ECOVITAL G3 PROFESSIONAL SRL
Adresa: STR. BUZESTI Nr. 27-29, Bucuresti
CIF: RO18965314/ Reg.com.: J40/15087/2013
E-MAIL: mioara.petrescu86@gmail.com/ NUMAR TEL: 0730 649 182

FORMULAR F-2/2018 V1./ CONFIDENTIAL DOCUMENT
Study report – version n°1 (28/06/2019)
HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL
STUDY REFERENCE: ECOVITAL Romania- ECOV 141/2019
INVESTIGATIONAL PRODUCT: HYGIENIUM SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ TRUSSA SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ ECOV 141/2019

SPONSOR	GRANDE GLORIA PRODUCTION SRL Sat Costi, Comuna Vanatori, strada Tuluc, nr. 1, hala nr 68. Biroul nr 2, jud Galati Nr.Ord.Reg. com : J17/1268/26.11.2014 C.U.I 33844286
STUDY MONITOR	Mioara Petrescu
INVESTIGATING CENTRE	ECOVITAL G3 PROFESSIONAL SRL Adresa: STR. BUZESTI Nr. 27-29, Bucuresti PUNCT LUCRU: STRADA FICUSULUI NR 10, MOGOSOAIA, ILFOV CIF: RO18965314 Reg.com.: J40/15087/2013 E-MAIL: mioara.petrescu86@gmail.com NUMAR TEL: 0730 649 182
SCIENTIFIC MANAGER OF THE INVESTIGATING CENTRE	Mioara Petrescu Adresa: STR. BUZESTI Nr. 27-29, Bucuresti PUNCT LUCRU: STRADA FICUSULUI NR 10, MOGOSOAIA, ILFOV CIF: RO18965314 Reg.com.: J40/15087/2013 E-MAIL: mioara.petrescu86@gmail.com NUMAR TEL: 0730 649 182
MAIN INVESTIGATOR	Dr. MARINCEA ELENA - CHIRURGIE PLASTICA-MICROCHIRURGIE RECONSTRUCTIVA, Registered N° (Romanian ministry of health): 2975/07.OCT.2009 Tel.:0722529728
CO-INVESTIGATOR	Mioara Petrescu (general practitioner) E-MAIL: mioara.petrescu86@gmail.com NUMAR TEL: 0730 649 182
Initiation date of study performance	24.06.2019
Completion date of study performance	28.06.2019

HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL/
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STUDY OBJECTIVE	To confirm the skin compatibility of the investigational product in a panel of healthy human subjects after a single application under maximising and controlled experimental conditions
SPONSOR	GRANDE GLORIA PRODUCTION SRL Sat Costi, Comuna Vanatori, strada Tuluc, nr. 1, hala nr 68. Biroul nr 2, jud Galati Nr.Ord.Reg. com : J17/1268/26.11.2014 C.U.I 33844286
STUDY MONITOR	Mioara Petrescu
INVESTIGATING CENTRE	ECOVITAL G3 PROFESSIONAL SRL Adresa: STR. BUZESTI Nr. 27-29, Bucuresti PUNCT LUCRU: STRADA FICUSULUI NR 10, MOGOSOAIA, ILFOV CIF: RO18965314 Reg.com.: J40/15087/2013 E-MAIL: mioara.petrescu86@gmail.com NUMAR TEL: 0730 649 182
SCIENTIFIC MANAGER OF THE INVESTIGATING CENTRE	Mioara Petrescu Adresa: STR. BUZESTI Nr. 27-29, Bucuresti PUNCT LUCRU: STRADA FICUSULUI NR 10, MOGOSOAIA, ILFOV CIF: RO18965314 Reg.com.: J40/15087/2013 E-MAIL: mioara.petrescu86@gmail.com NUMAR TEL: 0730 649 182
MAIN INVESTIGATOR	Dr. MARINCEA ELENA - CHIRURGIE PLASTICA-MICROCHIRURGIE RECONSTRUCTIVA, Registered N° (Romanian ministry of health): 2975/07.OCT.2009 Tel.:0722529728
CO-INVESTIGATOR	Mioara Petrescu (general practitioner) E-MAIL: mioara.petrescu86@gmail.com NUMAR TEL: 0730 649 182
TYPE OF THE STUDY	Monocentric randomized clinical study performed in simple blind
PROVISIONAL DATES OF STUDY PERFOR-MANCE	FROM: 24.06.2019-28.06.2019
INVESTIGATIONAL PRODUCT	HYGIENIUM SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ TRUSSA SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ ECOV 141/2019. Modalities of application in the study: As it is, under occlusive patch – (COSMOPOR ADVANCE®) – 20 µl

STUDY POPULATION:
Number of test subjects: 11 valid cases
Specific inclusion criteria: test subjects:
- aged from 18 to 68
- female and/or male
- with a phototype (Fitzpatrick): II, III, IV or V
- 100% with all type of skin on body

Specific non-inclusion criteria: test subjects
- with personal history of adverse reaction to colophony, rubber, nickel, aluminium, patch materials, adhesive plaster,
- with family or personal history of atopy
- with orthoergic skin reactivity on body
- with personal history of adverse reactions to the same type of product as the investigational product
- with documented history of contact allergy

Application of the investigational product , by the technician in charge of the study at the investigating centre to the upper back of the test subject:
- once (on D1),
- as it is,
- under maximizing conditions of exposure:
- under occlusive COSMOPOR ADVANCE standard : aluminium cupula kept in position by an
- hypoallergenic adhesive: Scanpor (inner diameter: 8 mm, surface: 65 mm²) -

METHODOLOGY :Application of the investigational product, by the technician in charge of the study at the investigating centre to the upper back of the test subject:
- once (on D1), as it is, under maximizing conditions of exposure: under occlusive COSMOPOR ADVANCE®: aluminium cupula kept in position by an hypoallergenic adhesive: (inner diameter: 8 mm, surface: 65 mm2) - quantity applied=20µl, measured with a single use syringe and put into the patch during a defined time (48 +/- 4 hours)

Application of distilled water to a skin area on the upper back under occlusive patch and during a defined time (48 +/- 4 hours) control area, to take into account the possible effects not directly related to the investigational product but due to the patch material.

Checking of the skin compatibility based on: a skin examination of the treated and control areas by the same investigator or technician, supervised by the investigator, at the investigating centre: on D1, before patching on D3, 15 to 30 minutes after patch removal , the analysis of the sensations of discomfort reported directly by the test , subjects to the investigator or technician during the study

Descriptive analysis – Percentage of reactive test subjects (erythema and other visible signs of reactivity)

Expression of the results:
For each test subject and each observation time, calculation of an individual daily irritation score (IDIS) = sum of the marks obtained for the visible clinical signs observed on the application area of the investigational product

For the panel and each observation time, calculation of a mean daily irritation score (MDIS) according to the formula: $MDIS = \Sigma (IDIS) / Nb$ of valid cases

RESULTS/ CONFIDENTIAL DOCUMENT

Characteristics of the included panel
Number of included subjects: 11
Number of exclusions (reason): None
Number of withdrawals (reason): None
Number of valid cases: 11
- Age: 18 to 68 (Mean= 46)
- Sex: F/M
- Phototype: II and III
- Skin type on the application site: ATS (100%, n= 11)

Checking of the skin compatibility
No reaction was noted on the control site.

Control time after patch re-moval	Types of reaction	Number of re-active subjects	% of reactive test subjects	Mean daily irritation score MDIS	Skin compati-bility of the product
T 15 minutes (D3)	None	0	0 %	0	Very good skin compatibility

OVERALL CONCLUSION

Under the experimental conditions adopted single application of the investigational product: Denomination HYGIENIUM SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ TRUSSA SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ ECOV 141/2019, under occlusive patch on a panel of 11 subjects with all types of skin on body, the product induced no re-action of irritation and has a very good skin compatibility.

HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL/CONFIDENTIAL DOCUMENT

Investigator: Dr. MARINCEA ELENA - CHIRURGIE PLASTICA-MICROCHIRURGIE RECO STRUCTIVA, Registered N° (Romanian ministry of health): 2975/07.OCT.2009

I the undersigned, Dr MARINCEA ELENA, declare that the overall conduct of the study was carried out 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), Romanian Order No. 904/25.07.2006.
I assume the responsibility of the validity of all the raw data obtained during the study which are reported in the present study report.

Date: 28.06.2019
Signature:

Co-Investigator: FARMACIST. MIOARA PETRESCU (general practitioner)
I the undersigned, FARMACIST. MIOARA PETRESCU, declare that the overall conduct of the study was carried out 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, Romanian Order No. 904/25.07.2006).
I assume the responsability of the validity of all the raw data obtained during the study which are reported in the present study report.

Date: 28.06.2019
Signature:

Head Manager of the investigating centre: MIOARA PETRESCU (Head Manager)
I the undersigned, MIOARA PETRESCU, declare that the overall conduct of the study was carried out under my responsibility in accordance with the protocol and 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.
I assume the responsibility of the validity of all the raw data obtained during the study which are reported in the present study report.

Date: 28.06.2019
Signature:

Quality Assurance Personnel: MIOARA PETRESCU (person in charge of the quality control)
I the undersigned, MIOARA PETRESCU, declare that:
- this type of study was audited according to the procedure of the investigating centre:
- the draft of the report was audited, on 27/06/2019
- the final report was audited, on 28/06/2019
- the reported results accurately and completely reflected the raw data of the study.

Date: 28.06.2019
Signature:

HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL/ CONFIDENTIAL DOCUMENT

I – INITIAL PROTOCOL DESIGN

I.1. STUDY OBJECTIVE

This study intended to confirm, in a panel of healthy human subjects, the skin compatibility of the investigational product, after a single skin application under maximising and controlled experimental conditions.

I.2. ETHICS

I.2.1. Ethical conduct of the study

• the general principles of medical ethics in clinical research coming from the Declaration of Helsinki (June1964) 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 recommendations of Colipa - August 1997 : "guidelines for the assessment of human skin compatibility",

• 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, and was in accordance with the European Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and with the Romanian Order N° 677/2001 for the protection of persons concerning the processing of personal data and free circulation of such data.

1.2.2. Relevance of the study

Based on the existing data, the aim of the study being a better knowledge of the skin safety of the investigational product and this product being applied under perfectly controlled conditions, the foreseeable risk incurred by the test subjects was minor.The single application was performed at the investigating centre by the technician and supervised by the investigator. Generally in this type of study, the possible adverse effects (as erythema, vesicles...) are limited on the application area and decrease in some days.The investigator had to ensure the clinical follow-up of the test subject(s) concerned, as long as it was necessary. So, there was suitability between the aim of the study and its eventual risks and the foreseeable troubles related to the experimental conditions of the protocol.The experimental conditions of product application created a certain occlusion and favoured the penetration of the product through the skin. The potential of irritation was more easily proved by this kind of approach.The product dose was perfectly controlled and the patch material and the conditions of use of the product were adapted to the product category.A control area (without investigational product) served as control to take into account the possible effects not directly related to the investigational product but due to the patch material.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 least 1 cm far apart). The areas of application of the different products and the control area(s) were chosen according to a clockwise distribution, altering of one rank from a test subject to another, to take into account the variability of the skin reactivity according to the area.The observance of the experimental conditions by the test subjects was assessed by a questionnaire at the end of the study.The skin examination was performed by the same investigator or technician, supervised by the investigator having the appropriate experience.

I.2.3. Survey committee

The study had to be devoid of any foreseeable serious risk for the safety of the test subjects.

According to the procedure of the investigating centre, the protocol, the informed consent form and the preclinical information concerning the investigational product (particularly referring to its safety) were submitted to the opinion of an internal committee, formed with members living in the country where the study has been carried out.

The committee got sure that the project meets the conditions of optimal scientific rigour, assessed its general relevance, the suitability between the aim followed and the means implemented and gave an opinion on the protection of the test subjects.The study did not begin without the approval of the Survey committee.The internal committee of the investigating centre gave a previous agreement (opinion n° 82/14 of 06th May 2014).

I.2.4. Information of the test subject and informed consent form

The information about the study was given to each test subject before the start of the study.This information was accessible, understandable and suitable for each test subject. It was orally given and then in a written specific document.This information was completed, if necessary, by the investigator (and the competent person designated) who answered all the questions asked by the test subject.The informed consent form was personal and previous to the start of the study.

It was clear, informed and explicit. It was written and given on the same support as the information on the study, in order to avoid any risk of dispute about its content.

The content of this document particularly specified:

- that the test subject declares to have a health coverage,
- the aim of the study,
- the study design and the experimental conditions of the study,
- the investigational product conditions of use,
- the approximate number of test subjects involved in the study,
- the expected duration of the study (for the test subject),
- the number of visits to the investigating centre, their dates and their duration,
- the study constraints (obligations, restrictions and troubles),
- the reasonable foreseeable risks,
- that skin site photographs can be taken and in this case, that the test subject will not be recognizable,
- that the test subject will be requested, if necessary, to take part in a complementary test to complete the study,
- the opinion of the internal committee of the investigating centre,
- the person to contact and the contact telephone number,
- that the personal data of the test subject will be confidentially treated by the study staff, available for the study monitor and possibly consulted (with the authorization of the test subject) by the auditors, the members of the internal committee and the Health Authorities (subject to non divulgation),
- the ban on taking part simultaneously in other clinical studies, that could interfere with the current study
- the amount of the compensation for the constraints to be undergone,
- the period of exclusion at the end of the study during which the test subject will not be allowed to take part in another clinical study,
- the confidential treatment of the study data,
- that the anonymity of the test subject will be preserved,
- the freedom for the test subject to refuse to participate or to stop his participation at any time without any justification and any legal consequences.

This document was previously approved by the Survey Committee.

At the beginning of the study, 2 copies of this document were dated and signed by the test subject and by the investigator and the competent person designated. One copy was given to the test subject, the other one was kept at the investigating centre.

I.2.5 . Confidentiality and identification of the test subject

The information concerning the test subject, required for his recruitment, his inclusion and particularly that related to his health, obtained during the medical examination prior to his admission in the general panel of the investigating centre, formed part of medical secret and was confidentially treated.The test subject was coded when included in when included in the current study in order to preserve his anonymity. If photographs of the skin had to be taken, the test subject had to be non recognizable.

I.3. INVESTIGATING CENTRE AND STAFF

I.3.1. Investigating centre

The study was performed at ECOVITAL G3 PROFESSIONAL SRL, certified ISO 9001, equipped with material and technical means suitable for clinical researches on cosmetic products and compatible with the safety requirements for human subjects.

I.3.2. Technical staff

The test was performed by a competent investigator and a trained and qualified technical staff.

Main Investigator: Dr. MARINCEA ELENA - CHIRURGIE PLASTICA-MICROCHIRURGIE RECONSTRUCTIVA, Registered N° (Romanian ministry of health): 2975/07.OCT.2009
Tel.:0722529728

Co-investigator: FARMACIST MIOARA PETRESCU(general practitioner)
E-MAIL: mioara.petrescu86@gmail.com
Tel.: 0730 649 182

Technician in charge of the study: MIOARA PETRESCU
E-MAIL: mioara.petrescu86@gmail.com
Tel.: 0730 649 182

I.3.3. Scientific management

Scientific manager: MIOARA PETRESCU
E-MAIL: mioara.petrescu86@gmail.com
Tel.: 0730 649 182

I.3.4. Quality assurance staff

Person responsible for quality control: MIOARA PETRESCU
E-MAIL: mioara.petrescu86@gmail.com
Tel.: 0730 649 182

I.4. DATES OF STUDY PERFORMANCE

Initiation date of study performance: 24.06 2019
Completion date of study performance: 28.06.2019

I.5. OVERALL STUDY DESIGN

I.5.1. Type of the study

This monocentric randomized clinical study was performed in simple blind, in a panel of healthy human subjects.
The test subject was used as own control.

I.5.2. General principle of the study

The study was performed on the basis of the protocol reference version 1 of 01/04/2018.
The investigational product had to be applied, in a panel of test subjects, once (on D1), to a skin area, by the technician in charge of the study at the investigating centre, under maximising conditions of exposure (under patch) and during a defined time = treated area.
A patch without investigational product but with distilled water had to be applied in parallel to a skin area during a defined time = control area.
The checking of the skin compatibility was based on:

- a skin examination of the treated and control areas, before patching and after patch removal by the same investigator or by the technician, supervised by the investigator
- the analysis of the sensations of discomfort reported directly by the test subjects.

The results of the skin compatibility were mainly descriptively expressed.

I.5.3. Chronology of the study

I.6. STUDY POPULATION

I.6.1. Constitution of the panel of test subjects and mode of recruitment

The investigating centre has at its disposal a general panel of subjects constantly renewed. These subjects come from all social categories. They either volunteer spontaneously to the investigating centre or reply to a direct call from the latter. Prior to their admission in this general panel, they are subjected to a clinical examination and a detailed cosmetological questionnaire, according to the corresponding procedure of the investigating centre.

All the data concerning the panel are computerized and on paper.

For the study, the test subjects were selected from this general panel on the basis of inclusion criteria and non-inclusion criteria specific to the study and on their ability to respect the constraints required by the protocol. They were definitely included in the study after a specific questioning and a clinical examination.

I.6.2. Number of test subjects

The number of test subjects with exploitable data (valid cases(1)) at the end of the study had to be at least 11.(1)valid case = test subject that respected the protocol with no significant deviation which could have some influence on the study results.

This empirically defined number was sufficient to achieve the study objectives.

At the beginning of the study, complementary test subjects were included to compensate the possible withdrawals or exclusions from the study independent of the investigational product.

The test subjects excluded from the study for reasons dependent of the investigational product had to be taken into account in the study results and did not have to be replaced.

If during the study, there was a risk not to have the required number of valid cases (great number of withdrawals...), the study monitor had to be informed and an additional quota of subjects had to be possibly included to reach the target.

At the end of the study, in spite of the precautions taken by the investigating centre, if the number of valid cases was less than the number of test subjects requested by the sponsor, the study monitor had to be informed.

Experimental times	**Types of reaction**
D1.	At the investigating centre: Checking of the inclusion and non inclusion criteria Delivery of the informed consent form after verbal explanation Signature of the informed consent form Inclusion of the subject in the study Clinical examination of the experimental area by the same investigator or by the technician supervised by the investigator Application of the patch with the investigational product and the control patch
D3.	At the investigating centre: Control of the observance Removal of the patches, Clinical examination of the experimental areas and questioning of the test subject by the same investigator or by the technician supervised by the investigator

I.6.3. Inclusion criteria

I.6.3.1. General inclusion criteria

According to the protocol, had to be included in the study, the subjects:

• suitable to participate in the study (after the clinical examination and questioning) and corrsponding to the quality of "healthy subject" as defined in the corresponding procedure of the investigating centre,

• declaring to have a health coverage,

• signing an "informed consent form" for this study,

• certifying not to take part in another clinical study,

• certifying the truth of the personal information declared to the investigator,

• capable of following directions and reliable to respect the constraints of the protocol (living not too far from the investigating centre, no linguistic and intellectual barrier),

• free to ensure the visits to the investigating centre,

• declaring not to have exposed themselves to a risk of pregnancy for at least 3 months before the beginning of the study and committing themselves to use effective contraceptive method throughout the study (for the women of childbearing potential).

I.6.3.2. Specific inclusion criteria

Subjects:

• aged from 18 to 68

• female and/or male

• with a phototype (Fitzpatrick): II, III, IV or V

• 100% with all type of skin on body

I.6.4. Non inclusion criteria

I.6.4.1. General non inclusion criteria

According to the protocol, did not have to be included in the study, the subjects:

• being in exclusion period,

• deprived of freedom by administrative or legal decision or under guardianship,

• who cannot be contacted in case of emergency,

• admitted in a residential care,

• planning an hospitalisation during the study,

• belonging to the staff of the investigating centre,

• being of age but protected by law,

• having received vaccination within the 3 weeks prior to the study or intending to be vaccinated during the course of the study,

• with personal history of adverse reactions to the same type of product as the investigational products,

• exhibiting skin marks and/or moles and/or freckles in too great quantity and/or hyperpilosity on the experimental area able to interfere with the assessment of the possible skin reactions,

• with still visible eczematous reaction, scar or pigmentary after-effects of previous tests on the experimental area

• under treatment, prior to the study, able to interfere with the interpretation of the study results, particularly: systemic retinoids (isotretinoin per os ...) within the 6 months, topical retinoids within the 2 months, other topical anti-acne medication within the month, topical or systemic medication with anti-inflammatory or antihistamine products within the 2 weeks, medication for malignancy (of any kind) within the 5 years, antibiotics within 2 weeks desensitisation treatment within the 6 months,

• foreseeing, during the study, a treatment able to interfere with the interpretation of the study results (systemic or topical anti-acne medication, anti-acne cosmetic products, topical or systemic medication with anti-inflammatory or antihistamine, antibiotics, desensitisation treatment, ...),

• having had a fever lasting more than 24 hours, within the 8 days prior to the study,

• having had any invasive aesthetic cares on chest and back (peeling, laser...) by a dermatologist within the 2 months prior to the study or foreseeing it for the duration of the study,

•

- having had any non invasive aesthetic cares on chest and back (scrub, skin cleansing...) by an aesthetician
- within the month prior to the study or foreseeing it for the duration of the study,
- having received excessive or intensive exposure to sunlight (natural or artificial) within the month prior to the study or foreseeing UV exposures for the duration of the study,
- under treatment with PUVA or UVB within the month prior to the study,
- having participated in a human repeated insult patch test with challenge with or without sun exposure within the 4 months prior to the study,
- having participated in a cumulative irritability test within the 2 months prior to the study or in a single patch
- test within the month prior to the study,
- having already participated in 5 clinical studies involving patch test, including 3 human repeated patch tests
- maximum with or without challenge within the year prior to the study,
- foreseeing bath (in bathtub, sea or swimming-pool), sauna or Turkish bath during the study period,
- regularly practicing intensive sport causing sweating and requiring frequent showers

I.6.4.2. Specific non inclusion criteria

Subjects:

- with personal history of adverse reaction to colophony, rubber, nickel, aluminium, patch materials, adhesive plaster,
- with family or personal history of atopy,
- with orthoergic skin reactivity on body,
- with personal history of adverse reactions to the same type of product as the investigational product,
- with documented history of contact allergy.

I.6.5. Specific information concerning the test subjects and medication

Skin reactivity, history of atopy, contraception (type) and possible current medication were documented by the technician, supervised by the investigator, in the case report form.

No medication likely to interfere with the study was allowed during the study; however, if the health state of the subjects justified some medication (particularly anti-inflammatory drugs), any information relating to this concomitant medication had to be carefully documented in the case report form.

The investigator had to exclude the test subjects taking concomitant medication likely to interfere with the study and the interpretation of the results.

I.6.6. Exclusion criteria

According to the study protocol and to the procedures of the investigating centre, had to be excluded from the study, the test subjects:

- who did not comply with the protocol and created deviation resulting in un-exploitable results,
- who took part in another clinical study that could interfere with the current study,
- who had adverse event (for example: inter-current disease requiring a concomitant medication interfering with the study and the interpretation of the results or severe skin intolerance to the investigational product), incompatible with a good protocol observance.

The temporary or definitive discontinuations decided by the investigator and their dates and reasons had to be carefully documented in the case report form.

I.6.7. Withdrawal criteria

According to the study protocol and to the procedures of the investigating centre, had to be considered as with drawals, the test subjects:

- who discontinued the study for personal reasons independent of the study (for example: moving house, new job),

• who did not come to the investigating centre for the checking in spite of phone calling.

The withdrawals and their dates and reasons had to be carefully documented by the investigator in the collective case report form (CRF).

I.6.8. Study constraints imposed on the test subjects

The constraints defined by the procedures of the investigating centre and in the study protocol, imposed on the test subjects, related the study, were the following ones:

• if justified and asked by the investigator, participation in a complementary test (additional visits to the investigating centre),

• exclusion period at the end of the study (according to the corresponding procedure of the investigating centre, and 3 months minimum before starting a human repeated insult patch test with challenge, 1 month minimum before starting another single patch test),

• no participation in another clinical study in another investigating centre, in the course of the study or during the specified exclusion period,

• if justified, description of any concomitant medical treatment not excluded by the inclusion and non inclusion criteria,

• no drug able to interfere with the study and the interpretation of the results, e.g. aspirin (except low dose maintenance therapy), products containing aspirin, antihistamine drugs, anti-inflammatory drugs, antibiotics...: concomitant medication (however, if therapeutic requirement: possible exclusion from the study),

• neither anti-acne nor anti seborrheic local treatment,

• neither invasive body aesthetic cares (peeling, laser...) nor non invasive body aesthetic cares (scrub, skin cleansing...) on chest and back, by a dermatologist or an aesthetician in Beauty Salon,

• neither initiation of an hormonal treatment nor change of the usual hormonal treatment,

• respect of the dates of visit to the investigating centre and possibly the defined hours,

• no application of cosmetic care products to the back other than the investigational ones,

• no change of the mode of contraception,

• no change in usual body hygiene products,

• no introduction of new cosmetic products,

• no significant change in lifestyle: diet, smoking, sport...,

• no intensive sun or UVA exposure (U.V. lamps) during the study and 2 weeks after the end of the study,

• no wearing of too tight or restraining clothes liable to produce frictions on the experimental area and to cause the un-sticking of the patch(es),

• neither Turkish bath nor sauna nor bath (in bathtub or swimming-pool or sea), liable to cause excessive sweating and/or the un-sticking of the patch(es),

• during shower, protection of the experimental area (no violent projection of water, no application of soap, very gentle wiping if necessary) to avoid the un-sticking of the patch(es) or the appearance of inter-current skin irritation,

• no intensive sport liable to cause excessive sweating and the un-sticking of the patch(es),

• in case of detachment or moving of the patch(es), contact with the investigating centre,

• no vaccination

The test subjects were questioned at the end of the induction phase and at the end of the challenge about the respect of the study constraints. The investigator had to assess the importance of the possible deviations in comparison with the experimental conditions required at the beginning of the study and their incidence on the validity of the results.

I.7. INVESTIGATIONAL PRODUCT

I.7.1. Identification of the investigational product

I.7.2. Coding and storage

The sponsor supplied to the investigating centre, the product in sufficient quantity for the study and the sampling, in neutral packaging, clearly identified.

Upon receipt, the investigating centre noted the date of the product receipt, checked the supplied quantities, the product aspect and got sure that the labelling was in accordance with the demand of the sponsor.

If requested, the sponsor received an acknowledgement of receipt, mentioning the remarks of the investigating centre. The conditions of coding, labeling, storing and destruction of the product units were defined according to the corresponding procedure of the investigating centre.

The product units were coded and labelled in Romanian according to the corresponding procedure of the investigating centre.

Product Denomination	HYGIENIUM SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ TRUSSA SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ ECOV 141/2019
Cosmetic category	HAND CAREPRODUCT
Reference /Formula number	ECOV/141-2019
Batch number	2019
Galenic form and organoleptic characteristics	Characteristic
Normal foreseeable conditions of use	HAND CARE/ 2 times/day , when is necessary- min 2 times/day
Number and type of product units	1 pcs/100 ML,
Content of product unit	HYGIENIUM SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ TRUSSA SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ ECOV 141/2019
Ecovital code:	ECOV/141-2019

Before starting the study, the storage of the investigational product units was carried out according to the conditions defined by the sponsor, in the product storage area and a product sample (one product unit) was taken and kept in the sample storage area of the investigating centre for at least 1 years after the end of the study then destroyed, according to the corresponding procedure of the investigating centre.

Apart from the specific demand of the sponsor, the used and unused product units will be kept at least 2 weeks after the sending of the final report then destroyed, according to the corresponding procedure of the investigating centre.

I.7.3. Information concerning the investigational product

The investigational product unit had to be supplied with a certificate that particularly referred to:

• the compliance of the ingredients of the investigational product formula with the European Regulation N° 1223/2009 of the European Parliament and Council on cosmetic products,

• the safety of the finished investigational product and the absence of foreseeable serious risk for the health of the test subjects.

The qualitative and quantitative formula of the product had to be supplied to the investigating centre by the study monitor.

I.7.4. Experimental conditions of use of the investigational product

The skin areas had to be defined by the technician in charge of the study, on the upper back of the test subject, taking into account the skin appearance and avoiding the areas of friction with clothes.

The quantity of investigational product had to be measured, by the technician in charge of the study, with a single use syringe and put into the patch.

Before patching, the skin had to be wiped with a cotton pad.The patch containing the investigational product had to be applied, by the technician in charge of the study, to the defined skin area.

The experimental conditions of patching at the investigating centre had to be the following ones:

Patch material	**Experimental conditions of use of the investigational product**	**Quantity to be applied**
COSMOPOR ADVANCE®: aluminium cupula kept in position by an hypoallergenic adhesive: (inner diameter: 8 mm, surface: 65 mm2)	As it is	20µl

An occlusive patch, containing 20 µl of distilled water had to be applied in parallel as control to eliminate, when the results would be interpreted, the possible inter-current effects due to the patch material.

The patches were applied on D1 and had to be worn for 48 hours ± 4 hours then removed at the investigating centre.

I.8. CHECKING OF THE SKIN COMPATIBILITY I.8.1. Recording of the skin reactions

A skin examination of the treated and control areas was performed at the investigating centre:

- visually, by the same investigator / technician, supervised by the investigator, under standard "daylight" source,
- on D1, before patching,
- on D3, 15 to 30 minutes (or more, if redness appeared after the removal of the adhesive) after patch removal

Concurrently with the clinical examinations performed after patches removal, the test subjects were questioned about the possible sensations of discomfort they felt.
In case of strong sensations of discomfort felt during the patch wearing at home, the test subjects had to inform by phone the investigator. If necessary, the patch had to be removed and a skin examination had to be quickly per- formed by the investigator (before the next planned visit to the investigating centre).
An area where erythema was graded 2 or more (with or without infiltration) had to be evaluated on subsequent days to note whether the reaction diminishes or increases, in order to differentiate between an allergic reaction and an irritation. Digital photographs of the skin had to be systematically taken when justified (adverse effects). All the data were recorded in the case report form.

Operations at the investigating centre	**Experimental times**	
	D1	**D2**
Application of the investigational product under patch to the defined area (upper back)	**X**	/
Removal of the patches	/	**X** After 48h of contact
Skin examination Questioning of the test subjects	x Before patching	x 15-30 minutes after patch removal

E = Erythema d=diffuse p=punctuated peri=peripheral	0 – no visible erythema 0.5 – very slight erythema – barely perceptible 1 – mild erythema – faint pink 2 – moderate erythema – well defined 3 – severe erythema 4 – caustic effect – erosive aspect and/or necrotic aspect

I.8.2. Expression of the results

All the reactions had to be accurately described at each experimental time using the criteria and the scale hereafter.
In case of erythema, the investigator had to proceed to palpation to assess infiltration / oedema.
The other clinical visible signs, if present, were assigned a mark for the calculation of the individual daily irritation score (IDIS).
The presence of a reaction on the control area leads the investigator to temper the skin compatibility conclusion of the investigational product.The results were expressed in percentage of reactive test subjects: for this calculation only the erythema and other visible signs of reactivity were taken into account. For each test subject and each observation time, an individual daily irritation score (IDIS) was calculated (sum of the marks obtained for the visible clinical signs observed on the application area of each investigational product).

M = Complementary mention : Other reactions		
Sv	Soap effect (shiny skin with possibly wrinkles)	1
D	Desquamation	1
Dr	Dryness	1
Sc	Scab	1
Hy	Hypopigmentation	1
C	Skin coloration – hyper-pigmentation	1
Oe	Homogeneous infiltration / oedema	2
P	Papules	2
V	Vesicles	2
Pe	Petechiae	2
Fr	Follicular reaction	2
I	Itching at the test site	2
F	Fissuring	3
Cr	Exudation and/or Surface encrustation	3
B	Bullae	3
E	Erosion	3
Pu	Pustules	
He	Heating	
/	No reaction	

For the panel and each observation time, a mean daily irritation score (MDIS) was calculated according to the for- mula: **MDIS = Σ (IDIS) / Nb of valid cases**

I.8.3. 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 or any other time.

The nature, intensity, appearance period from the application, disappearance period from the application, location (just on the application area or spreading beyond the application area) of the skin reaction were taken into account for the interpretation of the results.
In case of skin reactivity, the reaction observed could be an irritation reaction or an allergic reaction (if the test subject has been previously in contact with the allergen).
A quick decreasing reaction can be indicative of irritation. A reaction with infiltration / oedema and possibly spreading, itching, that persists or increases over time usually can indicate an allergic reaction. If a possible allergic reaction is observed, it can be the revelation of an allergy previously contracted. To appreciate the skin compatibility of the investigational product, the interpretation of the results was based on the experience of the investigator in this field.
The investigator concluded according to the scale: very good, good, medium or poor skin compatibility. In case of suspected allergic reaction or strong irritation, the study monitor had to be quickly informed. If justified in case of reactivity in some test subjects, a complementary study was possibly carried out in these test subjects, after agreement of the sponsor. The experimental conditions of this study had to be defined by the investigator, case by case.

I.9. SUSPENSION OF THE STUDY

The investigator had to stop the study if it showed a risk for the health or the integrity of the test subjects. The date of the suspension and the reasons had to be carefully documented by the investigator in the case report form. The investigator centre had to inform promptly the study monitor, by phone, fax or e-mail. The sponsor was able to stop the study at any time for administrative reasons or other ones.

I.10. ADVERSE EVENTS I.10.1. Definitions

Any topical product can induce, when used in Human, according to individual sensitivities, a local and minor reactivity, defined as follows: any slight local reaction of intolerance or sensation of discomfort, occurring in a test subject during a clinical study, completely reversible, expected, due to the investigational product and which does not question the observance of the study protocol or the good implementation of the study.

- **adverse event**: any harmful event with or without relationship with the investigational product, occurring in a test subject during a clinical study.
- **suspicion of adverse effect**: any adverse event with a quite possible relationship with the investigational product.
- **adverse effect**: any harmful and unwanted reaction, due to the investigational product, occurring in a test subject during a clinical study.
- **unexpected adverse effect**: any adverse effect due to the investigational product, the nature, the intensity and/or the evolution of which do not agree with the product information.
- **serious adverse event / effect**: any adverse event or adverse effect that causes death, endangers test subject's life, induces an hospitalisation or the prolongation of the hospitalisation, causes severe and lasting in- capacity or handicap or induces congenital anomaly or malformation.

I.10.2. Data collection The investigator had to accurately describe the adverse event and had to appreciate its seriousness.
According to the corresponding procedure of the investigating centre, he had to define the link of causality between this event and the investigational product, on the basis of the symptoms, the chronology, the results of the possible specific complementary tests undertaken and any available information.The imputability of the product had to be assessed according to the scale: very likely, likely, possible, questionable, excluded (in accordance with the recommendations of the European Council in its resolution ResAP (2006)1 of 08/11/2006).

I.10.3 . Conduct to be adopted in case of adverse event

Faced with an adverse event, the investigator had to freely define, case by case, the conduct to be adopted and the suitable steps to ensure the safety of the test subject concerned and of the other test subjects included in the study. In case of adverse effect (with a quite possible relationship withe investigational product), the investigator had to ensure the clinical follow-up of the test subject concerned, as long as necessary.

I.10.4. Communication with the study monitor

According to the corresponding procedure, the serious adverse events and the adverse effects had to be notified as soon as possible and within 24 hours at the latest, by the investigator centre to the study monitor, by phone, fax or e- mail.
The investigator had to send an adverse event form to the study monitor.
If justified, the investigator had to give to the study monitor complementary information when available.

I.11. RAW DATA RECORDING AND STUDY REPORT FILING

All the data gathered during the study were recorded accurately, legibly and indelibly by the investigator and the technician in charge of the study, under his control, in the case report form.
Each page of this document was initialled and dated by the technician; the whole was verified and validated by the investigator.
The content of this study report took into account the recommendations of the Colipa related to the assessment of the efficacy of cosmetic products (May 2008) and the explanatory note related to the structure and the content of the reports of clinical studies – ICH E3, of 28/11/1995.
At the end of the study, the information concerning the investigational product, the information concerning the test subjects (CRF(s), daily logs, informed consent forms) and the information related to the conduct of the study (proto- col signed by the sponsor, copy of this study report....) were filed and will be kept for 10 years, in the filing area of the investigating centre.
At the end of this period, the sponsor will choose among the 3 options:

- return of the study documentation to the sponsor,
- filing of the study documentation in the filing area of the investigating centre based on a specific contract,
- destruction of the study documentation (after sponsor's written and signed authorization).

I.12. REFERENCES

Numerous publications supported this methodology, notably:
• Cosmetic product test / Guidelines for the assessment of human skin compatibility – COLIPA – August 1997 • Mikulowska A., Reactive changes in human epidermis following simple occlusion with water, Contact Dermatitis, 1992, 26, pp. 224-227
• Matthies W., Test strategies for development of cosmetic products using dermatological test models, Seifen- Öle-Fette-Wachse, 1991, 117, pp. 42-43
• Frosch P.J. & Kligmann A.M., The Duhring Chamber: an improved technique for epicutaneous testing of irritant and allergic reactions, Contact Dermatitis, 1979, 5, pp. 73-81
• Draize J.H., Appraisal of the safety of chemicals in Food, Drugs and Cosmetics, edited by the FDA, USA, 1959, pp. 46-48

II – PRACTICAL CONDITIONS OF STUDY PERFORMANCE

II.1. PROTOCOL ADHERENCE

II.1.1 . Study population

II.1.1.1. Number of test subjects The number of recruited test subjects took into account the inclusion criteria, the constraints of the study and the period of the study performance.At the beginning of the study, one (1) complementary test subject was included to compensate the possible withdrawals or exclusions from the study independent of the investigational product. The number of recruited test subjects took into account the inclusion criteria, the constraints of the study and the period of the study performance. At the beginning of the study, one (1) complementary test subject was included to compensate the possible withdrawals or exclusions from the study independent of the investigational product.
II.1.1.2. Inclusion and non inclusion criteria: All the test subjects corresponded to the inclusion and non inclusion criteria. The individual typological characteristics of the test subjects are reported in

Appendix 1, and recapitulated below for the whole panel:

Number of test subjects included in the study	**11**	
Withdrawals	Test subjects concerned	Date and reasons
	None	Non applicable
Exclusion	Test subjects concerned	Date and reasons
	None	Non applicable
Valid cases	Skin compatibility	
	11	

II.1.1.3. Specific information concerning the test subjects and medication
The answers of the test subjects concerning the skin reactivity, the history of atopy, the type of contraception (for the women) and the current medication are reported in Appendix 2.

Age (years old)	Included test subjects and valid cases
Minimum	19
Maximum	68
Mean	46

II.1.1.4. Study constraints imposed on the test subjects
All the constraints of the study, defined in the protocol, were respected by the test subjects.The answers of the test subjects concerning the respect of the constraints defined in the protocol are reported in the CRF.

Criteria	Included test subjects and valid cases	
	Nb	%
Phototype		
II	3	27
III	8	73
Sex		
Female	8	82
Male	3	18

II.1.2. Experimental conditions of use of the investigational product

All the experimental conditions of application at the investigating centre on D1 defined in the protocol were respected.

II.1.3. Checking of the skin compatibility: recording of the skin reactions

All the skin examinations and questioning of the test subjects were performed in accordance with the conditions defined in the protocol.

III – RESULTS

III.1. RESULTS / DISCUSSION

III.1.1. Checking of the skin compatibility

The individual data of the skin examination an d questioning of the test subjects are reported in Appendix 3. **For the control area:**

Control time after patch re-moval	Types of reaction	Number of re-active subjects	% of reactive test subjects	Mean daily irritation score MDIS	Skin compati-bility of the product
T 15 minutes (D3)	None	0	0 %	0	Very good skin compatibility

For the investigational product:

Control time after patch re-moval	Types of reaction	Number of re-active subjects	% of reactive test subjects	Mean daily irritation score MDIS	Skin compati-bility of the product
T 15 minutes (D3)	None	0	0 %	0	Very good skin compatibility

III.2. OVERALL CONCLUSION

Under the experimental conditions adopted:

single application of the investigational product, HYGIENIUM SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ TRUSSA SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ ECOV 141/2019, under occlusive patch on a panel of 11 subjects with all types of skin on body, the product induced no reaction of irritation and has a very good skin compatibility.

III.3. QUALITY CONTROL AND QUALITY ASSURANCE

The study was performed in compliance with the procedures of the investigating centre, established according to the regulations in force.The investigator, in charge of the performance of the study, made sure of the quality of the work of the technical staff, particularly concerning the respect of the protocol and its appendices, the collection of raw data, the management of the investigational product.

The personnel of the Quality Assurance department controlled that the study documentation was present, dated and signed. The personnel of the Quality Assurance department regularly controls that the protocol and working procedures relevant to this type of study are duly applied.

Any significant change brought to the protocol was the subject of a protocol amendment, sig ned by the study monitor and the investigator. Any significant anomaly, occurring during the study, was documented in the case report form and reported to the study monitor.
Any deviation from the protocol was reported in the study report.

M = Complementary mention : Other reactions	
NA	Product not applied
T	Tape reaction
L	Loss of patch during the first 12 hours
Abs	Test subject absent

M = Complementary mention : Other reactions A = ICDRG scale	
IR	Irritation reaction
-	No Allergic Reaction
+	Doubtful reaction (only slight erythema)
(+)	Weak positive reaction (without vesicle): slight erythema and infiltration with presence of small papular elevations, possibly papules
(++)	Strong positive reaction: erythema, papules, vesicles, infiltration
(+++)	Extreme positive reaction: intense erythema, oedema, coalescent vesicles (bullae)

APPENDICES/CONFIDENTIAL DOCUMENT

TYPOLOGICAL CHARACTERISTICS OF THE TEST SUBJECTS

Legends:

Appendix 1 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

Test Subject		**Age (Years)**	**Sex F= Female, M=Male**	**Phototype**
Ref.	**Code :the first 4 letters of the surname and the first 2 letters of the first name**			
1	IRIN.MA	20	F	II
2	VERO.OL	65	F	III
3	RICA.OL	44	M	III
4	FLOR.TO	47	M	II
5	FLOR.OL	38	F	III
6	MIRU.MA	21	F	III
7	CATR.MA	47	F	III
8	LAUR.GE	22	F	II
9	ANIC.CO	65	F	III
10	RAZV.MA	47	M	III
11	ANDR.CO	22	F	III

Appendix 2

SPECIFIC INFORMATION CONCERNING THE TEST SUBJECTS/CONFIDENTIAL DOCUMENT

Test subjects		Orthoergic skin reactivity	Atopy	Current medication		Contraception
Ref.	Code :the first 4 letters of the surname and the first 2 letters of the first name			If yes (commercial denomination, active substance and dosage)		If yes (to be specified)
				At the inclusion	During the study	
1	IRIN.MA	/	/	NONE	NONE	CONDOM
2	VERO.OL	/	/	NONE	NONE	NC (MENOPAUSE)
3	RICA.OL	/	/	NONE	NONE	CONDOM
4	FLOR.TO	/	/	NONE	NONE	CONDOM
5	FLOR.OL	/	/	NONE	NONE	CONDOM
6	MIRU.MA	/	/	NONE	NONE	CONDOM
7	CATR.MA	/	/	NONE	NONE	CONDOM
8	LAUR.GE	/	/	NONE	NONE	CONDOM
9	ANIC.CO	/	/	NONE	NONE	NC (MENOPAUSE)
10	RAZV.MA	/	/	NONE	NONE	CONDOM
11	ANDR.CO	/	/	NONE	NONE	CONDOM

Legends: / = no NC = Not concerned

SKIN COMPATIBILITY - SKIN EXAMINATION AND QUESTIONING INVESTIGATIONAL PRODUCT/CONFIDENTIAL DOCUMENT

REACTIONS : Clinical signs E = Erythema: E1 = very slight, E2 = slight, E3 = moderate, E4 = severe D = Dryness: D1 = very slight, D2 = slight, D3 = moderate, D4 = severe Oe = Homogeneous infiltration/Oedema Pa = Papules : Pa1 = few (<3), Pa2 = numerous (>3) V = Vésicules : V1 = few (<3), V2 = numerous (>3) Bu = Bullae Cr = Scab – Exsudation and/or surface encrustation Sv = Soap effect (shiny skin with possibly wrinkles) Hypo = Hypo-pigmentation Hyper = Hyper-pigmentation C = Skin coloration Pu = Pustule Sensations of discomfort Pr = Pruritus: Pr1 = very slight, Pr2 = slight, Pr3 = moderate, Pr4 = severe B = Burning	d: diffuse p: punctuated peri: peripheral /: no reaction

Test Subject		**Experimental times**			
		D1/T0		**D3**	
Ref.	**Code**	Reactions + Intensity	IDIS	Reactions + Intensity	IDIS
1	IRIN.MA	NONE	0	NONE	0
2	VERO.OL	NONE	0	NONE	0
3	RICA.OL	NONE	0	NONE	0
4	FLOR.TO	NONE	0	NONE	0
5	FLOR.OL	NONE	0	NONE	0
6	MIRU.MA	NONE	0	NONE	0
7	CATR.MA	NONE	0	NONE	0
8	LAUR.GE	NONE	0	NONE	0
9	ANIC.CO	NONE	0	NONE	0
10	RAZV.MA	NONE	0	NONE	0
11	ANDR.CO	NONE	0	NONE	0
MDIS		**0**		**0**	

Appendix 3/2

SKIN COMPATIBILITY – SKIN EXAMINATION AND QUESTIONING CONTROL AREA/CONFIDENTIAL DOCUMENT

Test Subject		**Experimental times**			
		D1/T0		**D3**	
Ref.	**Code**	Reactions + Intensity	IDIS	Reactions + Intensity	IDIS
1	IRIN.MA	NONE	0	NONE	0
2	VERO.OL	NONE	0	NONE	0
3	RICA.OL	NONE	0	NONE	0
4	FLOR.TO	NONE	0	NONE	0
5	FLOR.OL	NONE	0	NONE	0
6	MIRU.MA	NONE	0	NONE	0
7	CATR.MA	NONE	0	NONE	0
8	LAUR.GE	NONE	0	NONE	0
9	ANIC.CO	NONE	0	NONE	0
10	RAZV.MA	NONE	0	NONE	0
11	ANDR.CO	NONE	0	NONE	0
MDIS		**0**		**0**	

CONCLUSION: The patch test study was performed under dermatological control on a group of 11 volunteers. The study allows to conclude that product HYGIENIUM SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ TRUSSA SAPUN LICHID ANTIBACTERIAN CU EXTRACT DE BUMBAC/ ECOV 141/2019 used by persons, for whom allergy to any of its ingredients hasn't been documented, is well tolerated by the skin. In the tested group of volunteers there were no irritations or allergic reactions. The product meets the requirements of compatibility test with the skin (Skin Compatibility Test) and can be classified as **NOT IRRITATING.**

DOCUMENT CONFIDENTIAL

INFORMATII PREALABILE FURNIZATE PENTRU INTOCMIREA DOCUMENTELOR NECESARE REALIZARII DE STUDII FARA BENEFICII TERAPEUTICE PE VOLUNTARI UMANI

Informatii relative despre produsul pe care intentionati sa il testati

INFORMATII GENERALE	
Numele si coordonatele	GRANDE GLORIA PRODUCTION SRL Sat Costi, Comuna Vanatori, strada Tuluc, nr. 1, hala nr 68. Biroul nr 2, jud Galati Nr.Ord.Reg. com : J17/1268/26.11.2014 C.U.I 33844286
Denumire Produs Indicati denumirea produsului care doriti sa apara in raportul de studiu	**Hygienium sapun lichid antibacterian cu extract de bumbac** **Trussa sapun lichid antibacterian cu extract de bumbac**
Referinta produs Indicati referinta corespunzatoare formulei produsului (a nu se confunda cu nr. lot de fabricatie)	TP1
Categoria de produs cosmetic Conf. Anexa 1 din Regulament 1223/2009	Produs pentru curatarea pielii
Mod de utilizare Indicati: locul de aplicare, conditii de utilizare - timpi de contact, indepartare, frecventa de aplicare, durata....	Sapun lichid antibacterial
Precautii de utilizare	A se pastra la temperaturi intre 4 si 30 grade C
Objective de vanzare Indicati obiectivul: populatia tinta (barbati, femei, adolescenti, copii...), categoria de varsta, tip de piele (uscata, sensibila), tip de par, etc... utilizare specifica profesionala: saloane de infrumusetare, saloane de coafura...sau utilizare directa de catre consumatori	Produs destinat adultilor dar poate fi folosit si de copii de peste 3 ani
Tip de conditioner prevazuta is capacitate Exemple: tuburi, aerosoli, cutii	Produsul se ambaleaza in PET de cu volume diferite

Eu, subsemnata Danielea Rautu, Administrator, certifica ca toate informatiile furniza

INFORMATII DESPRE COMPOZITIA PRODUSULUI SI INGREDIENTE	
Formula caritativa si/sau cantitativa si/sau confirmarea ca ingrediente inscriptionate pe ambalajul original sunt cei prezenti in formula	conform Anexei/formula calitativa
PH	5-6
Compozitia conform Regulamentului 1223/2009 cu amendamentele corespunzatoare (in particular cele care implica ingrediente pe listele pozitive si negative)	Substante care pot fi utilizate numai in anumite conditii si limite de admisibilitate: -PRODUSU ESTE UNUL BIOCID si intra in categoria TP1 Ingrediente: Chlorhexidine Digluconate 0,4%, Quaternary ammonium compounds benzyl-C12-16-alkyldimethyl, chlorides 1%. Other ingredients: Aqua,Cocamidopropyl Bataine, Gossypium Herbaceum Seed Extract, PEG-200 Hydrogenated Gliceryl Palmate, Lauryl Glucoside ,Parfum , CI 73015,CI 10020.
Ingredientele contain impuritati susceptible sa prezinte un risc toxicologic: Daca da, Listati	conf cosing lista astasata ingrediente
Parfumat	Da
	Lista alergenilor din parfum sau uleiurile esentiale: fara alergeni
INFORMATII DESPRE PRODUSUL FINIT	
Produsul este fabricant conform GMP	DA

DOCUMENT CONFIDENTIAL

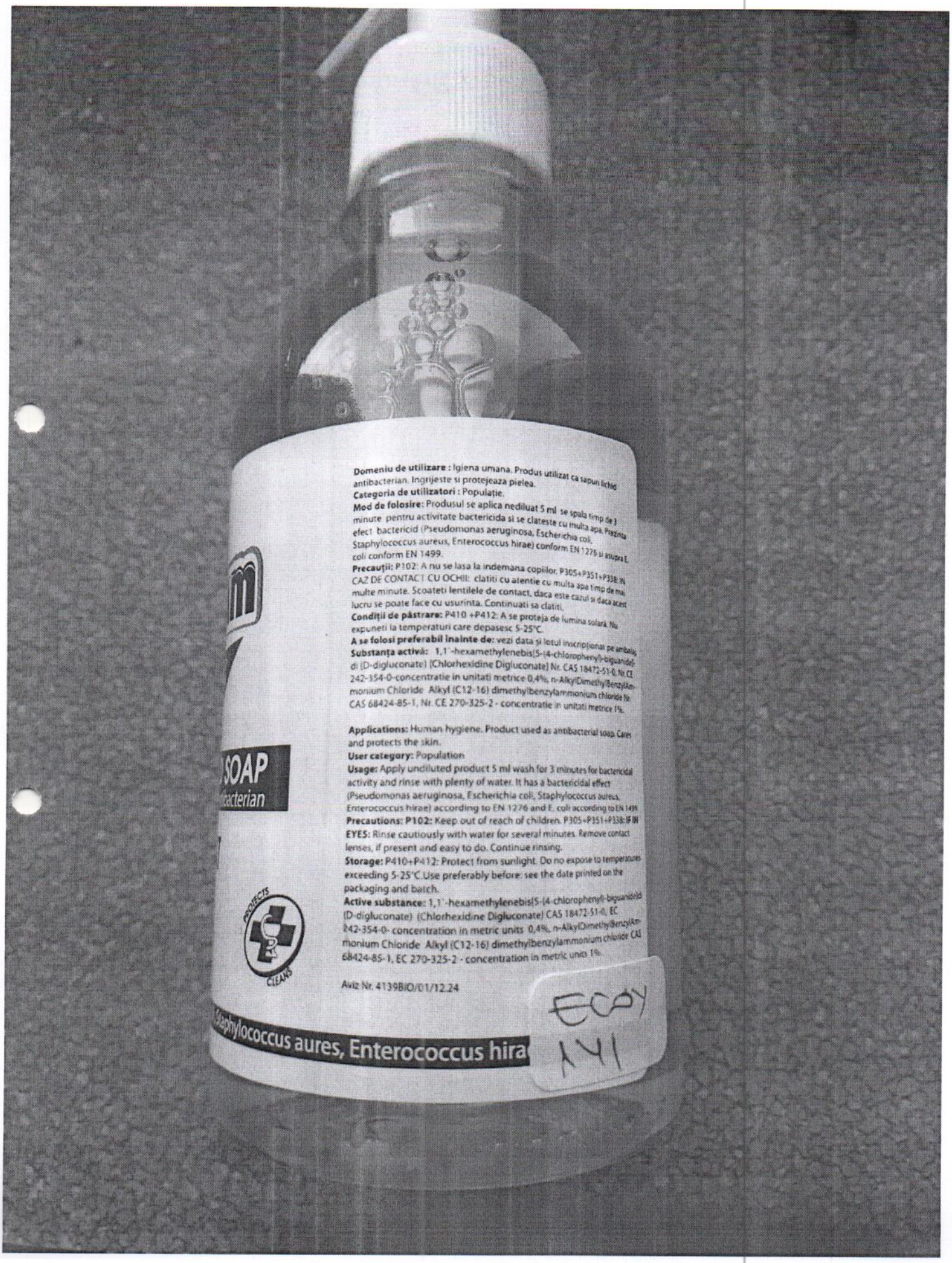
INFORMATII DESPRE COMPOZITIA PRODUSULUI SI INGREDIENTE	
Produs stabil din punct de vedere fizico-chimic si microbiologic	DA
Durabilitate > 30 luni	DA
Produs nou	DA
Produs care a facut obiectul testelor de toleranta IN VITRO Daca da, listati testele realizate si anexati un rezumat al metodologiei si rezultatele	NU NU
Produs reformulat dar care se afla deja pe piata inainte de cererea pentru efectuare stiudiu	NU
Produs care a stat la baza reformularii si care se afla pe piata: Daca da, istoric de vanzare pentru produsul pe baza caruia s-a formulat Indicati Tarile de comercializare, data punerii pe piata, reclamatii pentru probleme de toleranta	NU NU

te sunt exacte.

Numele semnatarului:
Semnatura/Stampila
Data: 14.06.2019

SOCIETATEA GRANDE GLORIA PRODUCTION S.R.L. GALATI - ROMANIA

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