HAMILTON

REPORT No. 336386/21/CGDA/S

Sponsor: **Sheleg consulting , 3877701 Industrial Park Emek Hefer, 5 Nahal Alexander**		Investigational product *(according to declaration of the Sponsor)* **MANUKA SERUM**
Report date:	04.08.2021	

HRIPT (Human Repeated Patch Test - 50 subjects)

CONTENT OF THE PROTOCOL

Authorised by: Karolina – Osiecka, Dermatologist - Venereologist, 2487308 (qualified electronic signature),
Marta Rosińska, Project Manager/Cosmetic Laboratory Manager (qualified electronic signature).

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STUDY REFERENCE

SPONSOR	**Sheleg consulting , 3877701 Industrial Park Emek Hefer, 5 Nahal Alexander**
STUDY MONITOR	Vardit Hadad
INVESTIGATING CENTRE	**J.S. HAMILTON POLAND Sp. z o.o** Ul. Bajana 3D 80-463 Gdańsk, POLAND
PROJECT MANAGER	Agnieszka Zdrójkowska
MAIN INVESTIGATOR	**Dr Karolina Osiecka** (dermatologist) Registered N° **2487308**
ETHICAL COMMITTEE APPROVAL	18.06.2021

Authorised by: Karolina – Osiecka, Dermatologist - Venereologist, 2487308 (qualified electronic signature),
Marta Rosińska, Project Manager/Cosmetic Laboratory Manager (qualified electronic signature).

1. INITIAL STUDI DESIGN

1.1. STUDY OBJECTIVES

This study intended to determine the allergic reactions of the product **MANUKA SERUM** in a panel of healthy human subjects using Draize Repeated Insult Patch Test.

1.2. ETHICAL CONDUCT OF THE STUDY

The described study was conducted in the spirit of the Good Clinical Practice defined by the ICH Topic E6 "Note for Guidance and good clinical practice" (CPMP/ICH/135/95), the Helsinki Declaration (1964, WMA) and its successive updates. The study was conducted according to Standard Operating Procedures and to the study protocol defined by the sponsor. All study events recorded during the study was reported. Controls on data veracity and conformity with the protocol was performed and confirmed by persons participating in the study.

SCOPE OF TESTS COMPLIANT WITH:

- Regulation of the European Parliament and of the Council (EC) No. 1223/2009 of 30 November 2009 on cosmetic products.
- Cosmetics Europe – The Personal Care Association (previously COLIPA) Guidelines "Product Test Guidelines for the Assessment of Human Skin Compatibility 1997."
- Cosmetics Europe – The Personal Care Association (previously COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008.
- "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics" by J.H. Draize, published by the Association of Food and Drug Officials of the United States.

1.3. QUALITY CONTROL

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.

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1.4. RELEVANCE OF THE STUDY

Based on the existing data, the main aim of the study being a better knowledge of the skin safety of the investigational product **MANUKA SERUM**. The purpose of the test is to examine whether a certain substance may have the allergic reactions in subjects with healthy skin. The skin examination was performed by the investigator or by the technician, controlled by the investigator having the appropriate experience.

1.5. ETHICAL COMMITTEE

According to the procedure of investigating center, the protocol, the informed consent form and the preclinical information concerning the investigational product **MANUKA SERUM** was submitted to the internal committee of the investigating center.

The committee got sure that the project meets the conditions of optimal scientific rigor, assessed its general relevance, the suitability between the aim followed and the means implemented and was gave an opinion on the protection of the test subjects.

The study do not begin without the approval of the Survey committee.

1.6. INFORMATION OF THE TEST SUBJECT AND INFORMED CONSENT FORM

The information about the study was given orally and as a written document to each test subject before the start of the study. This information is accessible, understandable and suitable for each test subject. This information was completed, if necessary, by the investigator (or the competent person designated) who answered all the questions asked by the test subject.

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 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),
· that skin site photographs can be taken and in this case, that the test subject would not be

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recognizable,

· the opinion of the internal committee,

· the person to contact and the contact telephone number,

· that the personal data of the test subject would 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 and the members of the internal committee,

· the ban on taking part simultaneously in other clinical studies,

· 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 would not be allowed to take part in another clinical study,

· the confidential treatment of the study data,

· that the anonymity of the test subject was 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.

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

1.7. CONFIDENTIALITY OF THE SUBJECT

The information concerning the subject, required for his recruitment, inclusion and particularly that related to his health, obtained during the medical examination, formed part of medical secret and was confidentially treated.

The test subject was coded when included in the study to preserve his anonymity.

1.8. THE BASIS TO CONDUCT THE STUDY

- Samples delivered by the Sponsor.
- The qualitative composition of the product delivered by the Sponsor.
- The results of microbiological purity of the product provided by the Sponsor (or declaration from the Sponsor about microbiological purity).

The Sponsor is responsible for conformity with the declared quality composition of the product as well as microbiological purity test of the delivered samples.

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2. SUBJECT OF THE TEST

2.1 Description of the product

Parameter	Description
Intended use	Serum
Appearance	Liquid
Color	Cloudy
Fragrance	Characteristic for used raw materials
Packaging	Repackaging containing the name and the number of sample

2.2 Qualitative composition of the product (INCI)

Aqua
Water & Sodium Hyaluronate & Phenoxyethanol
Honey
Propanediol
Xanthan Gum
Phenoxyethanol 0.534% & Ethylhexylglycerin 0.056%
Squalane
Ascorbyl Tetraisopalmitate
Alovera Barbadensis Leaf Juice powder
Simmondsia Chinesis Seed Oil
Rosa Moschata Oil
Butyrospermum parkii (Shea) Oil
Helianthus Annuus Seed Oil & Calendula Officinalis Flower Extract
Tocopherol (mixed), Beta-Sitosterol, Squalene

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Olea Europaea Fruit Oil
Bisabolol
Fragrance(Green)
Linoleic Acid & Oleic Acid & Linoleic Acid & Tocopherol
Retinyl palmitate
Pichia/Resveratrol Ferment Extract
Bee Venom
Linalool
Limonene
Citronellol
Hexyl Cinnamal
Geraniol
Hydroxycitronellal

3. STUDY DESIGN

3.1 AIM OF THE STUDY

The aim of the study is to determine the allergic reactions of the test article using Draize Repeated Insult Patch Test in human volunteers.

3.2 GENERAL PRINCIPLE OF THE STUDY

The investigational product **MANUKA SERUM** has to be applied on the intrascapular region of the back or upper area of the arm, by the trained technician. The sealing patch was kept on for 24 hours in induction phase (a series of nine applications) and in challenge phase with examination of the skin after 1 hour, 24h and 48h after patch removal.

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3.3 SCHEDULE OF THE STUDY

DELIVERY OF PRODUCT	09.06.2021
START OF STUDY	21.06.2021
END OF STUDY	29.07.2021
REPORT DATE	04.08.2021

3.4 TESTING METHODOLOGY

3.4.1 Human repeated insult patch test

The test was conducted on 50 subject, on a mixture of the wipe fabric and the material with which the wipe is impregnated. 15µl of the tested material was applied on the filter paper discs manufactured by SmartPractice® and sticked by surgical patch or using Finn Chamber or any other similar chamber.

Induction Phase: The patch was applied to its designated contact site and remained in place for 24 hours. At the end of this period the patch was removed and the site was examined for any dermal response. The panelists was rested for 24 hours, after which the skin site was examined again. A patch was then applied to the same site as previously used. The second application was identical to the first and remained in place 24 hours. This procedure was repeated on Mondays, Wednesdays and Fridays or Sundays, Tuesdays and Thursdays until a series of nine applications was made. The panelists were examined the site for any dermal response and report their observations prior to the next application. The same site was used throughout the study. Each application was put on and removed by the staff of the Institute. A quality control person was monitored the adherence to study protocol.

Challenge Phase: Following the 9th application, a rest period of 2 weeks elapsed after which a challenge application was applied in the same manner and to the same site described above. The challenge application was removed after 24 hours and the site was examined and graded for signs of irritation or sensitization after 1 hour (after removal of application). A follow-up

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examination was conducted at 48 hours after the challenge application (24 hours after patch removal), as well as at 48 hours after removal.

Grading scale:

0 - No visible reaction.

? - Doubtful reaction: faint, minimal erythema, no infiltration.

1 - Weak positive reaction: erythema, infiltration, discrete papules.

2 - Strong positive reaction: erythema, infiltration, papules, discrete vesicles.

3 -Extra positive reaction: intense erythema, infiltration, coalescing vesicles, bullous reaction.

IR - Irritant reaction: discrete erythema without infiltration/ patchy follicular e rythema/hemorrhagic and follicular pustules.

NT - Not tested.

3.5 SUSPENSION OF THE STUDY

The investigator has to stop the study if it shows a risk for the health or the integrity of the test subjects. The date of the suspension and the reasons has to be carefully documented by the investigator in the case report form (CRF).

The investigating centre has 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.

3.6 ADVERSE EVENTS

According to individual sensitivities, any product can induce a 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.

- **serious adverse event**: any adverse event that causes death, endangers test subject's life, induces an hospitalization or the prolongation of the hospitalization, causes severe and lasting incapacity or handicap or induces congenital anomaly or malformation.

The investigator has to accurately describe the adverse event and has to appreciate its seriousness. According to the corresponding procedure of the investigating centre, he has 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 investigational product has to be assessed according to the scale: very likely, likely, possible, questionable, excluded. In case of adverse effect (with a quite possible relationship with the investigational product), the investigator has to ensure the clinical follow-up of the test subject concerned, as long as necessary.

The serious adverse events had to be notified as soon as possible and within 24 hours at the latest, by the investigating centre to the study monitor, by phone, fax or e-mail.
The investigator had to send an adverse event form to the study monitor.

3.7 RAW DATA RECORDING

All the data gathered during the study was recorded accurately, legibly and indelibly by the investigator and the technician in charge of the study, under his control, in the case report form. This document was initialed by the technician or investigator.
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 (protocol signed by the sponsor, copy of this study report….) were filed and was kept for 10 years, in the filing area of the investigating centre.
At the end of this period the study documentation was destructed (after sponsor's authorization), unless he decides otherwise.

4. DESCRIPTION OF SUBJECTS

GENERAL INCLUSION CRITERIA	Healthy subject.	
	Sign an informed consent to participate in the study, were informed about the purpose of the study, the manner of its conduct and the possible side effects.	
	Skin without irritation and changes requiring pharmacological treatment.	
	Cooperative subject, aware of the necessity and duration of controls.	
SPECIFIC INCLUSION CRITERIA	Amount of subjects:	50 subjects
	Gender:	Woman, men
	Age:	18+ years old
	Skin type:	Normal
	Other:	Phototype: I – IV on Fitzpatrick scale; caucasians
NON INCLUSION CRITERIA	Subjects who use any treatment on the studied zone.	
	Subject exhibiting or having a known history of acute or chronic dermatological, medical and/or physical conditions that could influence the outcome of the test.	
	Pregnant or breastfeeding woman or woman planning a pregnancy during the study.	
	Subject having a known history of allergic reactions to cosmetics, soaps or toiletries.	
	Subject abusing alcohol and/or drugs and/or tobacco.	
	Subject with unstable weight.	
	Subject undergoing treatment with sympathomimetics, antihistamines, non-steroidal anti-inflammatory agents, corticosteroids and/or any other medications that could have interfered with the results of this study, within one week prior to initiation of this test.	
	Subject enrolled in another study during the study period (concerning the studied zone).	
	Subject considered by the investigator to be likely not compliant to the protocol.	
INFORMED CONSENT	After an explanation of the protocol, reasons for the study, possible associated risks and potential benefits of the treatment each subject signed an informed consent form before starting the study.	

The qualified subjects must not use any products on the back of one day before the study and was instructed to continue their usual cosmetic regiment, except no new cosmetic can be introduced during the study period.

Skin reactivity, history of atopy and contraception was documented by the investigator, in the case report form (CRF). No medication likely to interfere with the study was allowed during the study; however, if the health state of the subjects justifies 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.

5. TRIAL SCHEDULE

Induction phase (9 applications)

W1:

Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
Study day	D0	D1	D2	D3	D4	D5	D6
Product application	x		x		x		
Removal / Assessment		x		x		x	

W2:

Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
Study day	D7	D8	D9	D10	D11	D12	D13
Product application	x		x		x		
Removal / Assessment		x		x		x	

W3:

Day of the week	Mo	Tu	We	Th	Fr	Sa	Su	Mo
Study day	D14	D15	D16	D17	D18	D19	D20	D21
Product application	x		x		x			
Removal / Assessment		x		x		x		
Assessment								x

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Rest phase

W4 and W5: No application, nor assessment.

Challenge phase (10th application)

W6 :

Day of the week	Mo	Tu	We	Th	Fr	Sa
Study day	D35	D36	D37	D38	D39	D40
Product application	x					
Removal / Assessment		x				
Assessment			x	x	(x)*	

*If the response of the skin is positive after 48h, the skin is also observed after 72 and 96 hours. If the response of the skin is positive (grade min. 2), a visit to a dermatologist is arranged.

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6. RESULTS
6.1 CHARACTERISTICS OF SUBJECTS

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	JAN.JO	21.06.2021	54	F	II
2	PAL.MA	21.06.2021	35	F	II
3	RAD.MA	21.06.2021	49	F	II
4	GRZ.NA	21.06.2021	31	F	II
5	WAN.IW	21.06.2021	50	F	II
6	WIE.ZO	21.06.2021	65	F	II
7	SZR.MA	21.06.2021	45	F	II
8	SUC.EW	21.06.2021	56	F	II
9	CIE.MA	21.06.2021	60	F	II
10	ZOR.AL	21.06.2021	65	F	II
11	IVA.AN	21.06.2021	38	F	II
12	SEK.EL	21.06.2021	68	F	II
13	UGO.FI	21.06.2021	27	M	II
14	KRU.KA	21.06.2021	30	F	II
15	KAL.GR	21.06.2021	63	F	II
16	DUR.MI	21.06.2021	62	F	II
17	WLO.AG	21.06.2021	34	F	II
18	SOP.DO	21.06.2021	41	F	II
19	CYB.DA	21.06.2021	33	F	II
20	CYB.KR	21.06.2021	31	M	II
21	GUR.ED	21.06.2021	46	F	II
22	MAC.ZY	21.06.2021	60	M	II
23	MAC.JO	21.06.2021	60	F	II
24	WIE.RE	21.06.2021	46	M	II
25	WIE.JU	21.06.2021	49	F	II
26	ROM.FI	21.06.2021	24	M	II
27	DUR.KR	21.06.2021	30	M	II
28	DAS.EW	21.06.2021	68	F	II
29	IWA.AN	21.06.2021	42	F	II
30	LIS.AR	21.06.2021	39	M	II
31	KRU.NA	21.06.2021	42	F	II
32	CZE.MI	21.06.2021	66	F	II
33	POL.EL	21.06.2021	57	F	II
34	NAP.SV	21.06.2021	40	F	II
35	PIO.EL	21.06.2021	50	F	II
36	WLO.TE	21.06.2021	49	F	II
37	RYD.WI	21.06.2021	61	F	II
38	WOL.EW	21.06.2021	48	F	II

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39	MAZ.JO	21.06.2021	61	F	II
40	MAZ.MA	21.06.2021	57	F	II
41	GWI.AN	21.06.2021	65	M	II
42	JAS.KA	21.06.2021	45	F	II
43	SZY.UR	21.06.2021	35	F	II
44	WOL.ZB	21.06.2021	52	M	II
45	WOL.GR	21.06.2021	23	M	II
46	TAR.AG	21.06.2021	56	F	II
47	TRE.MI	21.06.2021	54	F	II
48	SEP.JA	21.06.2021	40	M	II
49	MAZ.AG	21.06.2021	20	F	II
50	KRY.BA	21.06.2021	25	F	II

Min	20	**No. F**	**phototype I**
Max	68	39	0
Average	47	**No. M**	**phototype II**
		11	50
			phototype III
			0
			phototype IV
			0

6.2 TABLE OF SKIN RESPONSE

The table presents the results of 50 volunteers (10 assessment/evaluations)

No. of subject	EVALUATIONS									
	1'st	2'nd	3'rd	4'th	5'th	6'th	7'th	8'th	9'th	10'th
1	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0

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MANUKA SERUM

13	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0

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6.2 TABLE OF SKIN RESPONSE

The table presents the results of 50 volunteers (10'th application)

No. of subject	Evaluation 1 hour after removal of application	Evaluation 24 hour after removal of application	Evaluation 48 hour after removal of application
	27.07.2021	28.07.2021	29.07.2021
1	0	0	0
2	0	0	0
3	0	0	0
4	0	0	0
5	0	0	0
6	0	0	0
7	0	0	0
8	0	0	0
9	0	0	0
10	0	0	0
11	0	0	0
12	0	0	0
13	0	0	0
14	0	0	0
15	0	0	0
16	0	0	0
17	0	0	0
18	0	0	0
19	0	0	0
20	0	0	0
21	0	0	0
22	0	0	0
23	0	0	0
24	0	0	0
25	0	0	0
26	0	0	0
27	0	0	0
28	0	0	0
29	0	0	0
30	0	0	0
31	0	0	0
32	0	0	0

33	0	0	0
34	0	0	0
35	0	0	0
36	0	0	0
37	0	0	0
38	0	0	0
39	0	0	0
40	0	0	0
41	0	0	0
42	0	0	0
43	0	0	0
44	0	0	0
45	0	0	0
46	0	0	0
47	0	0	0
48	0	0	0
49	0	0	0
50	0	0	0

7. SUMMARY OF RESULTS

Human Repeated Insult Patch Test was performed on a group of 50 subject. No subjects discontinued of evaluation. Results during the Induction Phase: no reaction was observed in any of the 50 subject.

8. CONCLUSION

In this HRIPT study, tested material: **MANUKA SERUM** did not induce in the 10'h application (Challenge Phase) a contact dermal irritation and/or sensitization in human subjects.

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SIGNATURES

PROJECT MANAGER	Sign and date:  04.08.2021
QUALITY ASSURANCE AUDITOR	Sign and date:  04.08.2021
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