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Study report #STUU524AA0122
Related to quote #C7TYPT240013-01

EVALUATION OF THE SKIN COMPATIBILITY OF A COSMETIC PRODUCT AFTER ONE SINGLE APPLICATION ON ADULT SUBJECTS WITH NORMAL SKIN UNDER DERMATOLOGICAL CONTROL: SINGLE PATCH TEST

GLOW SHOT REF: CHA001-1 BATCH#2549

CLINICAL INVESTIGATION CENTER	
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Investigator
Ms Justyna SOWIŃSKA (dermatologist)

Document 1/8 including 14 pages

TABLE OF CONTENTS

KEY ELEMENTS OF THE STUDY #STUU524AA0122

EVALUATION OF THE SKIN COMPATIBILITY OF A COSMETIC PRODUCT AFTER ONE SINGLE APPLICATION ON ADULT SUBJECTS WITH NORMAL SKIN UNDER DERMATOLOGICAL CONTROL: SINGLE PATCH TEST

Objective

To study the skin compatibility of a cosmetic product through the evaluation of its acute irritat-ing potential after single application under patch-test.

Methodology

Monocentric and simple-blind study.

Kinetics

	D0	D2	D2 t30min	D3 t24h
Collection of the subject's informed consent	●			
Verification of inclusion and non-inclusion criteria	●			
Patch-test: application	●			
Patch-test: removal		●		
Clinical scoring			●	●

Date

Product reception	Study start	Study end
23.02.2024	05.03.2024	15.03.2024

Product

Reference	Form	Storage temperature
Glow Shot Ref: CHA001-1 Batch#2549	Solution	Room temperature

Application

Zone	Patch duration	Concentration	Patch type
Back	48 hours	PURE	Occlusive

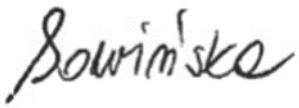
Studied Population

Main inclusion criteria	Average age (min-max)	Number of subjects analysed
Age: 18-70 years. Phototype I to IV.	48±3 years (21 - 70)	22

Results

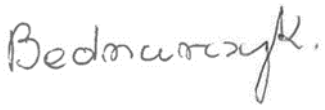
M.C.I.I. value: 0.00
Conclusion : Non irritating

Investigator

Name and quality	Date	Signature
Justyna Sowińska Dermatologist	**19.03.2024**	

1 QUALITY CONTROL STATEMENT

The person responsible for the final quality control certifies that the study above was conducted as closely as possible to Good Clinical Practice (GCP-ICH), in compliance with the study protocol and EUROFINS Dermscan/Pharmascan standard operating procedures and that the study report reflects raw data.

	QUALITY CONTROL ASSESSOR
Last name	**BEDNARCZYK**
First name	**Katarzyna**
Date	**19.03.2024**
Signature	

2 STUDY PROCESS

EUROFINS Dermscan/Pharmascan is certified ISO: 9001-2015.

EUROFINS Dermscan/Pharmascan benefits from a governmental Research Tax Credit from the French Ministry of Research.

The study is carried out on a cosmetic product whose safety has been assured by the Sponsor.

The European Directive 2001/20/EC and regulations issued by the Minister of Health (Order of the Minister of Health of May 2, 2012 regarding Good Clinical Practice, Dz.U. 2012, item 491) is not applicable. Therefore, this study is considered as non-interventional and does not require the Ethics Committee Approval and the Competent Authority Authorization.

+ See ethical requirements and regulatory standards in **Appendix 7.**

This study was conducted under the following conditions:

2.1 POPULATION

2.1.1 Inclusion criteria

- Subject having given his/her free informed, written consent,
- No previous experience of intolerance or allergic reactions to cosmetic products,
- Phototype I to IV,
- Age between 18 and 70,
- Subject willing to adhere to the protocol and study procedures,
- All skin type is accepted.

2.1.2 Inclusion criteria

- For women: pregnant or nursing woman or woman planning to get pregnant during the study,
- Cutaneous pathology on the study zone (psoriasis, eczema, vitiligo, pityriasis versicolor, acne, etc…),
- Subject with medical treatments which may interfere with the acute skin tolerance evaluation, according to the investigator,
- Exposure to the sun or to UV rays on the treated zone during the previous month,
- Subject with very irritative skin,
- Subject presenting an important hairiness, freckles, beauty spots or a tattoo on the treated zone,
- Subject with a serious or progressive disease,
- Subject enrolled in another clinical trial (concerning study zone) during the study period.

3 PRINCIPLES

3.1 EQUIPMENT, DOSE, DURATION

The studied product was applied under the following conditions:

Area:	Back: between hips and scapular part
Patch tests type:	Finn Chamber® 8mm (50mm²) – occlusive
Dose*:	20 µl
Application conditions:	PURE
Application duration:	48 hours
Control:	empty patch or patch with diluent

**Note: The quantity is determined according to the cupule capacity, indicated by the manufacturer*

3.2 READINGS

The macroscopic skin examinations were carried out under the same conditions, specifically the lighting (standardized light), 15-30 minutes after removal of the patch-tests and 24 hours later. If the subject had a cutaneous reaction >1, she/he had to return to the centre and readings were done until complete reversibility of the cutaneous reactions. The grading of the possible irritation reaction, on each zone that received the studied product and on the control zone, was done according to the following scales:

Score	Quotation	**CRITERIA**: description :	
		ERYTHEMA «**E**»	OEDEMA «**O**»
0	absent	no erythema	no oedema
0,5	very mild	fairly detectable: discreet pinkness of one part of the tested area	palpable, barely visible
1	mild	discreet pinkness of the complete tested area or rather visible on one part of the tested area	palpable, visible
2	moderate	clearly distinguishable, dull red erythema covering the whole tested area	obvious edema (thickness < 1 mm) with or without papule(s) or vesicle(s)
3	severe	deep dark or fiery bright red color covering all the tested area or moderate erythema diffusing outside the tested area	severe oedema (thickness ≥ 1 mm or diffusing outside the tested area) with or without vesicle(s) or blister(s)

A change in skin structure (dryness (D), roughness (R), thickness (T), reflectivity (Re)) that could be linked to the nature of the studied product or one of its components is clinically described and its intensity graded according to the following scale:

0.5 = doubtful
1 = mild
2 = obvious
3 = important.

3.3 RESULTS INTERPRETATION

The analysis and the interpretation were carried out according to the results obtained in the experimental conditions. They are descriptive and completed by the calculation of the cumulative irritation index (C.I.I.) for each subject according to the formula:

$$C.I.I. = \frac{\sum \text{grades (erythema + oedema)}}{\text{Total number of readings}}$$

This index is then divided by the number of subjects in order to obtain the Mean Cumulative Irritation Index (M.C.I.I.):

$$M.C.I.I. = \frac{\sum C.I.I.}{\text{number of subjects}}$$

The obtained index (maximum 6) allows to arbitrarily classify the studied product according to the following scale:

M.C.I.I.	Class
M.C.I.I. < 0.25	**Non irritating (NI)**
0.25 ≤ M.C.I.I. < 0.50	**Very slightly irritating (VSI)**
0.5 ≤ M.C.I.I. < 1	**Slightly irritating (SI)**
1 ≤ M.C.I.I. < 2	**Moderately irritating (MI)**
M.C.I.I. ≥ 2	**Irritating (I)**

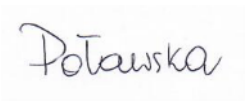
Individual values and the product class are taken into account to write a suitable conclusion under the study conditions.

4 CERTIFICATION

The study is conducted according to Helsinki Declaration (1964) and its successive updates. Data are obtained using the study protocol, current internal procedures and as closely as possible to the guidance on Good Clinical Practice CPMP / ICH / 135 / 95 (R2).

This study is totally performed under the responsibility of EUROFINS Dermscan/Pharmascan.

All the observations and numerical data collected throughout the study are reported in this document and are in accordance with the obtained results.

	DERMATOLOGIST	PROJECT MANAGER
Name	**Justyna SOWIŃSKA**	**Iwona POŁAWSKA**
Date	**19.03.2024**	**19.03.2024**
Signature		

Any modifications are the sole responsibility of the author of the modification, whether he/she is acting for the Sponsor or independently.

The on-line publishing, on the Internet, of this study report with the names and signatures is strictly prohibited.

5 BIBLIOGRAPHY

Regulatory

1. ICH TOPIC E6 (R2)/ Note for guidance on Good Clinical Practice- CPMP / ICH / 135 / 95, November 2016.

2. WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI/ Ethical Principles for Medical Research Involving Human Subjects- Helsinki Declaration (1964) and its successive updates.

3. Order of the Minister of Health May 2, 2012 (Dz.U. 2012 poz.491)

4. REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

5. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 30 November 2009 on cosmetic products (recast).

6. Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products

7. ANSM / IMPUTABILITE DES EFFETS INDESIRABLES LIES AUX PRODUITS COSMETIQUES, 2013. http://ansm.sante.fr/var/ansm_site/storage/original/application/5dbe53023c2f828bdbed348b4a942a91.pdf

Cutaneous compatibility

1. COLIPA "Cosmetic product test guidelines for the assessment of human skin compatibility" 2nd edition – August 1997.

2. Patch-testing with the patient's own products - Peter J. FROSCH, Johannes GEIER, Wolfgang UTER, An GOOSENS - CONTACT DERMATITIS 4TH EDITION – 2006.

3. Comparison of the cumulative irritation potential of Adapalene gel and cream with that of Erythromycin/Tretinoin solution and gel and Erythromycin/Tretinoin gel - Catherine QUEILLE-ROUSSEL, Michel PONCET, Stephane MESAROS, Alan CLUCAS, Michael BAKER and Andrew-Marc SOLOFF - CLINICAL THERAPEUTICS / VOL.23 N°2, 2001.

APPENDICES:

STUDY DOCUMENTS, DETAILED RESULTS & ETHICAL REQUIREMENTS AND REGULATORY STANDARDS

6 APPENDICES – STUDY DOCUMENTS

6.1 SUBJECTS CHARACTERISTICS

N° du sujet / *N° of subject*	Identification du sujet / *Identification of subject*	Age	Sexe / *Sex*	Phototype	Type de peau sur le dos / *Skin type on the back*	Début de l'étude / *Study Start*	Fin de l'étude/ *Study end*
1	012-ZA-U	63	F	II	S	March 5, 2024	March 8, 2024
2	013-HE-A	53	F	III	N	March 5, 2024	March 8, 2024
3	014-KR-M	39	F	II	N	March 5, 2024	March 8, 2024
4	015-KO-J	47	F	I	N	March 5, 2024	March 8, 2024
5	016-SZ-H	68	F	II	S	March 5, 2024	March 8, 2024
6	017-BE-K	35	F	III	N	March 5, 2024	March 8, 2024
7	018-ŻY-M	68	F	III	N	March 5, 2024	March 8, 2024
8	019-CZ-B	58	F	II	N	March 5, 2024	March 8, 2024
9	020-BU-T	66	F	II	S	March 5, 2024	March 8, 2024
10	021-PA-A	36	F	I	S	March 5, 2024	March 8, 2024
11	022-ST-Z	27	F	III	N	March 5, 2024	March 8, 2024
12	001-CI-M	63	F	II	N	March 12, 2024	March 15, 2024
13	002-PI-I	52	F	I	N	March 12, 2024	March 15, 2024
14	003-AN-Z	69	F	II	S	March 12, 2024	March 15, 2024
15	004-NO-D	70	F	II	S	March 12, 2024	March 15, 2024
16	005-WE-A	40	F	I	N	March 12, 2024	March 15, 2024
17	006-LE-D	51	F	II	N	March 12, 2024	March 15, 2024
18	007-SC-S	43	F	III	N	March 12, 2024	March 15, 2024
19	008-PA-M	21	F	I	N	March 12, 2024	March 15, 2024
20	009-ZI-K	23	F	II	S	March 12, 2024	March 15, 2024
21	010-NI-K	46	M	III	N	March 12, 2024	March 15, 2024
22	011-KO-P	26	F	II	N	March 12, 2024	March 15, 2024

Min	21	Femelle / *Female*	phototype I	Normale / *Normal*
Max	70	21	5	15
Moy/Average	48	Mâle/ *Male*	phototype II	Sèche / *Dry*
SEM	3	1	11	7
			phototype III	
			6	
			phototype IV	
			0	

6.2 TABLE OF READINGS

N° Volontaire / N° of subject	Lecture à 30 minutes / 30-minute reading				Lecture à 24 heures / 24-hour reading				IIC/CII	Modification de structure de la peau / Change in skin structure	
	T		P		T		P			Lecture 30 minutes / 30-minute reading	Lecture 24 heures / 24-hour reading
	E	O	E	O	E	O	E	O			
1	0	0	0	0	0	0	0	0	0	no change	no change
2	0	0	0	0	0	0	0	0	0	no change	no change
3	0	0	0	0	0	0	0	0	0	no change	no change
4	0	0	0	0	0	0	0	0	0	no change	no change
5	0	0	0	0	0	0	0	0	0	no change	no change
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20	0	0	0	0	0	0	0	0	0	no change	no change
21	0	0	0	0	0	0	0	0	0	no change	no change
22	0	0	0	0	0	0	0	0	0	no change	no change
					I.I.C.M. / M.C.I.I.				0,00		

T: Témoin / Control
P: Glow Shot Ref: CHA001-1 Batch#2549
E: Erythème / Erythema
O: Oedème / Oedema

7 APPENDICES - ETHICAL REQUIREMENTS AND REGULATORY STANDARDS

7.1 ADVERSE EVENT

7.1.1 Adverse Event (AE)

Any noxious symptom, occurring in a subject taking part in a clinical trial, whether or not this symptom is related to the study or the study product(s) (e.g. flu, headache, abnormal biological analysis…).

7.1.2 Undesirable Effect (UE) / Adverse Reaction (AR)

For a cosmetic product, an **undesirable effect** is defined as an adverse reaction for human health attributable to the normal or reasonably foreseeable use of the cosmetic product(s).
There are 5 levels of imputability: very likely, likely, not clearly attributable, unlikely and excluded (ANSM methodology).

The severity/intensity of undesirable effects/adverse events can be graded on a three-point scale:
- **mild**: discomfort noted, that does not disturb normal daily activities;
- **moderate**: discomfort sufficient to reduce or affect normal daily activities;
- **severe**: inability to work or have normal daily activities.

7.1.3 Serious Adverse Event (SAE) / Serious Undesirable Effect (SUE)

Any event that:
- results in death (note: death is the outcome, not the event);
- is life threatening;
- requires in-patient hospitalization (at least one night) or prolongation of existing hospitalization (does not include hospitalization scheduled before the inclusion);
- results in temporary or permanent functional incapacity or disability;
- is a congenital anomaly;
- is considered like by the investigator.

7.1.4 Documentation

All concomitant treatments are reported in the CRF (Case Report Form); only those started after the beginning of the study are reported in the study report.

All Undesirable Effects are reported in the CRF and the study report.
If it requires the temporary or definitive termination of the study product, the need for a corrective treatment or the withdrawal of the subject, an Adverse Event form is completed.

All SAE/SUE are reported in the CRF and the study report.

7.1.5 Notification

The investigator declares to the Sponsor, by e-mail, the occurrence of adverse reactions according to their severity and their unexpectedness (according to the investigator's advice).

All SAE/SUE are transmitted by e-mail to the Sponsor without delay, at the latest 24 hours after knowledge of their occurrence.
A SAE/SUE declaration form signed by a physician is sent, within 48 hours, by e-mail with acknowledgement of receipt.

7.1.6 Follow-up

When an adverse event linked to the investigational product or the protocol persists at the end of the study, the Investigator ensures that the subject is followed up until total resolution of the event or stabilization of the symptoms without releasing the Sponsor of any obligation or responsibility.

8.1.7 Occurrence of pregnancy

The occurrence of a pregnancy (reported or diagnosed) after inclusion in the study is considered as an intercurrent event not related to the study product(s) nor the protocol and induces the immediate dropping out of the subject.
Any pregnancy that occurs during the study period is reported by e-mail to the Sponsor within 24 hours following its discovering.
A follow-up is done according to the current internal procedures until the completion/termination of the pregnancy or its interruption.

7.2 PREMATURE TERMINATION OF SUBJECT PARTICIPATION

In compliance with the Helsinki Declaration (1964) and its successive updates, subjects have the right to exit from the study at any time and for any motive.

The investigator can also interrupt the subject participation in the study prematurely in the case of a disease occurrence, a pregnancy or the occurrence of an adverse reaction.

The Sponsor can demand that any subject be excluded from the study for major infringements to the protocol, for administrative reasons or any other motive however this would need to be clearly documented with a rationale as to why.

Nevertheless, premature removal of a high percentage of subjects from the study can make it difficult or impossible to interpret. Consequently, any premature exit without valid motives should be avoided as much as possible and is carefully documented in the case report form, the final report and, if necessary, in the Adverse Event form.

Every premature exit must be classified under one of the following headings:
- presence of a non-inclusion criteria;
- Undesirable Effect / Adverse Event occurrence;
- Serious Adverse Event / Serious Adverse Effect occurrence;
- withdrawal of consent;
- lost to follow-up;
- appearance of non-inclusion criteria;
- non-adherence to the protocol;
- other reason.

No replacement is foreseen as 10% additional subjects are planned to be included in the study.

7.3 CONFIDENTIALITY AND GENERAL DATA PROTECTION REGULATION

In this study, EUROFINS Dermscan/Pharmascan processes personal data of subjects on behalf of the Sponsor, in accordance with the rules on the protection of personal data and, in particular, the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. For this purpose, EUROFINS Dermscan/Pharmascan limits the collection and use of personal data to that which is needed for analysis and control purposes, by ensuring their security and integrity and by guaranteeing their confidentiality.
EUROFINS Dermscan/Pharmascan makes sure beforehand and throughout the duration of the data-processing:
- of the compliance with the obligations of the applicable data protection law,
- to inform subjects of their personal data-processing after obtaining their consent,
- to implement and maintain appropriate technical and organisational measures.

An identification code is attributed to each subject for the purpose to keep her identity confidential. This code consists of the first two letters of the subject's name and the first letter of her first name.

According to Article 14 of GDPR, the concerned subject must be informed of the identity and the contact details of the Controller and, where applicable, of the controller's representative. However, considering the objective of the study, to avoid any bias in the investigational product evaluation, the identity of the Sponsor is not revealed to the subject participating.

7.4 DATA COLLECTION AND VALIDATION

The personnel in charge of the study collects data into individual case report forms in electronic (e-CRF DataCapt™ internet platform) or paper format and/or directly from measurement software.
When information is collected in paper format, the simple/double data entry is then done from these supports by the designed operator(s), without any interpretation, in specific MS EXCEL databases.
The Project Manager or assistant checks the double data entry by comparing both databases.

Then the coherence of the whole data set is checked as well as formulas used in the EXCEL tables (calculation formulas, selected data…).
When all the controls are done, the database is locked.

7.5 QUALITY MANAGEMENT

In order to ensure that the clinical trials are in compliance with the Sponsor's requirement, EUROFINS Dermscan/Pharmascan has implemented a quality management system which has been certified ISO 9001: 2015.
This quality assurance system includes appropriate Good Clinical Practices (GCP) and regulation requirements.

Each study report is subjected to a quality inspection by a member of the EUROFINS Dermscan/Pharmascan Proofreading Committee. The proofreader is chosen because he(she) is not involved in the audited study. The inspection of the study report allows to confirm that the results reflect exactly the study raw data and that the study fulfils any standard and regulatory requirements.
A certificate of quality inspection signed by the person who checked the report is enclosed in each study.

7.6 ARCHIVES OF STUDY DOCUMENTS

<table>
<tr><td rowspan="2">STUDY DOCUMENTS AND DATA</td><td colspan="3">TIME AFTER DISPATCH OF THE FINAL REPORT:
investiga-tion center → service provider → destruction
0 1 (maximum) 10 YEARS</td></tr>
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