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24 HOUR PATCH TEST
SKIN IRRITATION EVALUATION
(Open Patch)

AMA Ref. No.: MS20.24HR.P6832OP.50.APP

Date: November 5, 2020

Sponsor: Applied Consumer Services, Inc.
11890 N.W. 87th Court, Unit 8
Hialeah Gardens, Florida 33018

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 24 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 November 2, 2020 one test sample labeled 36583/1 Varigard Hand Sanitizer Complex Lot ANT- 102920 was received from Applied Consumer Services, Inc. and assigned AMA Lab No.: P-6832.

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 but may 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 the Study:

- 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 the Study:

- Individuals under 18 years of age.
- Individuals who are currently taking any medication (topical or systemic) that may mask or interfere with the test results, at the discretion of the study director.
- 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 agreed 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		56
Number of subjects completing study		56
Age Range		18-73
Sex	Male	17
	Female	39
Race	Caucasian	27
	Hispanic	21
	African American/Black	8

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 or 0.2g of the test material is dispensed directly onto a designated area of the panelist's back and allowed to air dry.
- The subject is dismissed with instructions not to wet or expose the test area to direct sunlight, and to check for reactions 24 hours after application of the product.
- The patch area is observed and evaluated by a trained technician 48 hours after test material application, on the subject's return to the RIPT laboratory.
- In the event of an adverse reaction, the area of erythema and edema is measured. Edema is estimated by the evaluation of the skin with respect to the contour of unaffected normal skin.
- 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, copies of final reports and remaining specimens are maintained on the premises of AMA Laboratories, Inc. in limited access marked storage files for a period not to exceed two years. A duplicate copy of final reports is separately archived on digital media in a bank safe deposit vault. Sponsors are encouraged to keep all original signed, dated and certified reports. AMA will not be responsible, and it will not be possible to provide duplicate original hard copies of final reports once the documents leave our premises.

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.: P-6832; Client No.: 36583/1 Varigard Hand Sanitizer Complex Lot ANT- 102920) when tested under 24 hour 'open patch' conditions as described herein may be considered a **NON-PRIMARY IRRITANT** to the skin.

Ronda Bixon, M.D.
Clinical Laboratory Director

Yessenia Cortes, A.A.
Technician

11-9-2020
Date

TABLE
SUMMARY OF RESULTS
(Open Patch)

AMA Lab No.: P-6832
Client No.: 36583/1 Varigard Hand Sanitizer Complex Lot ANT- 102920

No.	SUBJECT ID	RACE	SEX	RESPONSE 0 HR	24 HR	48 HR
1	02 2853	AA	F	0.0	0.0	0.0
2	02 5818	H	F	0.0	0.0	0.0
3	10 0196	H	F	0.0	0.0	0.0
4	35 8496	H	M	0.0	0.0	0.0
5	36 1138	C	M	0.0	0.0	0.0
6	36 1634	H	F	0.0	0.0	0.0
7	38 0621	C	M	0.0	0.0	0.0
8	39 1287	C	F	0.0	0.0	0.0
9	40 0670	C	F	0.0	0.0	0.0
10	42 5232	C	F	0.0	0.0	0.0
11	44 8295	H	F	0.0	0.0	0.0
12	44 8342	H	F	0.0	0.0	0.0
13	44 9509	C	F	0.0	0.0	0.0
14	46 7508	C	M	0.0	0.0	0.0
15	48 2207	C	F	0.0	0.0	0.0
16	50 1810	C	M	0.0	0.0	0.0
17	50 4557	C	F	0.0	0.0	0.0
18	52 0525	C	F	0.0	0.0	0.0
19	52 5991	H	F	0.0	0.0	0.0
20	54 1758	C	F	0.0	0.0	0.0
21	54 4138	C	F	0.0	0.0	0.0
22	54 4408	C	F	0.0	0.0	0.0
23	56 8631	C	F	0.0	0.0	0.0
24	56 9114	C	F	0.0	0.0	0.0
25	58 2348	AA	M	0.0	0.0	0.0
26	58 6363	H	F	0.0	0.0	0.0
27	58 6702	B	M	0.0	0.0	0.0
28	60 1825	C	F	0.0	0.0	0.0
29	60 6310	C	M	0.0	0.0	0.0
30	62 4154	C	F	0.0	0.0	0.0
31	62 5227	B	F	0.0	0.0	0.0
32	64 0607	H	F	0.0	0.0	0.0
33	64 4259	C	M	0.0	0.0	0.0
34	66 6606	H	M	0.0	0.0	0.0
35	68 0405	H	M	0.0	0.0	0.0

TABLE (CONT'D)
SUMMARY OF RESULTS
(Open Patch)

AMA Lab No.: P-6832
Client No.: 36583/1 Varigard Hand Sanitizer Complex Lot ANT- 102920

No.	SUBJECT ID	RACE	SEX	RESPONSE 0 HR	24HR	48 HR
36	68 2278	C	F	0.0	0.0	0.0
37	68 8432	H	F	0.0	0.0	0.0
38	70 1220	C	F	0.0	0.0	0.0
39	70 6967	B	F	0.0	0.0	0.0
40	70 9820	C	M	0.0	0.0	0.0
41	76 7665	H	F	0.0	0.0	0.0
42	78 0519	H	F	0.0	0.0	0.0
43	80 5010	H	M	0.0	0.0	0.0
44	80 7367	H	F	0.0	0.0	0.0
45	82 3031	H	F	0.0	0.0	0.0
46	82 3036	H	F	0.0	0.0	0.0
47	82 4366	H	F	0.0	0.0	0.0
48	84 7424	C	M	0.0	0.0	0.0
49	84 8405	C	F	0.0	0.0	0.0
50	88 4232	C	F	0.0	0.0	0.0
51	88 5852	AA	M	0.0	0.0	0.0
52	92 0179	C	M	0.0	0.0	0.0
53	92 6471	AA	M	0.0	0.0	0.0
54	94 5644	AA	F	0.0	0.0	0.0
55	98 8131	H	F	0.0	0.0	0.0
56	98 9173	H	F	0.0	0.0	0.0

Evaluation Period: This study was conducted from November 02, 2020 through November 04, 2020.

Scoring Scale and Definition of Symbols Shown in Table:

0.0 - No evidence of any effect

0.5 - (Barely perceptible) minimal faint (light pink) uniform or spotty erythema

1.0 - (Mild) pink uniform erythema covering most of contact site

2.0 - (Moderate) pink\red erythema visibly uniform in entire contact area

3.0 - (Marked) bright red erythema with accompanying edema, petechiae or papules

4.0 - (Severe) deep red erythema with vesiculation or weeping with or without edema

S - Skin stained from pigment in product, unable to grade reaction

T - Tan, unable to grade reaction

[ ]^{E} - image of the patch site was electronically transmitted

M - Mixed Heritage

AA - African American

A - Asian

H - Hispanic

B - Black

C - Caucasian

NOTE: All technical employees of AMA LABORATORIES, INC. are required to take and pass a visual discrimination examination overseen 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:

Jennifer Conforto, M.A.
Quality Assurance Supervisor

11/11/2020
Date