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50 SUBJECT HUMAN REPEAT INSULT PATCH TEST FOR SKIN IRRITATION AND SKIN SENSITIZATION EVALUATION

Date: June 7, 2023

Study No.: 23-505A

Sponsor: Biolink Corporation
Jiyugaoka No.2 Mansion #104
Yagumo, Meguro-ku, Tokyo 152-0023 Japan

1.0 Objective: To determine the irritation and sensitization (contact allergy) potential of a test material after repeated application to the skin of human subjects.

2.0 Test Material:

2.1 Test Material Description:

Date Received: March 27, 2023

Received From: Biolink Corporation

Number Of Test Samples Received: 1

Label On Test Samples: Jevie the lotion

Accession No.: 1211938

2.2 Handling:

Upon arrival at ALS Pharmaceutical, Beauty, and Personal Care 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 tests requested.

Samples will be retained for a period of thirty (30) days beyond submission of final report unless otherwise specified by the sponsor or, if sample is known to be in support of governmental applications, in which case representative retained samples are kept two (2) years beyond final report

submission.

Sample disposition will be conducted in compliance with appropriate federal, state and local ordinances.

3.0 Panel Selection:

3.1 Standards for Inclusion in a Study:

- Individuals who were not currently under a doctor's care.
- Individuals who were free of any dermatological or systemic disorder that would interfere with the results, at the discretion of the Investigator.
- Individuals who were free of any acute or chronic disease that would interfere with or increase the risk of study participation.
- Individuals who completed a preliminary medical history form mandated by ALS and were in general good health.
- Individuals who read, understood and signed an informed consent document relating to the specific type of study.
- Individuals who were able to cooperate with the Investigator and research staff, and were willing to have test materials applied according to the protocol, and complete the full course of the study.

3.2 Standards for Exclusion from a Study:

- Individuals who were under 18 years of age.
- Individuals who were currently under a doctor's care.
- Individuals who were currently taking any medication (topical or systemic) that might mask or interfere with the test results.
- Individuals who had a history of any acute or chronic disease that might interfere with or increase the risk associated with study participation.
- Individuals who were diagnosed with chronic skin allergies.
- Female volunteers who indicated that they were pregnant or nursing.

3.3 Recruitment:

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

3.4 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 ALS 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.

4.0 Population Demographics:

Number of subjects enrolled	55
Number of subjects completing study	53
Age Range	19-62
Sex	
Male	11
Female	42
Fitzpatrick Skin Type*	
1 – always burn, does not tan	0
2 – burn easily, tan slightly	5
3 – burn moderately, tan progressively	20
4 – burn a little, always tan	26
5 – rarely burn, tan intensely	2
6 – never burn, tan very intensely	0

*[Agache P., Hubert P.. Measuring the skin. (p. 473, table 48.1) Springer-Verlag Berlin Heidelberg, 2004, (p. 473, table 48.1)]

5.0 Equipment:

Test materials to be tested under occlusive conditions were placed on an adhesive tape with paper filter discs with 1.0 cm2 (Adhesive tapes from 3M Company – Durapore (Code 1538) and Blenderm (Code 1525) or placed on an 8-millimeter aluminum Finn Chamber® (Epitest Ltd. Oy, Tuusula, Finland) supported on Scanpor® Tape (Norgesplaster A/S, Kristiansand, Norway) or an 8-millimeter filter paper coated aluminum Finn Chamber® AQUA supported on a thin flexible transparent polyurethane rectangular film coated on one side with a medical grade acrylic adhesive, consistent with adhesive used in state-of-the-art hypoallergenic surgical tapes or a 7mm IQ-ULTRA® closed cell system which is made of additive-free polyethylene plastic foam with a filter paper incorporated (It is supplied in units of 10 chambers on a hypoallergenic non-woven adhesive tape; the width of the tape is 52mm and the length is 118mm) or other equivalents.

Test materials to be tested under semi-occlusive conditions were placed on an adhesive tape with paper filter discs with 1.0 cm2 (Adhesive tapes from 3M Company – Durapore (Code 1538) or placed on a test strip with a Rayon/Polypropylene pad or on a 7.5mm filter paper disc affixed to a strip of hypoallergenic tape (Johnson & Johnson 1 inch First Aid Cloth Tape).

Test materials to be tested in an open patch were applied and rubbed directly onto the back of the subject.

Approximately 0.02-0.05 mL (in case of liquids) and/or 0.02-0.05 gm (in case of solids) of the test material was used for the study. Liquid test material was dispensed on a paper disk, which fit in the patch chamber.

6.0 Procedure:

- Subjects were requested to bathe or wash as usual before arrival at the facility.
- Patches containing the test material were then affixed directly to the skin of the intrascapular regions of the back, to the right or left of the midline and subjects were dismissed with instructions not to wet or expose the test area to direct sunlight.
- Approximately 1-3% sodium lauryl sulfate in distilled water will be applied as a positive control and approximately 0.02-0.05 mL of distilled water will be applied as a negative control. These will be applied on an occlusive patch the first induction only.
- Patches remained in place for 48 hours after the first application. Subjects were instructed not to remove the patches prior to their 48 hour scheduled visit. Thereafter, subjects were instructed to remove patches 24 hours after application for the remainder of the study.
- This procedure was repeated until a series of eight (8) to nine (9) consecutive, 24-hour exposures had been made three (3) times a week for three (3) consecutive weeks.
- Prior to each reapplication, the test sites evaluated by trained laboratory personnel.
- Following a 10-14 day rest period a retest/challenge dose was applied once to a previously unexposed test site. Test sites were evaluated by trained laboratory personnel 48 and 96 hours after application.
- In the event of a reaction, the area of erythema and edema were measured. Edema is estimated by the evaluation of the skin with respect to the contour of the unaffected normal skin.
- Subjects were instructed to report any delayed reactions that might occur after the final reading.
- Clients will be notified immediately in the case of an adverse reaction and a determination is made as to treatment program if necessary.

7.0 Scoring:

Scoring scale and definition of symbols shown below are based on the scoring scheme according to the International Contact Dermatitis Research Group scoring scale [Rietschel, R.L., Fowler, J.F., Ed., Fisher's Contact Dermatitis (fourth ed.). Baltimore, Williams & Wilkins, 1995] listed below:

0 no reaction (negative)
1 erythema throughout at least ¾ of patch area
2 erythema and induration throughout at least ¾ of patch area
3 erythema, induration and vesicles
4 erythema, induration and bullae

D Site discontinued
Dc Subject discontinued voluntarily
Dcl Subject discontinued per Investigator

NOTE: Clinical evaluations are performed by an ALS investigator or designee trained in the clinical evaluation of the skin. Whenever feasible, the same individual will do the scoring of all the subjects throughout the study and will be blinded to the treatment assignments and any previous scores.

8.0 Results:

Accession No.: 1211938
Test Material Description: Jevie the lotion
Patch Description: Occlusive

Subject Information					Induction									Challenge	
No.	Subject ID	Sex	Age	Skin Type	1	2	3	4	5	6	7	8	9	1	2
1	3000083	F	23	4	0	0	0	0	0	0	0	0	0	0	0
2	3000209	F	26	3	0	0	0	0	0	0	0	0	0	0	0
3	3000293	M	49	3	0	0	0	0	0	0	0	0	0	0	0
4	3000301	F	46	3	0	0	0	0	0	0	0	0	0	0	0
5	3000349	F	43	4	0	0	0	0	0	0	0	0	0	0	0
6	3000559	F	47	2	0	0	0	0	0	0	0	0	0	0	0
7	3000824	F	55	3	0	0	0	0	0	Dc	Dc	Dc	Dc	Dc	Dc
8	3000910	M	55	2	0	0	0	0	0	0	0	0	0	0	0
9	3000940	F	25	4	0	0	0	0	0	0	0	0	0	0	0
10	3001959	F	55	2	0	0	0	0	0	0	0	0	0	0	0
11	3002098	F	32	3	0	0	0	0	0	0	0	0	0	0	0
12	3003105	F	24	4	0	0	0	0	0	0	0	0	0	0	0
13	3007289	F	61	3	0	0	0	0	0	0	0	0	0	0	0
14	3009349	M	42	3	0	0	0	0	0	0	0	0	0	0	0
15	3009350	F	25	3	0	0	0	0	0	0	0	0	0	0	0
16	3009383	M	32	2	0	0	0	0	0	0	0	0	0	0	0
17	3009408	F	47	3	0	0	0	0	0	0	0	0	0	0	0
18	3011824	F	41	3	0	0	0	0	0	0	0	0	0	0	0
19	3015981	F	61	4	0	0	0	0	0	0	0	0	0	0	0
20	3022404	F	21	3	0	0	0	0	0	0	0	0	0	0	0
21	3022413	M	62	4	0	0	0	0	0	0	0	0	0	0	0
22	3022467	F	35	4	0	0	0	0	0	0	0	0	0	0	0
23	3022480	M	28	4	0	0	0	0	0	0	0	0	0	0	0
24	3022923	F	45	3	0	0	0	0	0	0	0	0	0	0	0
25	3023075	M	48	3	0	0	0	0	0	0	0	0	0	0	0
26	3023106	F	47	3	0	0	0	0	0	0	0	0	0	0	0
27	3023110	F	32	4	0	0	0	0	0	0	0	0	0	0	0
28	3023111	F	44	4	0	0	0	0	0	0	0	0	0	0	0
29	3023112	F	37	4	0	0	0	0	0	0	0	0	0	0	0
30	3023113	F	44	3	0	0	0	0	0	0	0	0	0	0	0
31	3023114	F	36	4	0	0	0	0	0	0	0	0	0	0	0
32	3023117	F	37	4	0	0	0	0	0	0	0	0	0	0	0
33	3023118	F	31	2	0	0	0	0	0	0	0	0	0	0	0
34	3023120	F	38	3	0	0	0	0	0	0	0	0	0	0	0

35	3023121	F	36	4	0	0	0	0	0	0	0	0	0	0	0
36	3023123	F	33	4	0	0	0	0	0	0	0	0	0	0	0
37	3023124	M	49	3	0	0	0	0	0	0	0	0	0	0	0
38	3023125	M	40	3	0	0	0	0	0	0	0	0	0	0	0
39	3023126	F	48	4	0	0	0	0	0	0	0	0	0	0	0
40	3023128	F	48	3	0	0	0	0	0	0	0	0	0	0	0
41	3023134	F	40	3	0	0	0	0	0	0	0	0	0	0	0
42	3023145	M	26	3	0	0	0	0	0	0	0	0	0	0	0
43	3023176	F	34	4	0	0	0	0	0	0	0	0	0	0	0
44	3023233	F	32	4	0	0	0	0	0	0	0	0	0	0	0
45	3023377	F	52	4	0	0	0	0	0	0	0	0	0	0	0
46	3023488	F	23	5	0	0	0	0	0	0	0	0	0	0	0
47	3023581	F	26	4	0	0	0	0	0	0	0	0	0	0	0
48	3023649	F	27	4	0	0	0	0	0	0	0	0	0	0	0
49	3023662	F	35	4	0	0	0	0	0	0	0	0	0	0	0
50	3023776	F	58	4	0	0	0	0	0	0	0	0	0	0	0
51	3023865	F	33	5	0	0	0	0	0	0	0	0	0	0	0
52	3023874	F	61	4	0	0	0	0	0	0	0	0	0	0	0
53	3023877	M	52	4	0	0	0	0	0	0	0	0	0	0	0
54	3023979	M	44	3	0	0	0	0	0	Dc	Dc	Dc	Dc	Dc	Dc
55	3025184	F	19	4	0	0	0	0	0	0	0	0	0	0	0

9.0 Evaluation Period:

The study was conducted from April 24, 2023 to June 2, 2023.

10.0 Observations:

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

There was two subjects (2) with a Grade 4 reaction, two subjects (2) with a Grade 2 reaction and fourteen (14) subjects with a Grade 1 reaction to the positive control (1.0% Sodium Lauryl Sulfate Solution).

No subjects showed any signs of reaction to the negative control (DI Water).

11.0 Study Archives:

All original samples, raw data sheets, technician's notebooks, correspondence files and copies of final reports and remaining specimens will be maintained on premises of ALS in limited access storage files marked "Archive".

12.0 Conclusions:

Under the conditions of the study, there was no indication of a potential to elicit dermal irritation or sensitization (contact allergy) noted for Jevie the lotion. Accession No. 1211938.

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