CANNASEN® CBD
THE MEDICAL BRAND
DENMARK

SUMMARIES

OF

A CLINICAL STUDY

&

A DERMATOLOGICAL TEST

ON

CANNASEN®CBD

ANTI-HAIR LOSS SERUM

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CONTENTS

SUMMARY OF CLINICAL STUDY ON HAIR SERUM

Initial report design

Study objectives

This study intended to check the efficacy of the investigational products SAMPLE A002 (Hair Serum) VS SAMPLE B001 (Placebo) in a panel of healthy human subjects after 141 days of daily use.

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.

Quality control

The study was performed in compliance with the procedures of the investigating center, 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.

Relevance of the study

Based on the existing data, the main aim of the study being a better knowledge of the skin acceptability and efficacy of the investigational products SAMPLE A002 VS SAMPLE B001. These products were used for 141 days. The foreseeable risk incurred by the test subjects were minor. So there was suitability between the aim of the study and its eventual risks and foreseeable troubles related to the experimental conditions of the protocol.

The skin examination was performed by the dermatologist.

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.

Investigational products

Parameter	Description
Products reference	SAMPLE A002 VS B001
Mode of application	On the scalp
Appearance	Transparent emulsion
Packaging	Tube
Direction of use	Apply the serum to a dry and clean scalp, line by line, concentrating on the areas where thinning is most noticeable. Massage gently to aid the serum penetration. Use once a day. One tube per week.

Each subject received one product according to the randomization list. Distribution of the product according to the randomization list presented in the Appendix.

Study description

Aim of the study

The study was performed under COVID-19 (18.12.2019 - 16.06.2020) where the STRESS LEVEL increased from 3.4 (before COVID-19) to 7.1 (during COVID-19) on a scale of 0-10. With stress being one of the main causes of hair loss, this study aimed to evaluate the hair growth efficacy of the products SAMPLE A002 (Hair Serum) VS B001 (Placebo).

Questionnaire "Quality of Life related to the COVID-19 situation" found in Appendix was filled out after 84 days of regular product use instead of 141 days due to COVID-19 lockdown period.

General principle of the study

The investigational products SAMPLE A002 VS B001 was taken by 32 subjects. SAMPLE A002 was taken by 16 subjects (8 women, 8 men), another 16 subjects (8 women, 8 men) was used SAMPLE B001. The test subject was used as own control. The study was carried out as a double-blinded.

Testing methodology

Use test under dermatologist supervision

The use test conducts at home under dermatologist supervision. The study concerns on:

- assess the impact of cosmetic on tolerance at the application site as a result of regular, repetitive application of the products, according to the purpose and use of the specified time (repetitive test);

- the scalp examination by investigator before the products application and after 28, 56, 84 and 141 days of use,
- the analysis of the sensations of discomfort reported directly by the test subjects to the investigator, during the study or in the daily logs.

- research leading to confirm or exclude the effect claimed for the cosmetic.

Tests

- The aim of the test was to define the direct influence of the tested products on hair density.
- The aim of the test was to define the direct influence of the tested product on hair thickness
- The aim of the test was to take pictures of the zone on the scalp to present hair growth and scalp state.

Statistical analysis

The results were statistically analyzed with STATISTICA 13. Paired sample T test or Wilcoxon signed rank test (according to the result of the previously applied normality test) were used to assess differences in comparison to measurement before. Additionally unpaired two-sample T test or Mann-Whitney U test (according to the result of the previously applied normality test and Levene'a test) were used to assess differences between two products. The level of significance was set $p<0,05$.

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.

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.

The investigator has to accurately describe the adverse event and has to appreciate its seriousness. The serious adverse events have to be notified as soon as possible and within 24 hours at the latest, by the investigating center to the study monitor, by phone, fax or e-mail. The investigator has to send an adverse event form to the study monitor.

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.	
	Phototype: I – IV on Fitzpatrick scale.	
	Cooperative subject, aware of the necessity and duration of controls.	
SPECIFIC INCLUSION	Number of subjects:	32 subjects
	Gender:	50% Women, 50% Men

CRITERIA	Age:	25–55 years old
	Hair type:	All
	Other:	• Subjects with score 3, 3V or 4 in Hamilton-Norwood scale (concerns men) • Subjects with score I2, I3 and I4 in Ludwig scale (concerns women)
NON-INCLUSION CRITERIA	Subjects who use any treatment on the studied zone.	
	Pregnant or breastfeeding woman or woman planning a pregnancy during the study.	
	Subject presenting a pathology on the studied zone (ex. severe acne, scars).	
	History of drug or sun hypersensitivity, recurrent dermatological diseases or recent sunburn.	
	Use of topical or systemic treatment during the previous weeks liable to interfere with the assessment of the tolerance of each studied product.	
	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.	
	Subject used any anti-hair loss, growth hair improvement products/supplements within one month prior to the study.	
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.	

Results

In this section, the highlights of the investigational product SAMPLE A002 (Hair Serum) vs SAMPLE B001 (Placebo) will be shown.

Table 1. Regular use of the investigational product SAMPLE A002 (Hair Serum) after 141 days.

AFTER 141 DAYS OF REGULAR USE	SAMPLE A002	SAMPLE B001	
The product increases volume.	73%	60%	positive responses
The product reduces the amount of falling out hair.	93%	80%	positive responses
The product provides an effective, clinically proven solution for treatment of hair loss and baldness.	87%	67%	positive responses
The product provides an effective, clinically proven remedy for male & female pattern baldness.	93%	60%	positive responses
The product thickens and strengths hair.	80%	73%	positive responses
The product gives thicker and healthier hair.	80%	73%	positive responses
The product improves general hair condition.	100%	87%	positive responses
The product makes hair look more beautiful.	93%	80%	positive responses
The product makes hair more shiny.	100%	87%	positive responses
The product softens hair.	80%	73%	positive responses
The product gives vitality.	93%	80%	positive responses

The product makes hair easier to style.	80%	87%	positive responses
The product protects hair from split end.	80%	67%	positive responses
The product is effective.	87%	87%	positive responses
Scalp becomes in a better condition.	93%	87%	positive responses
Scalp is not itching.	100%	87%	positive responses
The product does not cause the dryness on the scalp.	100%	73%	positive responses
The product does not cause the rash on the scalp.	100%	80%	positive responses
The product does not cause the redness on the scalp.	100%	80%	positive responses
The product does not cause the flaking-proner skin on the scalp.	100%	80%	positive responses
The product does not cause the greasy feel on the scalp.	100%	67%	positive responses
The product causes a feeling of coolness on the head.	93%	100%	positive responses
The product does not cause a feeling of burning.	100%	80%	positive responses
The product makes the scalp feel more vitality.	80%	87%	positive responses
The product makes the scalp better condition.	87%	87%	positive responses
The product makes the nails become stronger.	53%	27%	positive responses

Table 2. The mean results of hair density at the site of hair serum application on measurements before application (D0) and after 141 days (D141) of regular use in [average amount of hair/ cm^2].

Subject´s no.	Before (D0)	After 141 days (D141)	Difference (D141-D0)	Δ% (D141)
1.	99,0	123,3	24,3	25
2.	116,3	141,0	24,7	21
6.	133,7	151,0	17,3	13
7.	89,0	100,7	11,7	13
8.	104,3	125,0	20,7	20
10.	109,0	121,7	12,7	12
13.	81,3	90,7	9,3	11
14.	107,3	128,3	21,0	20
15.	87,0	118,3	31,3	36
18.	148,0	162,0	14,0	9
21.	149,3	170,7	21,3	14
25.	93,7	118,3	24,7	26
26.	88,7	116,3	27,7	31
27.	97,3	115,0	17,7	18
31.	104,0	114,7	10,7	10
33.	120,0*	Untraceable*	(-)*	(-)*
Mean	107,2	126,5	19,3	
Min	81,3	90,7	9,3	
Max	149,3	170,7	31,3	

SD	21,3	21,6	6,6
Median	104,0	121,7	20,7
p-value	0,0000		
Test type	T test		
Significance	Yes		
Δ%	18%		
% of subjects with the positive effect	100%		

Legend:

* The result was not included in the calculation on Day 141 (D141)

Table 3. The mean results of hair density on the scalp (600 cm2) before application (D0) and after 141 days (D141) of regular use in [average amount of hair/1 cm2].

Subject's no.	Before (D0) average amount of hair/1 cm2	After 141 days (D141) average amount of hair/1 cm2	Difference (D141-D0) average amount of hair/1 cm2	Difference (D141-D0) average amount of hair on the scalp/600 cm2
1.	99,0	123,3	24,3	14600
2.	116,3	141,0	24,7	14800
6.	133,7	151,0	17,3	10400
7.	89,0	100,7	11,7	7000
8.	104,3	125,0	20,7	12400
10.	109,0	121,7	12,7	7600
13.	81,3	90,7	9,3	5600
14.	107,3	128,3	21,0	12600
15.	87,0	118,3	31,3	18800
18.	148,0	162,0	14,0	8400
21.	149,3	170,7	21,3	12800
25.	93,7	118,3	24,7	14800
26.	88,7	116,3	27,7	16600
27.	97,3	115,0	17,7	10600
31.	104,0	114,7	10,7	6400
33.	120,0*	Untraceable*		
Mean	107,2	126,5	19,3	11560,0
Min	81,3	90,7	9,3	5600,0
Max	149,3	170,7	31,3	18800,0
SD	21,3	21,6	6,6	3984,4
Median	104,0	121,7	20,7	12400,0

Legend:

* The result was not included in the calculation on Day 141 (D141)
Conclusion: The product SAMPLE A002 (Hair Serum):

- improves hair density after 141 days.

Table 4. The mean results of hair thickness at the site of the product application on measurements before application (D0) and after 141 days (D141) of regular use in [mm].

Subject´s no.	Before (D0)	After 141 days (D141)	Difference (D141-D0)	Δ% (D141)
1.	0,075	0,084	0,009	12
2.	0,089	0,099	0,010	12
6.	0,066	0,074	0,008	12
7.	0,082	0,090	0,008	10

8.	0,091	0,096	0,006	6
10.	0,062	0,071	0,009	14
13.	0,083	0,084	0,001	1
14.	0,065	0,070	0,006	9
15.	0,085	0,085	0,000	0
18.	0,070	0,072	0,002	3
21.	0,076	0,081	0,005	7
25.	0,070	0,078	0,008	11
26.	0,095	0,096	0,002	2
27.	0,064	0,071	0,007	12
31.	0,072	0,080	0,008	11
33.	0,082*	Untraceable*	(-)*	(-)*
Mean	0,076	0,082	0,006	
Min	0,062	0,070	0,000	
Max	0,095	0,099	0,010	
SD	0,010	0,010	0,003	
Median	0,075	0,081	0,007	
p-value	0,0000			
Test type	T test			
Significance	Yes			
Δ%	8%			
% of subjects with the positive effect	100%			

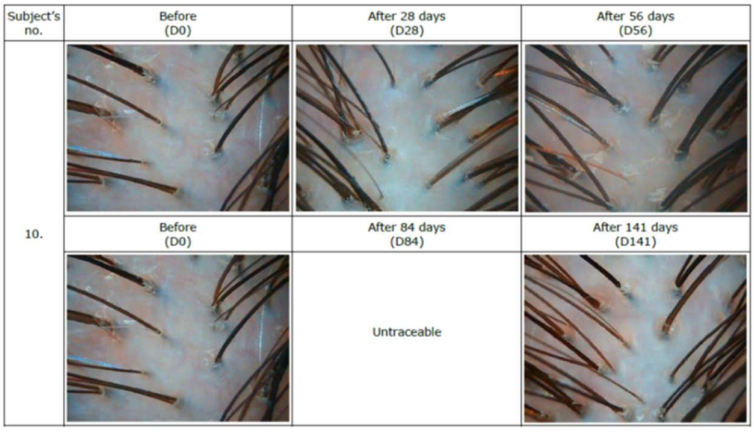
Legend:

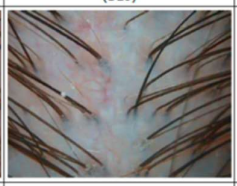
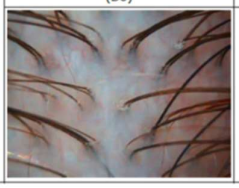
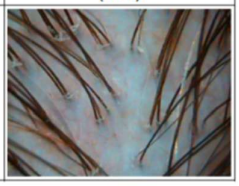
* The result was not included in the calculation on Day 141 (D141)

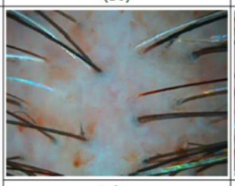
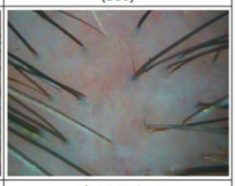
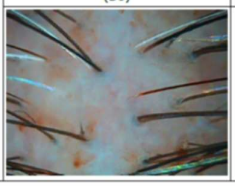
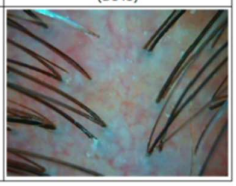
Conclusion: The product SAMPLE A002 (Hair Serum):

- improves hair thickness after 141 days.

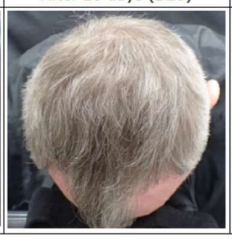
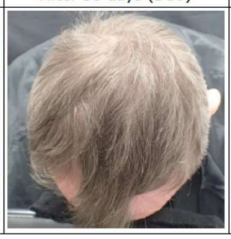
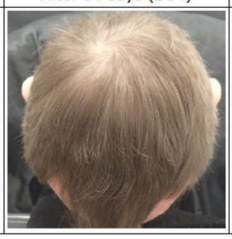
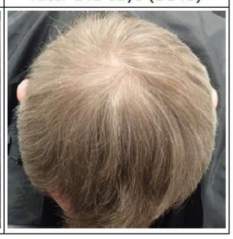
Macrophotography of the surface of the scalp and hair in zoom 60-times using Aramo SG® ASG 200F



Subject's no.	Before (D0)	After 28 days (D28)	After 56 days (D56)
18.			
	Before (D0)	After 84 days (D84)	After 141 days (D141)
		Untraceable	

Subject's no.	Before (D0)	After 28 days (D28)	After 56 days (D56)
31.			
	Before (D0)	After 84 days (D84)	After 141 days (D141)
		Untraceable	

Photography of the scalp

1.				
Before (D0)	After 28 days (D28)	After 56 days (D56)	After 84 days (D84)	After 141 days (D141)
				

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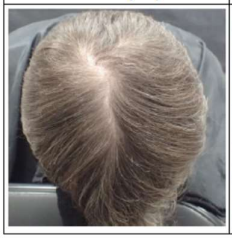
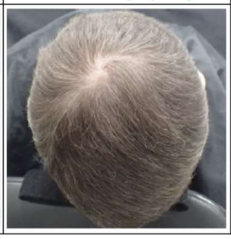
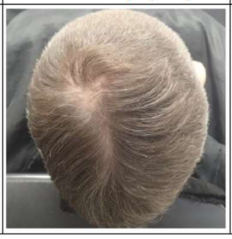
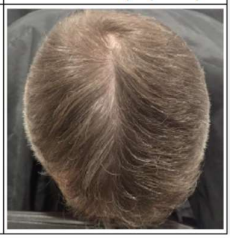
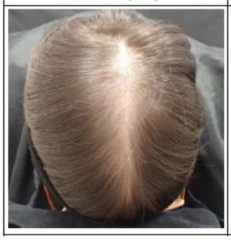
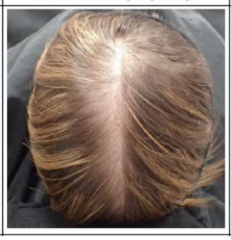
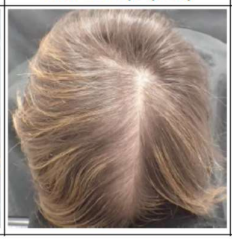
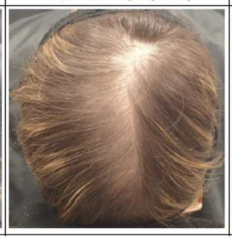
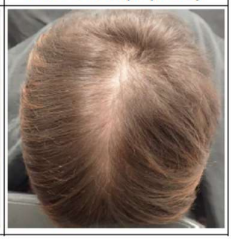
Before (D0)	After 28 days (D28)	After 56 days (D56)	After 84 days (D84)	After 141 days (D141)
			Untraceable	

7.				
Before (D0)	After 28 days (D28)	After 56 days (D56)	After 84 days (D84)	After 141 days (D141)
				

Conclusion

After 141 days of regular application (taking into account period of COVID-19 global situation):

SAMPLE A002 (Hair Serum):

- was tested under dermatologist supervision,
- properties declared by the Sponsor have been confirmed basing on a subjective questionnaire:
  - The product increases volume.
  - The product reduces the amount of falling out hair.
  - The product provides an effective, clinically proven solution for treatment of hair loss and baldness.
  - The product provides an effective, clinically proven remedy for male & female pattern baldness.
  - The product thickens and strengths hair.
  - The product gives thicker and healthier hair.
  - The product improves general hair condition.
  - The product makes hair look more beautiful.
  - The product makes hair more shiny.
  - The product softens hair.
  - The product gives vitality.
  - The product makes hair easier to style.
  - The product protects hair from split end.
  - The product is effective.
  - Scalp become in a better condition.
  - Scalp is not itching.
  - The product does not cause the dryness on the scalp.
  - The product does not cause the rash on the scalp.
  - The product does not cause the redness on the scalp.
  - The product does not cause the flaking-proner skin on the scalp.
  - The product does not cause the greasy feel on the scalp.
  - The product causes a feeling of coolness on the head.
  - The product does not cause a feeling of burning.
  - The product makes the scalp feel more vitality.
  - The product makes the scalp better condition.
  - The product makes the nails become stronger.

Properties declared by the Sponsor have been confirmed basing on instrumental tests:

- statistically significant improvement of hair density (p-value = 0,0000) by 18%, on average,
- the best single, noticeable improvement was the increase of average amount of hair per cm^2 up to 36%,
- increases of hair density on the scalp (600 cm^2) by 11560,0 on average,
- the best single improvement of hair density on the scalp (600 cm^2) by 18800,

- statistically significant improvement of hair thickness (p-value = 0,0000) by 8% on average,
- the best single, noticeable improvement of hair thickness was the increase up to 14%

Appendix

Randomization list

Subject's no.	Product
1.	Product A
2.	Product A
3.	Product B
4.	Product B
5.	Product B
6.	Product A
7.	Product A
8.	Product A
9.	Product B
10.	Product A
11.	Product B
12.	Product B
13.	Product A
14.	Product A
15.	Product A
16.	Product B
17.	Product B
18.	Product A
19.	Product B
20.	Product B
21.	Product A
23.	Product B
24.	Product B
25.	Product A
26.	Product A
27.	Product A
28.	Product B
29	Product B
30.	Product B
31.	Product A
33.	Product A
34.	Product B

Legend:

Product A – Sample A002

Product B – Sample B001

Summary of the questionnaire "Quality of Life related to the COVID-19 situation"

 AFTER 84 DAYS OF REGULAR USE

Quality of Life related to the COVID-19 situation						
		Definitely no	No	Yes	Definitely Yes	
1	Are you worried about your health?	6%	19%	31%	44%	
2	Are you worried about your economical situation?	0%	22%	25%	53%	
3	How worried are you about your family and the closest ones in terms of COVID-19 situation? (Select on a scale from 0 to 10 where 0 means I am not worried, they are safe! 10 – means that I am very worried)	1	2	3	4	5
		0%	0%	3%	3%	16%
		6	7	8	9	10
		19%	16%	19%	0%	25%
		Grade (average)				
		7,2				
4	In a scale from 0 to 10 please assess how worried are you about your health condition during COVID-19 situation (where 0 means I am not worried at all and 10 means I am very worried) ?	1	2	3	4	5
		0%	3%	3%	9%	16%
		6	7	8	9	10
		16%	16%	16%	0%	22%
		Grade (average)				
		6,8				
5	How would you assess your stress point in a scale from 0 to 10 (where 0 means I am not stressed at all and 10 means I am very stressed) ?	1	2	3	4	5
		0%	3%	3%	9%	16%
		6	7	8	9	10
		13%	28%	19%	0%	9%
		Grade (average)				
		6,5				
		Yes	No			
6	Have you experienced any physical stress under COVID-19 in the form: Surgical procedures, high fever, bleeding?	0%	100%			
7	Have your mood change during COVID-19 - like you have experienced any anxiety, depression, sudden shock or accidents?	31%	69%			
8	Have your diet changed during COVID-19 - like: dieting, irregular eating habits, vitamin and mineral deficiency?	3%	97%			
9	Do you often perform hard chemical-physical hair treatments - like frequent dyeing, permanent, excessive use of hair dryer, etc?	6%	94%			
10	Have your sleep pattern changed during COVID-19?	22%	78%			
11	Have your stress level increased due to COVID-19?	59%	41%			
		Before COVID-19 (average)	Now, under COVID-19 (average)			
11a	If yes, please indicate the score between 0-10	3,4	7,1			
		Definitely no	No	Yes	Definitely Yes	Type
12	Did you notice any skin changes in a last 2 months that might be related to the current COVID-19 situation (if yes, what type of the changes) ?	22%	78%	0%	0%	
13	Did you notice any hair changes/ stronger hair loss in a last 2 months that might be related to the current COVID-19 situation (if yes, what type of the changes) ?	22%	75%	3%	0%	Subject [4.] - I noticed a few more hair on the brush.

SUMMARY OF DERMATOLOGICAL TEST ON HAIR SERUM

Study purpose

The purpose of the study was to assess irritating properties (skin tolerance) of the investigational product 20002517 (Hair Serum) on a healthy adult skin, with applied patch test.

Description of volunteers

50 healthy volunteers were included in the study in the period of 09.12.2019 – 20.12.2019. 50 out of 25 volunteers had negative allergy history and other 25 individuals had positive allergy history. The volunteer selection was based on inclusion and exclusion criteria. General inclusion criteria: healthy men and women over 18 years old, phototype: I-IV on Fitzpatrick scale, Caucasians, skin without irritations and changes requiring pharmacological treatment. General exclusion criteria: volunteers who use any treatment on the skin area subject to the study, volunteers exhibiting or having a known history of acute or chronic dermatological, medical and/or physical conditions that could influence the outcome of the study, pregnant or breastfeeding women or women planning a pregnancy during the study. None of the volunteers reported documented oversensitivity or history of adverse reactions to individual ingredients of the product tested. All the volunteers fulfilled the requirements of inclusion for tests and signed the Informed Consent Form (ICF). Additionally, they were informed on the purpose, methodology of the study and possible adverse effects. The skin at the application spot (arms or interscapular area) was healthy, without lesions. The volunteers were advised to exercise caution in handling the applied contact tests.

Testing methodology

The preparation in the appropriate concentration is applied onto filter paper discs of 12 mm diameter and then fixed to the arm or interscapular area with the use of a sticking patch. Simultaneously, to objectify the results of the study and in order to exclude possible reading errors connected with dermal irritations two control samples (control sample called "blind" and control sample with water) are used. The purpose of this study is to exclude possible reading errors connected with dermal irritations. The results of the study are presented in Tables 6 & 8 of this report. The dermatologist removes the patch 48h after the application and examines the skin response 30 minutes after removal. 72h after the application, the dermatologist examines the skin again for a response. If irritations appear or persist 72h after the application, an additional examination takes place after 96 hours. Determining the response of the skin, the dermatologist assesses the irritating and sensitizing effects of the tested product. The study results may be influenced by factors such as lifestyle, stress, diet and environmental conditions, etc.

Evaluation parameters

EVALUATION PARAMETERS OF SKIN REACTION	
Erythema	Classification point
No erythema	0
Light erythema	0.5
Erythema and/or papules	1
Erythema and/or papules and/or vesicles	2
Erythema and/or papules and/or vesicles and/or blisters	3
Erythema Bullous and/or ulcerative reaction and/or papules and/or vesicles and/or blisters	4
Edema	Classification point
No edema	0
Very light edema (hardly visible)	1
Light edema	2
Moderate edema (about 1mm raised skin)	3
Strong edema (extended swelling even beyond the application area)	4

Results

Characteristics of volunteers with a negative history of allergy

Table 5

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype
1	GAS.ZE	10.12.2019	50	F	II
2	WIE.ZO	10.12.2019	64	F	II
3	SIW.JA	10.12.2019	65	F	II
4	DIE.BE	10.12.2019	45	F	II
5	PAS.AU	10.12.2019	67	F	II
6	WAN.IW	10.12.2019	49	F	II
7	NYK.EW	10.12.2019	35	F	II
8	TUR.MA	10.12.2019	61	M	II
9	TUR.MI	10.12.2019	62	F	II
10	MLY.MI	10.12.2019	61	F	II
11	SMI.MA	10.12.2019	29	F	II
12	ANT.ZO	10.12.2019	65	F	II
13	KAC.AN	10.12.2019	44	F	II
14	PIS.KA	10.12.2019	56	F	II
15	KOP.AN	10.12.2019	68	M	II
16	CHR.MA	10.12.2019	68	F	II
17	FLI.AN	10.12.2019	32	F	II

18	BOC.AL	10.12.2019	41	F	II
19	KLE.JO	10.12.2019	61	F	II
20	BIE.AL	10.12.2019	37	F	II
21	SIK.NA	10.12.2019	24	F	II
22	TOK.JO	10.12.2019	45	F	II
23	CZA.HA	10.12.2019	45	F	II
24	ZAW.BE	10.12.2019	44	F	II
25	STA.EM	10.12.2019	37	F	II

Min	24	No. F	phototype I
Max	68	23	0
Average	50	No. M	phototype II
		2	25
			phototype III
			0
			phototype IV
			0

Results for volunteers with a negative history of allergy

Table 6

No.	Evaluation after 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	Examination skipped	
2	0	0	0	0	Examination skipped	
3	0	0	0	0	Examination skipped	
4	0	0	0	0	Examination skipped	
5	0	0	0	0	Examination skipped	
6	0	0	0	0	Examination skipped	
7	0	0	0	0	Examination skipped	
8	0	0	0	0	Examination skipped	
9	0	0	0	0	Examination skipped	
10	0	0	0	0	Examination skipped	
11	0	0	0	0	Examination skipped	
12	0	0	0	0	Examination skipped	
13	0	0	0	0	Examination skipped	
14	0	0	0	0	Examination skipped	
15	0	0	0	0	Examination skipped	
16	0	0	0	0	Examination skipped	
17	0	0	0	0	Examination skipped	
18	0	0	0	0	Examination skipped	
19	0	0	0	0	Examination skipped	
20	0	0	0	0	Examination skipped	
21	0	0	0	0	Examination skipped	
22	0	0	0	0	Examination skipped	
23	0	0	0	0	Examination skipped	
24	0	0	0	0	Examination skipped	
25	0	0	0	0	Examination skipped	

Characteristics of volunteers with a positive history of allergy

Table 7

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype
1	CZA.HA	16.12.2019	64	F	II
2	KAL.GR	16.12.2019	61	F	II
3	CZE.NA	16.12.2019	28	F	II
4	ROZ.AG	16.12.2019	37	F	II
5	TAR.AG	16.12.2019	55	F	II
6	KOR.JO	16.12.2019	43	F	II
7	SIK.GR	16.12.2019	65	F	II
8	ZAW.GR	16.12.2019	20	M	II
9	BER.AN	16.12.2019	49	F	II
10	WAS.EW	16.12.2019	60	F	II
11	MIL.EW	16.12.2019	59	F	II
12	SZY.MA	16.12.2019	48	F	II
13	RAD.MA	16.12.2019	47	F	II
14	BAL.EW	16.12.2019	60	F	II
15	WIE.SL	16.12.2019	51	M	II
16	KAL.EW	16.12.2019	59	F	II
17	GRA.EL	16.12.2019	55	F	II
18	MAS.RE	16.12.2019	37	F	II
19	GRA.AL	16.12.2019	44	F	II
20	OKU.AG	16.12.2019	47	F	II
21	NOW.JA	16.12.2019	69	F	II
22	DUD.IR	16.12.2019	63	F	II
23	HIR.OL	16.12.2019	21	F	II
24	SEK.EL	16.12.2019	66	F	II
25	KRO.AL	16.12.2019	54	F	II

		Min	20	No. F	phototype I
		Max	69	23	0
		Average	50	No. M	phototype II
				2	25
					phototype III
					0
					phototype IV
					0

Results for volunteers with a positive history of allergy

Table 8

No.	Evaluation after 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	Examination skipped	
2	0	0	0	0	Examination skipped	
3	0	0	0	0	Examination skipped	
4	0	0	0	0	Examination skipped	
5	0	0	0	0	Examination skipped	
6	0	0	0	0	Examination skipped	
7	0	0	0	0	Examination skipped	
8	0	0	0	0	Examination skipped	
9	0	0	0	0	Examination skipped	
10	0	0	0	0	Examination skipped	
11	0	0	0	0	Examination skipped	
12	0	0	0	0	Examination skipped	
13	0	0	0	0	Examination skipped	
14	0	0	0	0	Examination skipped	
15	0	0	0	0	Examination skipped	
16	0	0	0	0	Examination skipped	
17	0	0	0	0	Examination skipped	
18	0	0	0	0	Examination skipped	
19	0	0	0	0	Examination skipped	
20	0	0	0	0	Examination skipped	
21	0	0	0	0	Examination skipped	
22	0	0	0	0	Examination skipped	
23	0	0	0	0	Examination skipped	
24	0	0	0	0	Examination skipped	
25	0	0	0	0	Examination skipped	

Conclusion

The patch test study was performed under dermatological control on a group of 50 volunteers, including 25 volunteers positive history of allergy/atopy (sensitive skin). The study allows to conclude that product 20002517 (Serum hair) used by volunteers, that didn't report documented oversensitivity or a history of adverse reactions to individual ingredients of the tested product, 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.