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HUMAN REPEAT INSULT PATCH TEST FOR SKIN SENSITIZATION (CONTACT ALLERGY) AND SKIN IRRITATION EVALUATION

Study Title:	Human Repeat Insult Patch Test for Skin Sensitization (Contact Allergy) and Skin Irritation Evaluation
Study Number:	BCS XX-XXXA
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I. OBJECTIVE

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

II. BACKGROUND[1, 2]

Allergic contact dermatitis (sensitization) results when a substance contacting the skin has undergone an immunological alteration in its reactivity. This altered reactivity is the result of prior exposure material to the skin, which may lead to the hallmark visual symptoms of erythema, edema, papules.

Primary (acute) irritation is a complex biologic syndrome, with a diverse pathophysiology, natural history and clinical appearance. When exposure is sufficient and the offending agent/test material is potent, classic symptoms of acute skin irritation are seen which include hallmark visual symptoms of erythema, edema, and papules. The irritant reaction quickly peaks and then begins to heal upon removal of irritant. The onset is acute and often after one single exposure. Predictive testing is widely performed to determine the irritant potential of test agents.

III. TESTING FACILITIES

BioScreen Clinical Services Division
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3305 N. 2nd Street
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IV. STUDY DURATION

Each study panel will be complete within a 6-week period.

V. STUDY DESIGN AND METHODS

A. Test Products

Test products that have been reviewed and approved for use by Regulatory and Safety representatives of the Sponsor company will be tested.

B. Subjects

1. Number of subjects: Study will be completed with the requested minimum number of healthy subjects per sponsor meeting inclusion/exclusion criteria detailed below.
2. Sex: Male or Female.
3. Age: 18 - 65 years.
4. Standards for inclusion in the study:
   a. Individuals who will be able to read, understand and give an informed consent relating to the study they are participating in.
   b. Individuals who will be free of any dermatological or systemic disorder, which in the Investigator's opinion, could interfere with the study results.
   c. Individuals who will be in general good health and who will complete a preliminary medical history form mandated by the testing facility.
   d. Individuals who will be able to and agree to cooperate with the Investigator and clinical staff.
   e. Individuals who will agree to have test products applied in accordance with the protocol and are able to complete the full course of the study.
   f. Individuals who have not participated in a similar study in the past 30 days.
5. Standards for exclusion from the study:
   a. Individuals who are currently taking any medications (topical or systemic) that may mask or interfere with the test results (specifically, corticosteroids, topical and/or systemic [except nasal steroids], non steroidal anti-inflammatory drugs [e.g. ibuprofen, Advil, Motrin, aspirin > 325mg/day], antihistamines, and topical/oral immunosuppressive medications).
   b. Individuals who have a history of any acute or chronic disease that might interfere with or increase the risk on study participation. (e.g., systemic lupus erythematosus, rheumatoid arthritis, HIV positive).
   c. Individuals who are diagnosed with chronic skin allergies (atopic dermatitis/eczema) or recently treated skin cancer within the last 12 months.
   d. Individuals who have damaged skin in close proximity to test sites (e.g., sunburn, uneven skin pigmentation, tattoos, scars, or other disfigurations).
   e. Individuals who control their diabetes using insulin.
   f. Individuals with any history, which in the Investigator's opinion, indicates the potential for harm to the subject or places the validity of the study in jeopardy.

g. Female volunteers who indicate that they are pregnant or are planning to become pregnant or nursing.
h. Individuals with a known history of hypersensitivity to any cosmetics, personal care products, fragrances, and/or adhesives.

6. Source of subject participation:
   Subjects will be recruited for the study via advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media or any combination thereof.

C. Informed Consent Form and Medical History Form

An informed consent for voluntary study participation will be obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects and associated risks of the treatment. Subjects will sign and date the informed consent form to indicate their voluntary study participation, authorization to proceed and acknowledge their understanding of the contents.[3]

Each subject will be assigned a permanent identification number and complete a medical history form. The medical history forms, along with the signed consent forms, will be available for inspection on the premises of the clinic only.

D. Procedure

1. Method of Application:
   Occlusive – Test products to be studied under occlusive conditions will be applied 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.[4]
   Semi-occlusive – Test products to be tested under semi-occlusive conditions will be placed on a 23-millimeter hypoallergenic skin bandage (Curad Sensitive Skin®, Beiersdorf Inc., Wilton CT) or on a 7.5mm filter paper disc affixed to a strip of hypoallergenic tape (Johnson & Johnson 1 inch First Aid Cloth Tape).
   Open Application – Test products to be tested without any occlusion will be rubbed directly on to skin (area 1cm^2) for approximately 1 minute.
2. Test products:
   Approximately 0.02-0.05 mL (in case of liquids) and approximately 0.02-0.05 g (in case of solids) of the test products will be applied to the test site.

Liquid test products will be dispensed on a 7.5mm paper disc, which will fit in chamber.

3. Test Product Preparation:
   Test Product Preparation will be performed as noted below unless otherwise requested by Sponsor.
   Solid/Powder test products – Solid test products and powder test products will be finely mixed with USP petrolatum (10% w/w) to obtain a semisolid preparation that will ensure extended contact.
   Test products containing surfactants – Test products containing surfactants will be diluted to 3% with distilled water before application to the test site.
   All test product preparation procedures will be recorded.
4. Positive Control:
   Approximately 1-3% sodium lauryl sulfate (Sigma Chemicals, St. Louis, Missouri) in distilled water will be applied as a positive control.
5. Negative Control:
   Approximately 0.02-0.05 mL of distilled water will be dispensed on a 7.5mm paper disc, which will fit in chamber.
6. Test Sites:
   The patches will be applied directly to the skin of the intrascapular regions of the back, to the right and/or left of the midline, and/or upper arms.
7. Subjects will be given a Panelist Instructions for Safety Patch Test (Appendix A). Subjects will be dismissed with instructions to keep the test area dry while the patches are in place and to not expose the test area to direct sunlight. Subjects will be instructed to notify clinical staff during the course of the study should they begin using any new medications, cease taking any medications or have any change in their medical condition.
8. Patches from the first induction will remain in place for 48 hours. Subjects will be instructed to not to remove the patches prior to their next scheduled visit.
9. Thereafter, subjects will be instructed to remove the patches 24 hours post-application.
10. The procedure will be repeated until a series of 8-9 consecutive 24-hour exposures have been made over 3 consecutive weeks. This is considered the induction phase
11. Before each re-application, the test sites will be visually evaluated for any reaction.
12. Following the induction phase, subject will be given a minimum of 10 day rest period.
13. A challenge or test dose will be applied once to a previously unexposed test site (preferably upper arms). Subjects will be instructed to remove the patches 24 hours post-application.
14. Reactions will be scored 48 (Challenge 1) and 96 (Challenge 2) hours post-application.
15. Comparisons will be made between the nine (9) inductive responses and the challenge response.

16. A trained skin grading technician or the Investigator/Sub-investigator will evaluate the test sites. The skin grader will be blinded to the treatment assignments and any previous scores.
17. Skin response to the test product will be evaluated according to the International Contact Dermatitis Research Group (ICDRG) scoring scale [5] 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

18. The Sponsor will be notified within 1-2 business days of any subject who:
    - exhibits an erythema score of 2 or greater
    - exhibits papules, vesicles, bullae and/or spreading beyond the patch site, regardless of the degree of erythema
    - requires follow-up
19. If any subject shows a significant reaction at the 96 hour evaluation during the challenge phase, the Investigator may decide to schedule a re-challenge patch test for confirmatory purposes. This follow-up investigation will be conducted approximately 4-12 weeks after the completion of the challenge phase and will be identical to the challenge phase.
20. In the event of a re-challenge patch the original test substance should be applied under the same testing conditions (concentration and patch type) to confirm delayed contact hyper-reactivity. Related substances (product reformulations, individual ingredients, ingredient groups, etc.) can also be applied to aid in determining the causative relationship.

VI. ADVERSE EVENTS

The most commonly observed reactions in this study are:

1. Itching, redness, rash, peeling, swelling and in rare cases blistering.
2. There is also a possibility of getting a reaction from the tape possible resulting in hyperpigmentation.

There also may be risks and discomforts, which are not yet known.

An adverse event (AE) is any unfavorable medical occurrence experienced by the subject, whether or not the event may be related to the test article.

A serious adverse event (SAE) as defined in the CFR 312.32 is "any experience that is fatal or life threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose". All serious

adverse events will be reported to the Sponsor within 24 hours of BioScreen Clinical Services notification.

If, according to the Investigator, medical care is warranted, appropriate referrals will be made. BioScreen Clinical Services will follow adverse events until resolution.

VII. SUBJECT DISCONTINUATION

Criteria for the discontinuation of a subject during the study will include the following:

1. Significant protocol violation
2. Serious adverse experience
3. Request of the subject
4. Any unmanageable factor, in the Investigator's opinion, that may significantly interfere with the protocol or interpretation of results.

VIII. PROTOCOL AMENDMENT

Neither BioScreen Clinical Services nor the Sponsor company will modify this protocol without prior written notification.

IX. STUDY MONITORING

In accordance with current FDA and GCP guidelines, a Sponsor's representative may periodically inspect the clinical records, including clinical report forms, source/back-up documents, research facilities and clinical laboratory facilities associated with this study at mutually convenient times during or after the completion of the study. The monitoring visits provide the Sponsor with the opportunity to evaluate the progress of the study, verify the accuracy and completeness of the clinical report forms, assure that all protocol requirements, applicable FDA laws and regulations and BioScreen's obligations are being fulfilled.

X. DATA REPORTING

Skin responses to the test product for each subject will be presented in a table in the final report.

Product reporting for skin irritation will be based on scores after the first 48 hour patch removal.

Product reporting for skin sensitization (contact allergy) will be based on scores after the 96-hour patch removal of challenge phase.

XI. STUDY REPORT

Within 3 business days of study completion a study report will be submitted to the Sponsor if no dermatologist review is required.

Within 8 business days of study completion a study report will be submitted to the Sponsor if dermatologist review is required.

XII. DATA ARCHIVES

All raw data sheets, correspondence files and any product related information will be maintained on the premises of the clinic in limited access marked storage files. A copy of the final report will be archived at BioScreen Testing Laboratories, Torrance, CA.

Samples will be retained for a period of 30 days beyond submission of final report. Sample disposition will be conducted in compliance with appropriate federal, state and local ordinances and Sponsor instructions, if any, set forth in Clinical Sample Submission Form.

REFERENCES

1. Weltfriend S, Ramon M, and Maibach H. Irritation Dermatitis, In Dermatotoxicology, 6th edition, CRC press, 2004, pp.181-235.
2. Contact Dermatitis, Dermatology, Volume 1, 2nd edition, by S Moschella MD, H Hurley MD, W.B Saunders, Company, 1985.
3. 21 CFR. Ch.1. Part 50, Subpart B.
4. Fischer T, and Maibach HI. Finn chamber patch test technique. Contact Dermatitis .11:137-40. 1984.
5. Rietschel, R.L., Fowler, J.F., Ed., Fisher's Contact Dermatitis (fourth Ed.). Baltimore, Williams & Wilkins, 1995.

APPENDIX A

PANELIST INSTRUCTIONS FOR SAFETY PATCH TEST

- Keep the first set of patches on for 48 hours. Do not remove these patches. They will be removed by a staff member at your next scheduled visit.

- Thereafter, keep the patches on for no less than 24 hours after application. After 24 hours you may take them off.

- Please keep patches out of direct sun light and water; bathing is okay, be careful during showering, try not to get water directly on the patches. DO NOT scrub or scratch the area.

- Once you have removed the patches, you will still need to keep the test area out of direct sunlight.

- If patches fall off **do not** attempt to re-patch to the skin. Simply report back to the facility and inform the clinical staff of the day and time that the patches came off.

- The patches may mildly itch, and the skin around the patches may turn slightly red. The itching and redness should dissipate on its own. However, if you have intense itching and/or burning (at a level where you cannot tolerate or sleep) remove the patches and contact BioScreen at (602) 277-1154 or (424) 212-6380.

- Please remember to let the clinical staff know at your next visit if:

    - You start taking any new medications. Remember to refrain from taking aspirin, antihistamines, and corticosteroids during the course of this study. Tylenol or any generic acetaminophen is okay (under 325 mg per day). Tylenol PM contains antihistamine; you cannot take it during the study.

    - You stop taking a medication you were on at the beginning of the study.

    - You have any change in your medical condition.

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

Date: May 20, 2015

BCS Study No.: 15-609A

Sponsor: Westwood Laboratories
710 South Ayon
Azusa, CA 91702

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: 03/12/2015

Received From: Westwood Laboratories

Number Of Test Samples Received: 3

Label On Test Samples: Curx Ointment

Accession No.: 892112

2.2 Handling:

Upon arrival at BioScreen Clinical Services (BCS) 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 BCS 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 BCS 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	53
Number of subjects completing study	53
Age Range	18-63
Sex	
Male	13
Female	40
Fitzpatrick Skin Type*	
1 – always burn, does not tan	0
2 – burn easily, tan slightly	4
3 – burn moderately, tan progressively	47
4 – burn a little, always tan	2
5 – rarely burn, tan intensely	0
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 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 a 23-millimeter hypoallergenic skin bandage (Curad Sensitive Skin[↓], Beiersdorf Inc., Wilton CT) 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 7.5mm paper disk, which fit in the Finn 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.
- 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 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 an adverse 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

NOTE: Clinical evaluations are performed by a BCS 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.: 892112
Test Material Description: Curex Ointment
Patch Description: Semi-Occlusive

Subject Information					Induction									Challenge	
No.	ID	Sex	Age	Skin Type	1	2	3	4	5	6	7	8	9	1	2
1	1571322	M	53	3	0	0	0	0	0	0	0	0	0	0	0
2	1701456	F	47	2	0	0	0	0	0	0	0	0	0	0	0
3	1746891	F	37	3	0	0	0	0	0	0	0	0	0	0	0
4	1763298	F	45	3	0	0	0	0	0	0	0	0	0	0	0
5	1810290	M	43	3	0	0	0	0	0	0	0	0	0	0	0
6	1880191	M	40	3	0	0	0	0	0	0	0	0	0	0	0
7	2281358	F	23	4	0	0	0	0	0	0	0	0	0	0	0
8	2370001	F	53	3	0	0	0	0	0	0	0	0	0	0	0
9	2374373	F	53	3	0	0	0	0	0	0	0	0	0	0	0
10	2374957	F	52	3	0	0	0	0	0	0	0	0	0	0	0
11	2423281	F	48	3	0	0	0	0	0	0	0	0	0	0	0
12	2471400	F	43	2	0	0	0	0	0	0	0	0	0	0	0
13	2485049	M	41	3	0	0	0	0	0	0	0	0	0	0	0
14	2488912	F	41	3	0	0	0	0	0	0	0	0	0	0	0
15	2493113	F	39	2	0	0	0	0	0	0	0	0	0	0	0
16	2518510	F	38	3	0	0	0	0	0	0	0	0	0	0	0
17	2518816	M	38	3	0	0	0	0	0	0	0	0	0	0	0
18	2539007	F	35	3	0	1	0	0	0	0	0	0	0	0	0
19	2541101	F	36	3	0	0	0	0	0	0	0	0	0	0	0
20	2545275	M	35	3	0	0	0	0	0	0	0	0	0	0	0
21	2559285	F	34	3	0	0	0	0	0	0	0	0	0	0	0
22	2562479	F	32	3	0	0	0	0	0	0	0	0	0	0	0
23	2580551	F	31	3	0	0	0	0	0	0	0	0	0	0	0
24	2600140	F	30	3	0	0	0	0	0	0	0	0	0	0	0
25	2610099	F	28	3	0	0	0	0	0	0	0	0	0	0	0
26	2664853	M	25	4	0	0	0	0	0	0	0	0	0	0	0
27	2672278	M	25	3	0	0	0	0	0	0	0	0	0	0	0
28	2673570	F	25	3	0	0	0	0	0	0	0	0	0	0	0
29	2676546	F	24	3	0	0	0	0	0	0	0	0	0	0	0
30	2696876	F	24	3	0	0	0	0	0	0	0	0	0	0	0
31	2701564	M	23	3	0	0	0	0	0	0	0	0	0	0	0
32	2729924	F	20	3	0	0	0	0	0	0	0	0	0	0	0
33	2735118	F	20	3	0	0	0	0	0	0	0	0	0	0	0

Subject Information					Induction									Challenge	
No.	ID	Sex	Age	Skin Type	1	2	3	4	5	6	7	8	9	1	2
34	2737757	F	20	3	0	0	0	0	0	0	0	0	0	0	0
35	3211612	F	59	3	0	0	0	0	0	0	0	0	0	0	0
36	4111410	F	59	2	0	0	0	0	0	0	0	0	0	0	0
37	4219740	M	21	3	0	0	0	0	0	0	0	0	0	0	0
38	4781290	F	39	3	0	0	0	0	0	0	0	0	0	0	0
39	5251296	F	46	3	0	0	0	0	0	0	0	0	0	0	0
40	6099116	F	63	3	0	0	0	0	0	0	0	0	0	0	0
41	6150951	F	55	3	0	0	0	0	0	0	0	0	0	0	0
42	6195040	F	49	3	0	0	0	0	0	0	0	0	0	0	0
43	6274890	F	44	3	0	0	0	0	0	0	0	0	0	0	0
44	7128056	F	25	3	0	0	0	0	0	0	0	0	0	0	0
45	9081655	M	55	3	0	0	0	0	0	0	0	0	0	0	0
46	110140252	F	36	3	0	0	0	0	0	0	0	0	0	0	0
47	112670783	F	37	3	0	0	0	0	0	0	0	0	0	0	0
48	115310029	M	22	3	0	0	0	0	0	0	0	0	0	0	0
49	115870666	F	20	3	0	0	0	0	0	0	0	0	0	0	0
50	116200521	M	19	3	0	0	0	0	0	0	0	0	0	0	0
51	117130161	F	18	3	0	0	0	0	0	0	0	0	0	0	0
52	601061044	F	61	3	0	0	0	0	0	0	0	0	0	0	0
53	15681 3174928	F	34	3	0	0	0	0	0	0	0	0	0	0	0

9.0 Evaluation Period:

The study was conducted from April 6, 2015 to May 15, 2015.

10.0 Observations:

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

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 BCS in limited access storage files marked "Archive".

12.0 Conclusions:

Under conditions of the study, there were no identifiable signs or symptoms of primary irritation or sensitization (contact allergy) noted for Curex Ointment; Accession No. 892112.

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