NAOLYS
NATURE EXPANDED

ASSESSMENT ON HUMAN BEINGS OF THE EFFECT ON THE HAIR OF A COSMETIC PRODUCT AND CONFIRMATION OF ITS CUTANEOUS ACCEPTABILITY AFTER APPLICATIONS IN CONDITIONS OF NORMAL USE

Self-assessment of the cosmetic qualities and acceptability
Use test under dermatological control

Product: ETHAIREAL PEPPERMINT BATCH 310.717
(Liquid version at 0.5%)

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1. Objectives of the study

The first objective of the study was to assess the effect on the lipidic index of the product **"EtHAlReal Peppermint"** after 28 days of application to the hair and scalp in conditions of normal use, on at least **20** subjects.

The effect on the lipidic index was assessed by sebum rate measurements with Sebumeter®SM815 performed by the Technician on the scalp at level of the Vertex area on **D0** and **D28**.

The second objective of the study was the self-assessment of the cosmetic qualities and acceptability of the product, performed by these same subjects on **D28**, using a self-assessment questionnaire.

Considering that this study aimed to assess the effect on the cutaneous state and on the lipidic index and to self-assess the cosmetic qualities and acceptability of the investigational product and that the foreseeable risks incurred by the subjects who took part in this study being minute, we can say that the objectives of the study were consciously set taking into account the potential risks taken.

2. Methodology

2.1 Experimental schedule

This study was without any individual direct benefits, each subject was used as her/his own control.
This monocentric study was performed in open.
The study was performed for 28 ± 2 days and was composed of 2 visits at the Investigating Centre (D0 and D28) of 30 minutes each. Each visit included acclimatization's period of 15 minutes.

3. Dates relatives to the study

Date of the D0 inclusion visit:	**the 1st of August 2017**
Dates of the D28 visit:	**the 29th and 30th of August 2017**

4. Investigational product

4.1. Information

In accordance with Good Clinical Practice guidelines and with regulations in force, the Sponsor provided, at the same time as the investigational product, the letter of agreement in which the study Monitor certifies the safety of the product to test on the subject.

4.2. Identification

The samples of investigational product were kept in the Investigating Centre, at room temperature in a place provided for this purpose. The subjects were asked to keep the investigational product, at home, at room temperature.

Name of the investigational product	Number of distributed samples for each subject
EtHAIReal Peppermint	1

4.3. Site and conditions of use during the study

Name of the investigational product	Site and conditions of use during the study		
	Application's area	Application's frequency	Study's duration
EtHAIReal Peppermint	Hair and scalp	3 times a week	28±2
	From D0 until D27	Application 3 times a week after the usual shampoo step during 28 consecutive days in conditions of normal use. Apply the product on wet hair by massaging the scalp, leave on 2 to 3 minutes, then rinse.	

The date of application of the investigational product was noted daily by the subject in the daily log.

As soon as the investigational products were received, the Investigating Centre made sure that the information written on the label complied with those transmitted by the Sponsor. If it had not been the case, the Sponsor would have immediately been informed.

As part of the management of the consumed investigational products, the samples were weighed at the beginning and at the end of the study, away from the subjects' sight. The products were destroyed at the end of the study, except a glass dispenser containing the product to be tested.
This is performed by the laboratory and consists in pipette sampling or taking the required amount of product out of one of the untouched packaging received, with a single-use pipette or spatula and to drop it in a clean but not sterile glass dispenser, in non-controlled atmospheric conditions.
The experimental conditions of use of the investigational product corresponded to the conditions of normal use. The results of the study, obtained on a population sample, are representative of the population on a larger scale.

4.4. Investigational product distribution

Each subject received by the Technician during the inclusion visit on D0, an investigational product identified by its subject number in the study.

Given that subjects receive the investigational product in the morning or afternoon during the inclusion visit of the study (D0), and depending on the category of investigational product, the number of application(s) at D0 may not have corresponded to the study's experimental conditions of use. This was not considered as deviations from the Investigating Centre.

5. Subjects

5.1. Number

Number of included subjects	Number of non-valid cases		Number of valid cases
	Withdrawn from the study / Lost to follow up / Voluntary quit	Non exploitable data	
24	2 - Withdrawn from the study for non-respect of the constraints : subject ref. 12 - Voluntary quit: subject ref. 4	/	22

- Deviations (number of deviating subjects): 2 (the subjects ref. 15 et 18) (These deviations do not compromise the validity of the results of the study) (cf. part 6 "Amendments and deviations to the protocol")

- Panel (n=22):
  - Mean age: 47.2 years old
  - Minimum age: 19 years old
  - Maximum age: 64 years old
  - Female: 9 subjects (40.9%)
  - Male: 13 subjects (59.1%)
  - Sensitive skin on the scalp: 3 subjects (13.6%)
  - Non-sensitive skin on the scalp: 19 subjects (86.4%)
  - Oily hair: 22 subjects (100%)

5.2. Inclusion criteria

The inclusion criteria were the following ones:

- Skin type origin: Caucasian
- Age: from 18 to 65 years old
- Gender: 50% female and 50% male
- Specific criteria: oily hair
- Usual or occasional user of hygiene and/or care products for the hair and scalp
- Able to give him/her informed consent
- Covered by Health Insurance

All the subjects corresponded to these inclusion criteria. The typological characteristics are defined in **Appendices 1.**

5.3. Non-inclusion criteria

The non-inclusion general criteria were the following ones:

- Allergies or reactivity to cosmetic products,
- For the subjects undergoing hormonal treatment, change of treatment within 3 months preceding the inclusion visit,
- Expectation of change in the current hormonal treatment during the study,
- Anti-allergic, antibiotic, anti-inflammatory, dermatological treatment or corticosteroid therapy within 2 weeks before the inclusion visit,
- Having a chronic pathology,
- Performing or prevision to perform another test during the study or during the exclusion period,
- Employee of the laboratory,
- Pregnant or breast-feeding woman (NA for men),
- Woman not taking precaution to prevent pregnancy (NA for men).

The non-inclusion specific criteria were the following ones:

- No application of shampoo the day preceding the inclusion visit,
- Application of shampoo or care products for the oily hair within 2 weeks preceding the inclusion visit,
- Application of styling products to the hair the day of the inclusion visit,
- Expectation of haircut, perm, hair dye (streaks, highlighting or hair colour) or of visit to the hairdresser during the study,
- Contraception use such as Diane 35® or ANDROCUR®,
- Stopping any sebum regulation treatment on the experimental area less than 2 weeks preceding the beginning of the study,
- Stopping any isotretinoin based treatment such as ROACCUTANE® less than 3 months preceding the beginning of the study,
- Stopping any Vitamin A acid based treatment or one of its by-products less than 3 months preceding the beginning of the study,
- Cutaneous marks on the scalp which could interfere with the skin's clinical signs assessment (pigmentation issues, scar tissues, over-developed hairiness, too many ephelides and naevi, sunburns...),
- Expectation of intensive solar exposition (natural sun or UVA) during the study,
- Vitamin A acid treatment or its derivatives within 3 months preceding the inclusion visit,
- Retinoid based oral treatment within 6 months before the inclusion visit, or local treatment within 2 months prior to this visit,
- Carotene based treatment within 2 weeks preceding the inclusion visit,
- Expectation or having undergone aesthetic or dermatological surgery on the scalp.

No subject corresponding to these criteria was included in the study.

5.4. Constraints of the study

The constraints imposed on the subjects from D0 to D27 were the following ones:

- No application of care products to the hair and scalp other than the investigational product,
- Keeping their hygiene habits,
- Neither haircut, perm, hair dye (streaks, highlighting or hair colour) nor visit to the hairdresser,
- No local or oral antibiotic,
- No change of diet,
- Scrupulous respect of the investigational product's conditions of use,
- No intensive solar exposition (natural sun or UVA),
- Neither corticosteroid therapy nor anti-allergic, antibiotic, anti-inflammatory, dermatological treatment or medication containing Vitamin A acid or its derivatives (if treatment is necessary: exclusion considered),
- Neither oral nor local treatment based on retinoid or carotene,
- No change of the current hormonal treatment,
- Description of each therapeutic treatment begun during the study, and of each deviation,
- No further test or clinical study participation,
- Neither aesthetic or dermatological surgery nor injections on the experimental areas.

The constraints imposed on the subjects the day of the visit on D28 were the following ones:

- No application of care and hygiene products to the scalp and hair,
- No application of styling products to the hair and hair,
- Last application of the investigational product the day before the visit.

Some deviations were registered, which do not compromise the validity of the results of the study **(Appendices 2)**.

5.5. Premature stop criteria

The subjects could stop the study for one of the following reasons:

- Voluntary withdrawal: the subjects are free to withdraw from the study at any time and for any reason, without incurring any responsibility or damage. The Investigator or the Responsible Technician under his authority must enquire as to the reasons for the withdrawal from the study and record these on the last page of the Case Report Form entitled "Formulaire de fin d'étude".
- Medical reasons: when a subject informs the Investigator or the Responsible Technician under his authority, in accordance with the protocol, that he/she undergoes a medical treatment likely to interfere with the test results, the Investigator writes these information on the case study report form and if necessary decides in agreement with the Dermatologist to exclude the subject from the study in accordance with the Sponsor. The Dermatologist in agreement with the Investigator is free at any time to exclude the subject from the study for medical reasons. This action will be registered on the last page of the Case Report Form entitled "Formulaire de fin d'étude".
- Adverse event: any unfavourable and unintended sign (according to the type, the frequency and the severity, including an abnormal laboratory finding), symptom, or disease

temporally associated with the use of an investigational product, whether or not related to the investigational product.

- Serious adverse event: an adverse event is considered as serious, if, independently of its relation with the applications of the investigational product, it is part of one of the following categories: death or imminent risk of death, serious or permanent disability, deformity or infirmity (break of one of the essential functions to lead a normal life), hospitalisation of the subject, any congenital anomaly or malignant manifestation, situation able to cause a major risk for the safety of the subject.
- Exclusion criteria: any non-inclusion criteria emerging/becoming apparent during the participation of the subject in the study. In that case, the Investigator or the Responsible Technician under his authority will record this on the last page of the Case Report Form entitled "Formulaire de fin d'étude".

5.6. Gathering of adverse events and serious adverse events

At each visit or if the subject calls, the subject is questioned in order to give impartial answers as to the occurrence of adverse events, serious or not.

Each adverse event, in connection or not with the investigational product, is reported on the form at the end of the CRF of the subject with the date of occurrence, it intensity, the relation with the investigational product and the follow-up. For each adverse event (severe or not), a clinical investigation is performed by the Investigator and the Dermatologist and reported on the form "Enquête clinique suite à la survenue d'un évènement indésirable" with photographs included. Any adverse event which would persist until/after the end of the study is followed by the Investigator and the Dermatologist who keeps contact with the subject until it is resolved.

For each concomitant treatment taken during the study, when judged necessary by the Investigator, the form "Formulaire de fin d'étude" at the end of the CRF of the subject is completed specifying the reason for this treatment.

5.7. Statement of adverse events and serious adverse events

Any adverse event has to be declared to the Sponsor **within 48 hours of the occurrence of the event**. Any serious adverse event has to be declared to the Sponsor **immediately after the occurrence of the event**.

5.8. Subjects lost to follow up

If a subject did not come to a visit, the Investigator or laboratory employees tried several times to call him/her before considering him/her as lost to follow up. These steps were registered in the case study report form.

5.9. Exclusion period

The subjects are excluded from any other clinical study during their participation and for a period of at least 14 days after the end of the study.

6. Regulatory disposals

- *Regulatory procedures*

This study was carried out in accordance with the following regulatory requirements:

- In the spirit of the "International Conference on Harmonization" of Good Clinical Practices (ICH Adopted by CPMP, July 1996, issued as CPMP/ICH/135/95/Step5),
- The law of the 20th of December, 1988, amended by the law n°2004-806 of the 9th of August, 2004,
- The Helsinki declaration (1964) and its successive modifications.

- *Internal Advisory Council*

This clinical study was agreed by an Internal Advisory Committee of the laboratory comprising the Commercial Manager, the Recruitment Manager and the Investigator, in order to check the concordance between the objective of the study, the risks incurred by the subjects and the means used to ensure that the ethic requirements are well respected. This study's validation consists in two steps; firstly the contract's review is validated by the Commercial Manager and the Recruitment Manager; thereafter, the safety notification is validated by the Investigator.

- *Independant Ethics Committee*

The study was not submitted to the Independent Ethics Committee as it is exempted under law N° 2004-806 of 08/09/2004.

- *Subjects' recruitment*

The subjects' recruitment was performed through laboratory's database, declared to the CNIL under number 1015566. The identification of the subjects participating in the study remained confidential thanks to an identification code guise "XXX/YY", with "XXX" for the first three letters of the surname, and "YY" for the first two letters of the forename.

- *Informed consent (LICP = Lettre d'Information et Consentement à la Participation)*

Each subject participating to the test was fully informed about the study before its beginning, in accordance with the HELSINKI declaration (1964) and its successive modifications. The Responsible Technician and the subject **dated and signed** two copies of the LICP the day of the inclusion visit. The Responsible Technician kept a copy of the document in the study file and the second copy was kept by the subject. This document points out to the subject when and how to use the investigational product, as well as the constraints to respect.

- *Amendments and deviations to the protocol*

  - Amendments

There was no dated and signed amendment to the protocol.

  - Deviations

Some deviations were registered, which do not compromise the validity of the results of the study:

- The subject ref 15 did not apply the product on D24 (one application in less during week 4)
- The subject ref 18 applied the product 4 times during week 4
- There were 40.9% of female and 59.1% of male instead of the 50% of female and 50% of male requested by the sponsor.

- *Data management*

Each section of the study documentation was filled with a black pen, legibly and with precision. Any missing data had to be clearly explained. Any correction was dated, motivated and signed by the person who did it. The identity of the persons who took part in the study remains anonymous. Only an alphanumeric code reported at the top of each page appeared on the case study report form. Data input was performed by the laboratory under Microsoft Excel for Windows 7. Data were subject to a quality control carried out by laboratory. Statistical analyses were performed using SPSS software, version 17.0.

- *Monitoring*

In conformity with the Good Clinical Practices, the study could have been monitored by the Sponsor's representatives. The Sponsor would have been able to control the conformity of the data registered in the data collection sheets with those mentioned in the source-documents. The resulting monitoring reports have also been archived with the study documentation. Inspections and audits could also have been performed by the Regulatory Body, by the Quality Assurance Department of the Sponsor, or by an independent Quality Assurance auditor.

- *Insurance*

Laboratory is insured by the CNA Insurance Company Limited, covering the liability insurance of the laboratory as Investigating Centre in application with the article L1121-10 from CSP ("Code de la Santé Publique").

- *Indemnity for the subject*

An indemnity was paid to each subject as compensation for the caused expenses and for the undergone constraints because of their participation in the study. The amount of the indemnity was given in the LICP handed to the subject at the beginning of the study.

- *Quality Assurance*

At each step of the treatment of the raw data, a quality audit was performed to check its accuracy. The Investigating Centre complied with a quality audit program guaranteeing the study's progress and that the report was written accordingly to the study's protocol, to the Investigating Centre's and Sponsor's procedures, and to the Good Clinical Practices (BPC ICH E6).

- *Archives*

An original copy of all the data of the study (signed protocol, safety assessment letter of the Sponsor, case study report form, LICP, extracted raw data, administrative file including all the correspondence) is kept in the records of the laboratory for 10 years.
The archives are destructed after receipt of a written and signed authorization provided by the Sponsor upon request to the Investigating Centre.

- *Contractual obligations*

A Financial Appendix to the Contract was established and signed by the Sponsor and the Investigating Centre before the beginning of each study. This document contains practical details of the financial agreement and schedule of the study. This amount covers the expenses for the study's execution, as well as the indemnities paid by the Investigating Centre to the subjects participating to the study in accordance with the article L1121-11 from CSP. The payment is done by the Sponsor upon presentation of bills.

7. Assessment

7.1. Schedule

Schedule of the study	D0	D28
Weighing of the product	X (before the subject's arrival)	X (after the subject's departure)
Informed consent (LICP)	X	
Inclusion	X	
Dermatological examination by the Responsible Technician	X	X
Sebumetric measurements by the Responsible Technician	X	X
Self-scoring	X	X
Delivery of the product and daily log	X	
Application of the product	← By the subject at home, from D0 to D27 →	
Recovery of the product and daily log		X
Observance		X
Self-assessment questionnaire		X

7.2. Environmental conditions

The environmental conditions imposed on the subjects were the following ones:

- *controlled temperature*: $t° = 21°C \pm 1°C$
- *controlled relative humidity*: $HR = 45\% \pm 5\%$

The temperature and humidity were recorded during the study visits, for each waiting room and test room. Those data are available at the Sponsor's request.

7.3. Assessment of the effect on the lipidic index by casual level measurements (Sebumeter®)

- Principle and device

The Sebumeter® SM 815 device is composed of a photometric sensor and a mirror situated on the inside of the central unit of the apparatus (Combiné®). The measurement scoring scale is spaced out from 0 to 350, it corresponds to the quantity of sebum sampled on the film and expressed in µg/cm².

The sebum capture film is semi-see-through, and the accumulation of sebum modifies its transparency. The Sebumeter® SM 815 records the film transparency before the measure taking and also after 30 seconds of application. The difference of transparency allows deducting the quantity of sebum present on the film and in consequence the quantity of sebum present on the skin.

- Evaluation criteria

The casual level (lipidic index) are collected and expressed in µg/cm² ranging from 0 to 350.

- Measurements

– Site

The instrumental measurements were performed by the Responsible Technician on the scalp at level of the vertex area.

– Frequency

The measurements were performed before by the Responsible Technician on D0 and after 28 days of application of the investigational product on D28.

- Results

The results are expressed:

- In mean values, standard deviations, min, max and medians for each experimental time (D0 and D28).
- In percentages of variation of the means at D28 compared to D0 [% var. mean = ((mean$_{D28}$-mean$_{D0}$)/mean$_{D0}$) x 100].
- In mean values, standard deviations, min, max and medians for the difference (D28-D0).

- Statistical protocol

The interpretation of the results was performed by comparing the values obtained on D28 to those obtained on D0. This was performed by a Student test for paired series (threshold of risk of 5%) if the result of the normality test of Shapiro-Wilk was superior to 1%, or by a Wilcoxon test (threshold of risk of 5%) if the result of the normality test of Shapiro-Wilk was inferior to 1%.

7.4. Assessment of the effect on the cutaneous state by self-scoring

- Principle

The self-scoring consists in a visual assessment of the cutaneous state before then after application of the investigational product to the experimental areas, in order to determine its cosmetic efficacy. For this purpose, the subject sits in front of the table Evalux bench® (Orion concept) with a long-life and calibrated lighting (leds - 6000°K).

- Assessment criteria

The self-scoring was performed using a scale scored in 10 points (from 0 to 9) according to the following items defined by the Sponsor:

Oily aspect of the hair and scalp
(0= Not oily, 9= Very oily)
Discomfort sensations on the scalp
(0= no sensations discomfort, 9= a lot of discomfort sensabons)
Dull aspect of the hair
(0= Not dull, 9= Very dull)

0	1	2	3	4	5	6	7	8	9

- Self-scoring

- Site

The self-scoring was performed by the subjects on the hair and scalp.

- Frequency

The self-scoring was performed on D0 and D28.

- Results

The results are expressed for each item:

- In mean value, standard deviation, min, max and median for each experimental time (D0 and D28),
- in percentage of variation of the means on D28 compared to D0 [% var. means = ((mean$_{D28}$-mean$_{D0}$)/mean$_{D0}$) x 100],
- In mean value, standard deviation, min, max and median for the difference (D28 -D0).

- Statistical protocol

The interpretation of the results was performed for each item by comparing the values obtained on D28 to those obtained on D0. This was performed by a Student test for paired series (threshold of risk of 5%) if the result of the normality tests of Shapiro-Wilk was superior to 1% or by a Wilcoxon test (threshold of risk of 5%) if the result of the normality test of Shapiro-Wilk was inferior to 1%.

7.5. Self-assessment of the cosmetic qualities and acceptability

The subjects answered a self-assessment questionnaire about the investigational product after 28 days (D28) of application in conditions of normal use.

The answering modalities were the following: "agree", "somewhat agree", "somewhat disagree", "disagree" / "yes", "no".

For each item, the percentage of satisfaction (= percentage of "agree" + percentage of "somewhat agree", or percentage of "yes") was calculated.

List of the items:

N°	Items	D28
1	The colour of the product is pleasant	+
2	The aspect of the product is pleasant	+
3	The scent of the product is pleasant	+
4	The texture of the product is pleasant	+
5	The product is easy to apply	+
6	The application is homogeneous/uniform	+
7	The product is gentle for the hair	+
8	The product is comfortable	+
9	The product does not leave the hair sticky	+
10	The product does not leave the hair oily	+
11	The product is suitable for me	+
12	The product is suitable for my hair type	+
13	Globally, the product is pleasant	+
14	Would you like to continue using the product? (Yes/No)	+
15	At the end of the product, would you have purchase the product (regardless of its price)? (Yes/No)	+

8. Results and discussions

8.1. Assessment of the effect on the lipidic index by casual level measurements (Sebumeter®)

The individual and mean data are presented in **Appendix 3**.

- Mean data and statistical analyses

Parameter	Mean data			Student test		% of variation
	Time	Mean	S.D.	p	Significance	
Sebum rate	D0	74.2	70.9	0.013	S↓	-44.03%
	D28	41.5	52.3			

Legend:
↓: statistically significant decrease of the parameter
S: comparison statistically significant with p<0.05

The results of these analyses show a statistically significant decrease of the parameter "Sebum rate" on D28 compared to D0.

- Interpretation

We can conclude to an effect on the lipidic index by casual level measurements (Sebumeter®) after 28 days of application in conditions of normal use.

8.2. Assessment of the effect on the cutaneous state by self-scoring

The individual and mean data are presented in **Appendix 4**.

- Mean data and statistical analyses

Items	Mean data			Student tests		% of variation
	Time	Mean	S.D.	p	Significance	
Oily aspect of the hair and scalp	D0	5.8	1.5	<0.001	S↓	-59.38%
	D28	2.4	2.1			
Discomfort sensations on the scalp	D0	2.9	2.3	0.002	S↓	-71.88%
	D28	0.8	1.6			
Dull aspect of the hair	D0	5.3	2.5	<0.001	S↓	-62.07%
	D28	2.0	1.9			

Legend:
↓: statistically significant decrease of the scores
S: comparison statistically significant with p<0.05

The results of these analyses show a statistically significant decrease of all the items on D28 compared to D0.

- Interpretation

We can conclude to an improvement of the cutaneous state on scalp and hair by self-scoring according to the items "Oily aspect of the hair and scalp", "Discomfort sensations on the scalp" and "Dull aspect of the hair" after 28 days of application in conditions of normal use.

8.3. Self-assessment of the cosmetic qualities and acceptability

The percentages of satisfaction calculated for each item are presented in the table below (**Appendix 5**):

N°	Items	Percentages of satisfaction
		D28
1	The colour of the product is pleasant	100%
2	The aspect of the product is pleasant	100%
3	The scent of the product is pleasant	95%
4	The texture of the product is pleasant	100%
5	The product is easy to apply	95%
6	The application is homogeneous/uniform	100%
7	The product is gentle for the hair	95%
8	The product is comfortable	95%
9	The product does not leave the hair sticky	95%
10	The product does not leave the hair oily	95%
11	The product is suitable for me	91%
12	The product is suitable for my hair type	91%
13	Globally, the product is pleasant	91%
14	Would you like to continue using the product? (Yes/No)	82%
15	At the end of the product, would you have purchase the product (regardless of its price)? (Yes/No)	82%

9. Conclusion

According to the experimental conditions adopted, the investigational product "EtHAlReal Peppermint" applied 3 times a week for 4 consecutive weeks to the hair and scalp, on 13 male and 9 female subjects presenting with oily hair, led to:

- Assessment of the effect on the lipidic index by casual level measurements (Sebumeter®)

An effect on the lipidic index by casual level measurements (Sebumeter®) after 28 days of application in conditions of normal use.

- Self-assessment of the cosmetic qualities and acceptability

Cosmeticity

All the subjects declared that the color, the aspect and the texture of the product were pleasant and that the application was homogeneous/uniform.
95% of the subjects declared that the scent of the product was pleasant and that the product was easy to apply.

Acceptability

95% of the subjects declared that the product was gentle for the hair, was comfortable, did not leave the hair sticky and oily.
91% of the subjects declared that the product was suitable for them and for their hair type.

Appreciation

91% of the subjects declared that globally the product was pleasant.
82% of the subjects declared that they would like to continue using the product and that they would have purchase it at the end (regardless of its price).

APPENDICES

1.1 Individual Data

Subjects		Age (years)	Gender	Scalp type	Hair type
Ref.	Initials				
1	SID/MA	64	F	Non sensitive	Oily
2	DUL/SE	43	M	Non sensitive	Oily
3	LOI/JE	61	M	Non sensitive	Oily
4	HOX/EN**	44	F	Non sensitive	Oily
5	DAN/PA	53	M	Non sensitive	Oily
6	LAU/JU	19	F	Non sensitive	Oily
7	MON/ST	53	M	Non sensitive	Oily
8	BEG/TH	47	M	Non sensitive	Oily
9	DAL/JE	42	M	Non sensitive	Oily
10	CHO/GI	61	M	Non sensitive	Oily
11	MAN/CL	31	M	Non sensitive	Oily
12	BAU/MA***	39	F	Non sensitive	Oily
13	VIA/FL	33	F	Non sensitive	Oily
14	COP/SY	41	M	Sensitive	Oily
15	CHA/FR	41	M	Non sensitive	Oily
16	BEA/CY	35	F	Sensitive	Oily
17	BOU/NA	51	F	Non sensitive	Oily
18	SEG/FL	52	F	Non sensitive	Oily
19	LEG/RI	45	M	Non sensitive	Oily
20	GAR/JE	63	M	Non sensitive	Oily
21	CAP/PH	55	M	Sensitive	Oily
22	BAR/MA	59	F	Non sensitive	Oily
23	CAL/MA	59	F	Non sensitive	Oily
24	MER/CL	30	F	Non sensitive	Oily

Legend: Gender: F = female / M = male

***phototype according to Fitzpatrick:** *cf. Appendix 1-2*

** *Subject voluntary quit*

*** *withdrawn from the study*

1.2 Phototype according to Fitzpatrick

Phototype according to Fitzpatrick, established on the principle of a first 30 to 40 minutes sun exposure after winter or a period without sun exposure of an equivalent duration:

TYPE	HAIR	SKIN	LENTIGOS	SUN BURNS
I	redhead	milky	+++	burns easily never tans
II	fair-haired	fair-complexioned	++	burns moderately tans gradually
III	fair-haired brown	fair-complexioned	+	burns slightly tans easily
IV	brown	dark-complexioned	0	burns rarely tans intensely
V	black and frizzy	black	0	o

2.1 Respect of the experimental conditions of use

Experimental conditions of use	22	valid cases	Subjects who respected the experimental conditions of use	
			Number	Percentage
Application area:	**hair and scalp**		22	100.00%
Deviation: none				
Frequency of application at home	**3 times a week**		20	90.91%
Deviations:				
The subject ref 15 did not apply the product on D24 (one application in less during week 4) The subject ref 18 applied the product 4 times during week 4				
Duration of application at home	**28 ± 2 consecutive days**		22	100.00%
Deviation: none				
Last application of the investigational product the day before the visit			22	100.00%
Deviation: none				

2.2 Respect of the constraints of the study

Constraints of the study	22	valid cases	Subjects who respected the constraints of the study	
			Number	Percentage
Imposed on the subjects from D0 to D27				
No application of care products to the hair and scalp other than the investigational product			22	100%
Deviation: none				
Keeping their hygiene habits			22	100%
Deviation: none				
Neither haircut, perm, hair dye (streaks, highlighting or hair colour) nor visit to the hairdresser			22	100%
Deviation: none				
No local or oral antibiotic			22	100%
Deviation: none				
No change of diet			22	100%
Deviation: none				
No intensive solar exposition (natural sun or UVA)			22	100%
Deviation: none				
Neither corticosteroid therapy nor anti-allergic, antibiotic, anti-inflammatory, dermatological treatment or medication containing Vitamin A acid or its derivatives (if treatment is necessary: exclusion considered)			22	100%
Deviation: none				
Neither oral nor local treatment based on retinoid or carotene			22	100%
Deviation: none				
No change of the current hormonal treatment			22	100%
Deviation: none				
Description of each therapeutic treatment begun during the study, and of each deviation			22	100%
Deviation: none				
No further test or clinical study participation			22	100%
Deviation: none				
Neither aesthetic or dermatological surgery nor injections on the experimental areas			22	100%
Deviation: none				
Imposed on the subjects the day of the visit on D28				
No application of care and hygiene products to the scalp and hair			22	100%
Deviation: none				
No application of styling products to the hair and hair			22	100%
Deviation: none				

Treated area

Subjects	Sebum rate (µg.cm-²)		
	D0	D28	D28-D0
1	68	13	-55
2	66	14	-52
3	4	2	-2
5	14	30	16
6	45	10	-35
7	2	14	12
8	265	240	-25
9	107	33	-74
10	45	79	34
11	171	65	-106
13	98	3	-95
14	30	92	62
15	94	37	-57
16	100	5	-95
17	20	8	-12
18	13	55	42
19	38	32	-6
20	67	74	7
21	183	65	-118
22	15	2	-13
23	6	10	4
24	182	31	-151
Mean	**74.2**	**41.5**	**-32.7**
S.D.	**70.9**	**52.3**	**56.2**
Min	**2**	**2**	**-151**
Max	**265**	**240**	**62**
Median	**56**	**31**	**-19**
% var. means = (meanD28-meanD0) / meanD0 x 100	**/**	**-44.03%**	**/**

4.1 Treated Area

Subjects	Oily aspect of the hair and scalp		
	D0	D28	D28-D0
1	6	0	-6
2	6	1	-5
3	5	1	-4
5	7	6	-1
6	7	4	-3
7	4	3	-1
8	7	5	-2
9	7	5	-2
10	5	2	-3
11	7	3	-4
13	6	1	-5
14	6	2	-4
15	8	3	-5
16	8	0	-8
17	3	3	0
18	7	1	-6
19	4	0	-4
20	6	0	-6
21	7	7	0
22	5	4	-1
23	3	0	-3
24	4	1	-3
Mean	5.8	2.4	-3.5
S.D.	1.6	2.1	2.1
Min	3	0	-8
Max	8	7	0
Median	6	2	-3
% var. means = (meanD28-meanD0) / meanD0 x 100	/	-59.38%	/

4.2 Treated area

Subjects	Discomfort sensations on the scalp		
	D0	D28	D28-D0
1	3	0	-3
2	3	0	-3
3	1	0	-1
5	1	0	-1
6	0	0	0
7	3	2	-1
8	5	0	-5
9	2	0	-2
10	2	0	-2
11	1	0	-1
13	5	0	-5
14	1	2	1
15	5	1	-4
16	6	0	-6
17	2	5	3
18	5	0	-5
19	0	1	1
20	5	1	-4
21	6	6	0
22	8	0	-8
23	0	0	0
24	0	0	0
Mean	2.9	0.8	-2.1
S.D.	2.3	1.6	2.6
Min	0	0	-8
Max	8	6	3
Median	3	0	-1
% var. means = (meanD28-meanD0) / meanD0 x 100	/	-71.88%	/

4.3 Treated area

Subjects	Dull aspect of the hair		
	D0	D28	D28-D0
1	7	1	-6
2	5	2	-3
3	5	1	-4
5	2	2	0
6	3	3	0
7	2	1	-1
8	7	0	-7
9	6	2	-4
10	4	0	-4
11	6	2	-4
13	7	6	-1
14	8	6	-2
15	7	1	-6
16	8	3	-5
17	4	5	1
18	8	0	-8
19	5	1	-4
20	6	0	-6
21	7	5	-2
22	9	2	-7
23	0	1	1
24	0	0	0
Mean	5.3	2.0	-3.3
S.D.	2.5	1.9	2.7
Min	0	0	-8
Max	9	6	1
Median	6	2	-4
% var. means = (meanD28-meanD0) / meanD0 x 100	/	-62.07%	/

5.1 D28 Repartition of the answers in scores

N°	Items	Ordinal scale in 4 points				Number of satisfied subjects
		Agree	Somewhat agree	Somewhat disagree	Disagree	
1	The colour of the product is pleasant	16	6	0	0	22
2	The aspect of the product is pleasant	13	9	0	0	22
3	The scent of the product is pleasant	15	6	0	1	21
4	The texture of the product is pleasant	18	4	0	0	22
5	The product is easy to apply	16	5	1	0	21
6	The application is homogeneous/uniform	18	4	0	0	22
7	The product is gentle for the hair	14	7	1	0	21
8	The product is comfortable	13	8	0	1	21
9	The product does not leave the hair sticky	19	2	1	0	21
10	The product does not leave the hair oily	18	3	1	0	21
11	The product is suitable for me	14	6	1	1	20
12	The product is suitable for my hair type	13	7	1	1	20
13	Globally, the product is pleasant	17	3	2	0	20

N°	Items	yes / no		Number of satisfied subjects
		YES	NO	
14	Would you like to continue using the product? (Yes/No)	18	4	18
15	At the end of the product, would you have purchase the product? (regardless of its price) (Yes/No)	18	4	18

5.2 D28 Repartition of the answers in percentages

N°	Items	Ordinal scale in 4 points				Peroentages of satisfaction
		Agree	Somewhat agree	Somewhat disagree	Disagree	
1	The colour of the product is pleasant	72.73%	27.27%	0%	0%	100%
2	The aspect of the product is pleasant	59.09%	40.91%	0%	0%	100%
3	The scent of the product is pleasant	68.18%	27.27%	0%	4.55%	95%
4	The texture of the product is pleasant	81.82%	18.18%	0%	0%	100%
5	The product is easy to apply	72.73%	22.73%	4.55%	0%	95%
6	The application is homogeneous/uniform	81.82%	18.18%	0%	0%	100%
7	The product is gentle for the hair	63.64%	31.82%	4.55%	0%	95%
8	The product is comfortable	59.09%	36.36%	0%	4.55%	95%
9	The product does not leave the hair sticky	86.36%	9.09%	4.55%	0%	95%
10	The product does not leave the hair oily	81.82%	13.64%	4.55%	0%	95%
11	The product is suitable for me	63.64%	27.27%	4.55%	4.55%	91%
12	The product is suitable for my hair type	59.09%	31.82%	4.55%	4.55%	91%
13	Globally, the product is pleasant	77.27%	13.64%	9.09%	0%	91%

N°	Items	yes / no		Percentage of satisfaction
		YES	NO	
14	Would you like to continue using the product? (Yes/No)	81.82%	18.18%	82%
15	At the end of the product, would you have purchase the product? (regardless of its price) (Yes/No)	81.82%	18.18%	82%

In order to guarantee a total of 100%, the values in the tables are expressed to the hundredth. The percentages of satisfaction values are rounded to the nearest inferior value if < 0.50 and to the nearest superior value if ≥ 0.50.