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HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL

STUDY REFERENCE: INNT PT 108/17

EXPERTTO SAPUN LICHID ANTIBACTERIAN

Referinta produs: 2022839

STUDY REPORT

Bucharest, 05.06.2017

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CENTRU DE CERCETARE SI TESTARE

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SUMMARY OF THE STUDY REPORT

Investigated product	**EXPERTTO SAPUN LICHID ANTIBACTERIAN**
Product reference	2022839
Objective of study	To confirm the skin compatibility of the investigational product through assessment of the skin irritation potential and/or existing allergic sensitization of the investigational product, after a single skin application under controlled experimental conditions.
Sponsor	**TOTAL POLIPACK LINE SRL** DN26 Galati-Tg. Bujor, km 8, T43 Loc. Vinatori, Jud. Galati, 807325 e-mail: office@asilgroup.ro website: http://www.asilcosmetics.ro/ Phone: + 40 236 470890
Study Monitor	**Elena Violeta Mititelu** Chem. Eng. Mob.: +40 743 655 023 E-mail: elena.mititelu@asilgroup.ro
Date of performance of the study	From May, 29th to May, 31st 2017
Investigation center	**INNOVATIVE TEST** 102 Dristorului Street, District 3 031541 – Bucharest, Romania e-mail: office@innovativetest.ro Phone: +40 726 208710
Investigator	**Dr. Florentina Zaharia** (dermatologist) Tel: +40726208710 office@innovativetest.ro
Scientific Manager	**Ioana Obada** 102, Dristorului Street, District 3 031541 – Bucharest, Romania e-mail: ioana.obada@innovativetest.ro Phone: +40 726 208710
Type of the study	Monocentric study performed in open

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Metodology:

Single application of the product under occlusive patch for 48 hours.
The investigational product is applied diluted at 10% with distilled water, under occlusive patch (IQ Chamber™), on the upper back, for 48 hours.
The amount applied, 65µl, is measured with a disposable syringe.
Treated area is assessed before the first application of the investigational product and at 30 minutes after patch removal.
Control area is used to take into account the possible effect not directly related to the investigational product but due to the patch material.
Skin reactions are scored throughout the test by the same experienced assessor, a dermatologist, who made the baseline assessment and under the same lighting source, following a pre-defined scoring scale. The quantification of the skin irritation is given through a numeric scale (erythema, edema, dryness/desquamation, vesicles, papule, bullae, pustules, soap effect). The average irritant score of the investigational product is calculated from the average of the quotations obtained for each volunteer, allowing ranking the product from "nonirritant to severely irritant".

Study subjects

Number of test subjects: 10 valid cases
Specific inclusion criteria:

- aged from 18 to 70
- female and/or male
- with a phototype (Fitzpatrick): II, III or IV
- 100% with all type of skin on body

Results

The average irritant score of the product is 0.00.

Conclusion:

In the experimental conditions adopted, after a single application of product diluted at 10% with distilled water, under occlusive patch for 48 consecutive hours, on a panel of 11 healthy subjects and according to the scale use for the interpretation of the results, the product **EXPERTTO SAPUN LICHID ANTIBACTERIAN,** reference **2022839,** can be considered as **Non Irritant** and **has very good skin compatibility.**

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HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL

Signature and dates

Investigator: Florentina ZAHARIA (dermatologist)

The study subject of the present report was conducted under my responsibility in accordance with the protocol, the internal procedures and in the spirit of the principles of Good Clinical Practices (International recommendations ICH E6 (R1) of 10/06/1996), Directive of the European Parliament and Council 2001/20/EC - OJ/EC of 01/05/2001) and Declaration of Helsinki (June 1964). I assume the responsibility of the validity of all the data obtained during the study which are reported in the present study report.

Date: 05.06.2017

Signature: Dr. FLORENTINA ZAHARIA MEDIC PRIMAR D.V. COMPETENȚĂ LASER cod: 610850

Head manager of the investigator center: Ioana OBADA

The study subject of the present report was conducted under my responsibility in accordance with the protocol, the internal procedures and in the spirit of the principles of Good Clinical Practices (International recommendations ICH E6 (R1) of 10/06/1996), Directive of the European Parliament and Council 2001/20/EC - OJ/EC of 01/05/2001) Declaration of Helsinki (June 1964). All observations and numerical data obtained during this study are reported in the present document. I certify that these data are an accurate reflection of the results obtained and I agree with its content.

Date: 05.06.2017

Signature: SOCIETATEA COMERCIALA INNOVATIVE TEST S.R.L. BUCUREȘTI - ROMÂNIA

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1. OBJECTIVE OF STUDY

To confirm the skin compatibility of the investigational product through assessment of the skin irritation potential and/or existing allergic sensitization of the investigational product, after a single skin application under controlled experimental conditions.

2. REGULATORY, ETHICS, CONFIDENTALITY AND ARCHIVING

2.1. Regulatory

The study has been conducted by suitably trained, qualified and experienced personnel in spirit of:

- the general principles of medical ethics in clinical research coming from the Declaration of Helsinki (June 1964) and its successive amendments,
- the international recommendations relating to Good Clinical Practices for conducting clinical trials for drugs ICH E6(R1) of 10/06/1996 (CPMP/ICH/135/95),
- the Directive of the European Parliament and Council 2001/20/EC concerning the harmonization of legislative, statutory and administrative provisions of the member States relating to the application of good clinical practices when conducting clinical trials for drugs for human use - OJ/EC of 01/05/2001,
- the Romanian Order No. 904/25.07.2006 on approval of rules relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use,
- the recommendations of Colipa - August 1997 : "Guidelines for the assessment of human skin compatibility",
- Regulation of the European Parliament and the Council (EC) No. 1223/2009 of 30 November 2009 on cosmetic product.

Precautions have been taken to avoid the possibility that participants in the study might experience undesirable effects.

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2.2. Ethics

Ethical requirements which have been taken into consideration in the planning of the study include:

- participants are informed subjects, selected after application of inclusion/non-inclusion criteria,
- participants are aware of the purpose and nature of the study and of any foreseeable risks involved in participation in the study and have given written informed consent before the study starts,
- a safety evaluation has been conducted on the product tested, before the study starts,
- the test procedures conforms specific regulations,
- before the starting of the study, the protocol, the informed consent form and the relevant and available information concerning the investigational product (particularly referring to its safety) were submitted to the opinion of an Internal Ethics Committee. The Committee of the investigating center has consider the general ethics of the test and verified that the safety and integrity of the participants in the test are protected, taking into account information on the ingredient(s),
- all reasonable care has been taken to avoid causing excessive skin reactions or other adverse health effects in the participants during the study,
- safety procedures are in place in the event of any unexpected/adverse reactions, including appropriate medical cover,
- subjects are rewarded for their time, inconvenience, etc., but the reward is not so great that it would persuade them to participate.

2.3. Confidentiality

The study was in accordance with the European Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and of the free movement of such data, and with the Romanian Order No. 677/2001 for the protection of persons concerning the processing of personal data and free circulation of such data.

Processing of subjects personal data is carried out by doctors or other persons rendering medical services, provided that the Controller is bound by medical confidentiality or other obligation of professional secrecy, provided for in Law or code of practice, and data are neither transferred nor disclosed to third parties. Processing is carried out within the laboratory premises

and relates to personal data of the subjects, provided that the latter have given their consent and that such data are neither transferred nor disclosed to third parties. The anonymity of the subjects is respected within all studies carried out in our laboratories. Each subject can be identified by the Investigator, the doctors and all the persons in charge of the study, thanks to personal code of volunteers attributed when they are included in the study.

2.4. Archiving

The laboratory book which contains all the information (raw data and results) regarding the study and the study reports are kept in the laboratory archives during 2 years.

3. DATE OF PERFORMANCE OF THE STUDY

Initiation date of study performance: May 29th 2017

Completion date of study performance: May 31st 2017

4. TYPE OF THE STUDY

The clinical study was monocentric and performed in open, in a panel of human subject.

5. PRINCIPLE OF THE STUDY

Skin compatibility is defined as the absence of skin irritation potential under normal conditions of use and reasonably foreseeable misuse, taking into account objective reactions.

Skin irritation is defined as non-immunological local skin inflammation.

The investigational product was applied, on the skin under occlusive patch for 48 hours, to an appropriate concentration.

The experimental conditions of products application created a certain occlusion and favored the penetration of the product through the skin. The potential of irritation was more easily proved by this kind of approach.

The treatment site was assessed before the first application of test material and after treatment at 15-30 minutes after patch removal. A control area (without investigational products) was used to take into account the possible effects not directly related to the investigational product but due to the patch material.

Skin reactions were scored throughout the test by the same experienced assessor, a dermatologist, who made the baseline assessment and under the same lighting source, following a pre-defined scoring scale. The quantification of the skin irritation is given through a numeric scale (erythema, edema, dryness/desquamation, vesicles, papule, bullae, pustules, soap effect). The average irritant score of the product to be tested is calculated from the average of the quotations obtained for each volunteer, allowing ranking the product from "nonirritant to very irritant".

According to the scale the product is classified as: very good, good, medium or poor skin compatibility.

Generally in this type of study, the possible adverse effects (as erythema, vesicles…) are limited on the application area and decrease in some days.

In case of occurrence of undesirable reactions, the investigator had to ensure the clinical follow-up of the test subject(s), as long as it is necessary.

The products dose was perfectly controlled and the patch material and the conditions of use of the products were adapted to the product category.

The investigational product was tested with other products at the same time, the experimental area chosen (upper back) enabling to test easily several products (maximum 20 product areas at least1 cm far apart).

The skin compatibility of the test product, after application under normal conditions of use, was assessed by extrapolation of the results obtained under these specific experimental conditions.

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6. PANEL STUDIED, INCLUSION / NON INCLUSION CRITERIA

6.1. Panel of the subjects

6.1.1. Panel characteristics

The included subjects are from a general panel of the company. Each subject, in order to belong the panel, must undergo a clinical examination and detailed cosmetologically questionnaires, with the recruiting doctor of the center.

For the study, the test subjects were selected from this general panel on the basis of inclusion and non-inclusion criteria. The subjects satisfy all the inclusion criteria and are not in conflict with any of the non-inclusion criteria and had health coverage. The subjects are clearly informed, verbally and in writing, regarding the nature of the study, the timetable, constraints and possible risks. They give their written informed consent before participation in the study.

6.1.2. Number of test subjects

11 subjects have been included in the study.

6.1.3. Inclusion criteria

The following criteria had to be fulfilled in order to include a subject in the study:

- Informed volunteers who agree to follow the conditions specified,
- Age from 18-70 years old,
- female and/or male,
- with phototype (Fitzpatrick): II, III or IV,
- all type of skin,
- free from any dermatological problems on the area studied,
- able to understand the study requirements,
- without any allergy history to cosmetic product and atopic,
- declaring to have a health coverage,
- signing an "informed consent form" for this study.

6.1.4. Non-inclusion criteria

The subjects who did not meet one of several of the following criteria were not included:

- pregnancy or nursing condition,
- irritated skin on test site(s),
- blemishes, marks (e.g. tattoos, scars, sunburn) on the test site(s),
- medication which may affect skin response and/or past medical history,
- presenting skin pathology which may interfere with the aim(s) of the study,
- presenting contact allergy to one of the ingredients of the tested product,
- participation in another simultaneous study,
- participation in a previous study without an appropriate rest period between studies,
- minors or majors protected by the law and people admitted in a sanitary or social institution for other purpose than research,
- persons deprived of liberty by legal or administrative decision, patients in emergency situations, volunteers who refused to give their free and informed consent,
- people who was exposed excessive at sunlight or artificial tanning within a month prior to the study or foreseeing UV exposures during the study,
- foreseeing bath (in bathtub, sea or swimming-pool) during the study,
- practicing intensive sport causing sweating and requiring frequent showers.

6.1.5. Study constrains

During the length of the study the subjects are asked:

- not to put any product, also water on the patches area,
- not to have a bath, neither to expose themselves to UV,
- to avoid all intense sportive activities that could remove the patch,
- Not to take aspirin, anti-histaminic, corticoids, anti-inflammatories and any other treatment decreasing or avoiding inflammations or allergies or interfering with the skin metabolism,
- no participation in another clinical study in another investigating center, in the course of the study or during the specified exclusion period,
- no wearing of too thigh or restraining clothes liable to produce frictions on the experimental area and to cause the un-sticking of the patch.

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6.1.6. Withdrawal criteria

Participants will be withdrawn for the following reasons:

- they do not follow the conditions of the Study Information Sheet,
- they suffer any illness or accident or develop any condition during the study which could affect the outcome of the study,
- they discontinued the study for personal reasons independent of the study.

7. INVESTIGATIONAL PRODUCT

7.1. Identification of investigational product

Denomination:	EXPERTTO SAPUN LICHID ANTIBACTERIAN
Reference / Code:	2022839
Cosmetic category:	Liquid soap; rinse-off product
Product characteristics:	Viscous liquid, pearl white color, with pleasant smell, characteristic
Innovative test code:	INNT 350

Further information provided by the customer:

a) declaration that the tested cosmetic product does not contain any substance which is forbidden by the EEC legislation as far as the use of cosmetic and personal hygiene products is concerned; that the preservatives in the formula are in the list of the accepted components published by the EEC and are used in a concentration approved by the law; that there are no substances with a limit of concentration.

b) qualitative formula (INCI)

INGREDIENTS: AQUA, SODIUM LAURETH SULFATE, GLYCOL DISTEARATE, COCAMIDE MEA, LAURETH-10, SODIUM CHLORIDE, COCAMIDOPROPYL BETAINE, COCAMIDE DEA, GLYCERIN, CLORHEXIDINE DIGLUCONATE, PARFUM, METHYLCHLOROISOTHIAYOLINONE, METHYLISOTHIAZOLINONE, CITRIC ACID.

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7.2. Coding and storage

The sponsor supplied to the investigating center the product in sufficient quantity for the study and the sampling.

The investigating center checked the packaging, the labeling (the denomination and reference) and the product aspect.

The product units were coded, according to the corresponding procedure of the investigating center.

A sample of the tested product is kept at the investigating center for 1 year after the end of the study. After this date the product will be destroyed, unless there is contrary requirement from the study sponsor.

8. STUDY METODOLOGY

The principle of the study is based on the single application of 65 µl of tested product, diluted at 10% with distillated water, under occlusive patch (IQ Chamber™), on the skin of the upper back of adult subjects. The product is kept in contact with the skin for 48 hours under occlusive patch.

The area on which the patch is applied is previously cleaned up with demineralized water and dried with cellulose cotton wool tissue.

The products are tested pure or diluted depending on their type and their use:

- Mostly, the products are tested pure.
- Rinse-off products are tested diluted at 10%.
- Hydrophilic products are diluted in demineralized water.
- Lipophilic products are diluted in mineral oil.
- Powders are put pure in the patch small cavity and then moistened sufficiently with a drop of mineral oil in order to ensure good contact with the skin and avoid the product dispersion while applying the patch.

The patch was applied on D1 and removed after 48 hours at the investigating center.

The quantity of the product was measured with the single use syringe and put into the patch.

The patch containing the investigational product was applied to the defined skin area.

Negative controls

Whilst this activity is always be on a case-by-case basis and will depend on the nature and type of study, the most common approach is to compare the results obtained for the test materials with those of suitable positive and/or negative controls, or with similar materials.

A "negative" control is a patch without any product, applied in the same conditions as the product to be tested:

- if the product is tested pure: patch with of distillated water
- if the product is tested diluted: patch with 65 µl of the solvent used (demineralized water or mineral oil).

Patch material:	**Occlusive patch** IQ Chamber™ is made of additive free polyethylene plastic attached on a hypoallergenic non-woven adhesive tape. The volume of the chamber is 65 µl and the inside area of the chamber is 9x9 mm (81mm^2).
Experimental conditions of use:	Diluted at 10% with distillated water
Quantity applied:	65 µl

An occlusive patch, containing 65 µl of distilled water was applied in parallel as control to eliminate, when the results were interpreted, the possible inter-current effects due to the adhesive.

The amount of test material applied to each patch was sufficient to fill the chamber and saturate the pad without overflowing from it when applied to the skin.

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9. SKIN COMPATIBILITY ASSESSEMENT

9.1. Visual assessment

Treatment sites are visually assessed before the first application of test material (baseline) and after treatment at 15-30 minutes after patch removal. Negative controls are used to facilitate evaluation.

Skin reactions are scored throughout the test by the same experienced assessor who made the baseline assessment and under the same lighting source, following a pre-defined scoring scale.

9.2. Scoring scale of skin reaction

The sites were graded according to the following scoring system:

ERYTHEMA

0	No erythema
1	Very slight erythema (hardly visible) on at least ¾ of the application area, or well visible on a smaller area
2	Clearly visible erythema, uniformly allocated on at least ¾ of the application area
3	Moderate to severe erythema (dark red)
4	Severe erythema (crimson red) with slight eschar formation (injuries in depth)

EDEMA

0	No edema
1	Very slight edema and palpable on at least ¾ of the application area, or slight edema on a smaller surface.
2	Slight edema (edges well defined) on at least ¾ of the application area
3	Severe edema (1 mm thick at least) on a surface greater than the application area

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PAPULAE/VESICLES/BULLAE/PUSTULES

0	No papule, vesicles, bullae, pustules
1	Papule, or small vesicles (less than about 1 mm in diameter)
2	Vesicles 1 to 2 mm in diameter
3	Pustules
4	Bullae with clear liquid

DRYNESS/DESQUAMATION

0	No dryness or desquamation
1	Slight dryness = mat, unpolished aspect, on at least ¾ of the application area, or pulverulent (whitish) aspect on a surface smaller than ¾ of the application area
2	Clear dryness = pulverulent aspect on at least ¾ of the application area, or desquamatory aspect on a surface smaller than ¾ of the application area
3	Moderate desquamation = desquamatory aspect on at least ¾ of the application area, or presence of thick squamae on a surface smaller than ¾ of the application area
4	Severe desquamation = presence of thick squamae or at least ¾ of the application area, with possibility of tegument fissuration

SOAP EFFECT

0	No rugosity
1	Slight rugosity = slightly worn aspect on at least ¾ of the application area, or clearly worn aspect on a surface smaller than ¾ of the application area
2	Clear rugosity = clearly worn aspect on at least ¾ of the application area, or very worn aspect (presence of wrinkles with well pronounced crests) on a surface smaller than ¾ of the application area
3	Moderate rugosity = very worn aspect on at least ¾ of the application area, or presence of deep wrinkles on a surface smaller than ¾ of the application area
4	Severe rugosity = presence of deep wrinkles on at least % of the application area

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9.3. Expression of the result

SUBJECTS REFERENCE	Erythema	Edema	Papulae/Vesicles/ Bullae/Pustules	Dryness / Desquamation	Soap effect	Cutaneous Irritation Score (CIS)
SAEL	0	0	0	0	0	0
PRMA	0	0	0	0	0	0
PADA	0	0	0	0	0	0
AVAN	0	0	0	0	0	0
OBGA	0	0	0	0	0	0
BAVI	0	0	0	0	0	0
BAMI	0	0	0	0	0	0
ZGFR	0	0	0	0	0	0
VLEU	0	0	0	0	0	0
DIGE	0	0	0	0	0	0
FLCO	0	0	0	0	0	0
DIMA	0	0	0	0	0	0
Weighting	**1**	**2**	**2**	**0.5**	**0.5**	**1**

All the reactions had to be accurately described at each experimental time using the criteria and the scale the above mentioned.

For each subject a cutaneous irritation score **(CIS)** was calculated by the method of the differences (product – control): mean of the weighted sum of marks obtained for the visible clinical signs observed on the application site of the investigational product, according to a given numerical scale (erythema: factor 1, edema, papulae / vesicles / bullae / pustules: factor 2, dryness / desquamation, soap effect: factor 0.5).

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Determination of the **Index of Primary Cutaneous Irritation (PCI):** mean of the scoring obtained on the whole panel.

Primary Cutaneous Irritation index (PCI) is calculated according to the formula:

$$PCI = (\sum CIS) / \text{No of valid cases}$$

9.4. Interpretation of the results

All the test subjects included in the study were taken into account to appreciate the skin compatibility of the investigational product as long as they were submitted at least to one post application examination at the defined time.

The reactivity of the skin observed can be an irritation reaction or an allergic reaction.

So, the dermatologists had to classify the reaction according to the scale:

P. C.I.	Classification of the irritation degree
≤ 0.50	Not irritating
From 0.50 (not included) to 1	Slightly irritating
From 1 (not included) to 2	Moderately irritating
From 2 (not included) to 3	Very irritating
From 3 (not included) to 4	Severely irritating

The dermatologists had to conclude according to the scale: very good, good, medium or poor skin compatibility.

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9.5. Statistical analysis

The statistical analysis is descriptive.

The clinical data and the characteristic of the subjects are described by descriptive statistics.

The description of the individual evaluation is noted during every visit.

10. RESULTS

No skin reaction was noticed by the dermatologist on the reference area for all the volunteers.

Results obtained for each volunteer as well as the corresponding irritation scale.

Control time after patch removal	Number of reactive subjects	Types of reaction	Primary Cutaneous Irritation (P.C.I.)	% of reactive subjects
T 15 minutes	0	None	0	0%

11. CONCLUSION

Under the experimental conditions adopted, after a single application of product diluted at 10% with distilled water, under occlusive patch for 48 consecutive hours, on a panel of 11 healthy subjects and according to the scale use for the interpretation of the results, the product **EXPERTTO SAPUN LICHID ANTIBACTERIAN**, reference **2022839**, can be considered as **Non Irritant** and has **very good skin compatibility**

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APPENDICES

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Appendix 1

CHARACTERISTICS OF THE SUBJECTS

Reference Subject	**Code subject**	**Age** (years)	**Sex** F=female M=male	**Phototype***
1	SAEL	46	F	III
2	PRMA	54	F	IV
3	PADA	45	F	II
4	AVAN	49	F	IV
5	OBGA	45	M	III
6	BAVI	58	F	IV
7	BAMI	38	F	III
8	ZGFR	34	F	III
9	VLEU	58	F	III
10	DIGE	49	F	IV
11	FLCO	31	F	IV

Legends:
***phototype:Type I: Always burns easily, never tans, Type II: Always burns easily, tans minimally, Type III: Burns moderately, tans gradually, Type IV: Burns slightly, always tans easily, Type V: Burns rarely, tans intensely, Type VI: Never burns, strongly pigmented**

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Appendix 2/1

CHECKING OF THE SKIN COMPATIBILITY OF THE INVESTIGATIONAL PRODUCT AT 15 MIN AFTER PACH REMOVAL

Reference Subject	Code subject	Erythema	Edema	Papulae/Vesicles/ Bullae/Pustules	Dryness / Desquamation	Soap effect
1	SAEL	0	0	0	0	0
2	PRMA	0	0	0	0	0
3	PADA	0	0	0	0	0
4	AVAN	0	0	0	0	0
5	OBGA	0	0	0	0	0
6	BAVI	0	0	0	0	0
7	BAMI	0	0	0	0	0
8	ZGFR	0	0	0	0	0
9	VLEU	0	0	0	0	0
10	DIGE	0	0	0	0	0
11	FLCO	0	0	0	0	0
Weighting		1	2	2	0.5	0.5

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Appendix 2/2

PRIMARY CUTANEOUS IRRITATION INDEX (PCI) AT 15 MIN. AFTER PATCH REMOVAL

Reference Subject	Code subject	CUTANEOUS IRRITATION SCORE (CIS)
1	SAEL	0
2	PRMA	0
3	PADA	0
4	AVAN	0
5	OBGA	0
6	BAVI	0
7	BAMI	0
8	ZGFR	0
9	VLEU	0
10	DIGE	0
11	FLCO	0
Primary Cutaneous Irritation Index (PCI)		**0**