACE	SEX	RESPONSE	
				0 HR	48 HR
1	25 0215	C	M	0	0
2	32 4178	C	F	0	0
3	36 8214	C	F	0	0
4	36 9096	C	F	0	0
5	40 1274	C	F	0	0
6	44 0899	C	F	0	0
7	44 9258	C	F	0	0
8	44 9339	C	F	0	0
9	44 9509	C	F	0	0
10	44 9681	C	F	0	0
11	46 4172	C	F	0	0
12	46 7866	C	F	0	0
13	48 0738	C	F	0	0
14	48 2320	C	F	0	0
15	48 4004	H	F	0	0
16	50 2032	C	F	0	0
17	50 2448	C	M	0	0
18	50 4689	C	F	0	0
19	50 7536	C	F	0	0
20	50 8924	C	F	0	0
21	52 3942	C	F	0	0
22	52 4017	C	F	0	0
23	54 1112	H	F	0	0
24	54 5868	C	F	0	0
25	54 6664	H	F	0	0
26	54 9874	C	F	0	0
27	56 3465	H	F	0	0
28	56 3659	C	F	0	0
29	56 5529	C	F	0	0
30	60 2057	C	M	0	0

TABLE (CONT'D)
SUMMARY OF RESULTS
(Semi-Occlusive Patch)

AMA Lab No.: N-7063
 Client No.: Hydromer Foaming Antimicrobial Soap Lot # 2319-145,
 Batch/Formula # 2319-140LC
 Dilution: 10% in distilled water

No.	SUBJECT ID	RACE	SEX	RESPONSE	
				0 HR	48 HR
31	60 3008	C	M	0	0
32	60 3496	C	F	0	0
33	62 0840	C	F	0	0
34	62 0956	C	F	0	0
35	62 4302	C	F	0	0
36	62 4776	C	F	0	0
37	62 5697	C	F	0	0
38	66 1649	C	F	0	0
39	66 6225	C	M	0	0
40	66 8507	C	M	0	0
41	70 2480	C	F	0	0
42	70 6353	C	F	0	0
43	70 7182	A	F	0	0
44	70 8932	C	F	0	0
45	72 3483	H	M	0	0
46	72 3637	H	F	0	0
47	73 6193	H	F	0	0
48	74 0600	C	F	0	0
49	84 8870	H	F	0	0
50	88 4232	C	F	0	0

Evaluation Period:

This study was conducted from September 22, 2014
 through September 26, 2014.

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
- Dc - Discontinued due to absence of subject on evaluation date
- S - Skin stained from pigment in product
- T - Tan

NOTE:

All technical employees of AMA 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.

13.0 Quality Assurance Statement:

This study was inspected in accordance with the Standard Operating Procedures of AMA Laboratories, Inc. To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the study records and report.

Report reviewed by:



Tasmiya Masud, B.A.
Quality Assurance Supervisor

9/29/14

Date