Pilot study. Assessment of the efficacy of a cosmetic ingredient claimed to reinforce hair structure and to reduce hair loss

KERAT'INNOV

CYNATINE® TOP

(ref. no. 32019891 - MA190001E/C15)

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STUDY DESIGN

1.1. Title

Pilot study. Assessment of the efficacy of a cosmetic ingredient claimed to reinforce hair structure and to reduce hair loss.

1.2. Aim of the study

The study is aimed to assess the efficacy of a cosmetic ingredient claimed to reinforce hair structure and to reduce hair loss. In order to reach this goal a clinical study is carried out on 45 healthy male and female subjects with ongoing acute telogen effluvium. The ingredient is tested both in a rinse off (shampoo) and in a leave on formulation. Product efficacy is assessed both subjectively and objectively. The clinical/instrumental assessments are integrated by the self-assessment of the subjects participating in the study.

1.3. Tested products

1.3.1. Information provided by the Customer

☒ Products identification: **CYNATINE® TOP**

☒ Way of use: 1) Shampoo: apply the right quantity of shampoo on wet hair. Massage the product until a dense foam appears. Leave on rest for some minutes. Rinse the hair. Style your hair as usual. 2) Lotion: Apply the lotion on the scalp and the hair. The frequency of use for both products is at least 3 times per week.

☒ The tested cosmetic products conform to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) and to its annexes.

☒ The cosmetic product to be tested is safe under normal or reasonably foreseeable conditions of use.

☒ Qualitative EU INCI formula. The ingredient was formulated at 0.5% concentration in both a rinse off and a leave on formulation. The ingredient INCI name is "*Hydrolyzed Keratin Peptide Powder*". The placebo formulations are the same of the active formulation except for the active ingredient. Here below are reported the INCI formula of both products.

- **Shampoo Active**. AQUA, COCAMIDOPROPYL BETAINE, SODIUM LAUROYL SARCOSINATE, DECYL GLUCOSIDE, SODIUM COCOYL GLUTAMATE, GLYCERIN, HYDROLYZED KERATIN PEPTIDE POWDER , GLYCOL DISTEARATE, STEARETH-4, FRAGRANCE, PROPYLENE GLYCOL, PHENOXYETHANOL, DECYLENE GLYCOL, CITRIC ACID.
- **Lotion**. AQUA, CETRIMONIUM CHLORIDE, MYRISTYL ALCOHOL, HYDROLYZED KERATIN PEPTIDE POWDER, FRAGRANCE, PANTHENOL, PROPYLENE GLYCOL, PHENOXYETHANOL, DECYLENE GLYCOL.

1.4. Ethical requirements

The study is carried out according the ethical requirements listed here below.

1.4.1. All participants in the study are healthy volunteers, aged over 18 years old.

1.4.2. All participants in the study are screened and enrolled under the supervision of an experimenter, according to specific inclusion/non-inclusion criteria.

1.4.3. Volunteers participation in the study is free.

1.4.4. All participants in the study are informed of the aim and the nature of the study.

1.4.5. All participants in the study are informed of the possible risks involved in the study.

1.4.6. All participants in the study sign a written consent form before the study begins.

1.4.7. Before volunteers are exposed to the tested product, all safety information regarding the product and its individual ingredients are assessed.

1.4.7. All the study procedures are carried out in compliance with the ethical principles for medical research (Ethical Principles for Medical Research Involving Human Subjects, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and its amendment).

1.4.9 All the precautions are taken in order to avoid adverse reactions occurrence.

1.4.10 In case of non-expected/adverse reaction occurrence the medical investigating specialist evaluate the severity of the reaction (reporting it in the data collecting sheet of the volunteer) and as a consequence start the appropriate therapy.

1.5. Subjects participating in the study

1.5.1. Subjects enrolment

The subjects participating in the study are screened and enrolled in the study under the supervision of a board certified dermatologist from a panel of healthy female subjects, in accordance with the inclusion and non-inclusion criteria reported in the sections here below.

1.5.1.1. Inclusion criteria

☑ Healthy male and female subjects

☑ Caucasian ethnicity

☑ Age between 18 and 60 years old

☑ Acute telogen effluvium

☑ Mild to moderately damaged hair

- ☑ Subjects who have not been recently involved in any other similar study
- ☑ Willingness to not use during all the study period topic products/dietary supplements with similar effect to that one of the product to be tested
- ☑ Willingness to not vary the normal daily routine
- ☑ Subject is under effective contraception (oral/not oral) therapy

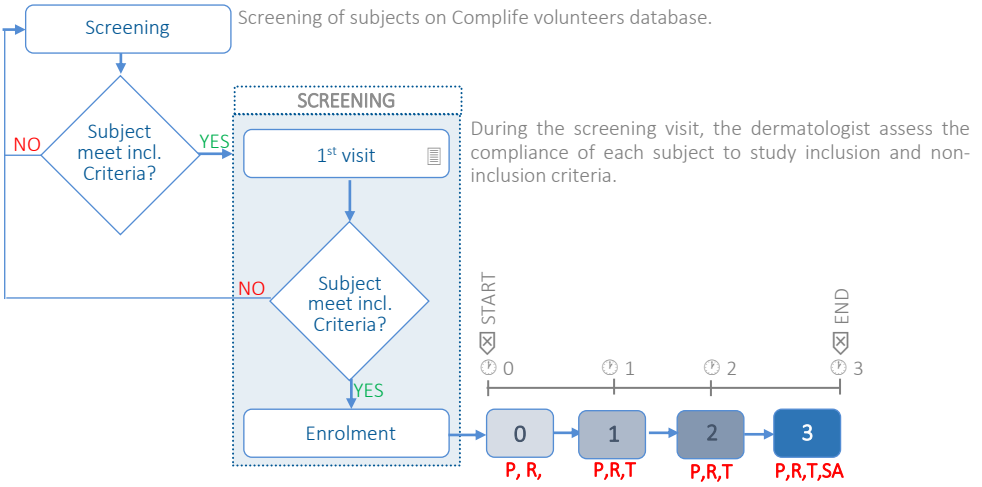
1.5.1.2. Non-inclusion criteria

- ✘ Subject does not meet the inclusion criteria
- ✘ Positive history for atopy or hypersensitive skin
- ✘ Past history of allergy or sensitivity to cosmetics, toiletries, to solar and/or topical medications
- ✘ Any skin condition that the principal investigator deems inappropriate for participation
- ✘ Pregnancy or nursing women
- ✘ Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications
- ✘ Pharmacological treatments (topic or systemic) known to interfere with skin metabolism/physiology
- ✘ Severe concurrent diseases
- ✘ Adult protected by the law (under guardianship, or hospitalized in a public or private institution, for a reason other than the research, or incarcerated)
- ✘ Subject is unable to communicate or cooperate with the Investigator due to language problems, poor mental development, or impaired cerebral function

1.6. Study development

The study flow and the schedule of assessments chart is reported in figure 1.6.1.

Figure 1.6.1 Study flow and schedule of assessments chart



Legend

P Pull test **R** Hair radiance **T** Tolerability **SA** Self-assessment questionnaire

1.7. MATERIALS AND METHODS

In the sections here below are reported the materials and the methods employed in the study.

1.7.1. Pull test

Gentle traction is exerted on a cluster of hairs (approximately 60 hairs) on three different areas of the scalp (frontal, temporal and occipital), and the number of extracted hairs is counted. Normally, less than three telogen-phase hairs should come out with each pull. If at least three hairs are obtained with each pull or if more than ten hairs total are obtained, the pull test is considered positive and suggestive of telogen effluvium.

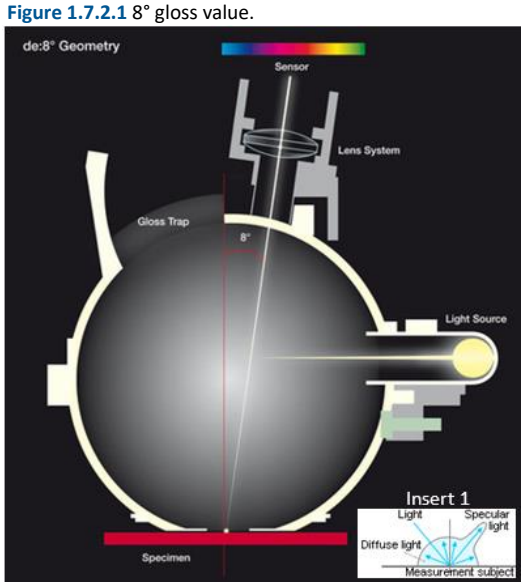
1.7.2. Hair radiance

Hair radiance is measured using a spectrophotometer/colorimeter CM 700D (Konica Minolta). The measured parameter is the 8° gloss value (Fig. 1.7.2.1).

1.7.3. Self-assessment

At the end of the test subjects are asked to give their opinion on the tested product by means of a self-assessment questionnaire.

Figure 1.7.2.1 8° gloss value.



When light reach a surface it is reflected at the equal but opposite angle from the light source; this is called specularly reflected light. This specular component is reflected as if reflected by a mirror. The light that is not specularly reflected, but scattered in many directions, is called diffuse reflectance (insert 1). The sum of the specular reflectance plus the diffuse reflectance is called the total reflectance. For objects with shiny surfaces, the specularly reflected light is relatively strong and the diffused light is weaker. On rough surfaces with a low gloss, the specular component is weak and the diffused light is stronger.
The measuring geometry d:8° features an optical device which provides diffuse illumination (Ulbricht sphere). The light (Xenon lamp) is projected into a sphere. The interior of the sphere is coated with a white highly reflecting substance (barium sulphate, ceramic, special plastic) which reflects the light manifold. A shutter, an optical element inside the sphere, prevents the directional rays from reaching the measuring sample directly. The sample is positioned at an opening of the sphere and is illuminated from all directions with a close to perfect diffuse light. Through an opening at the top of the sphere the sensor is viewing the surface being measured with an angle of 8° to the vertical. In order to prevent reflection of specular light from the sample surface, the instrument feature a gloss trap. When the trap which is arranged with an angle of -8° to the viewing opening, is open, the light which would otherwise be reflected from the interior wall of the sphere, will be eliminated and can therefore not illuminate the sample. The relation between directional and diffuse reflection allows calculating the gloss component. The measuring system including gloss is named di:8° whilst the measuring system excluding gloss is described as de:8°.

1.8. Results and statistic

1.8.1. Results

Results are reported in tables in their respective units.

1) Mean values are calculated as:

$$m = \frac{\sum_{1}^{n} p}{n}$$

where: p is the value of the parameter under analysis; n is the number of subjects participating in the study

2) Percentages are calculates as follows:

$$\%var.vs.T0 = \left(\sum_{1}^{n} \frac{p_t - p_0}{p_0}\right) x100$$

or

$$\%of\ subjects = \left(\frac{\sum_{1}^{n} answers}{n}\right) x100$$

where: p_t is the value of the parameter under analysis after product application; p_0 is the value of the parameter under analysis before product application; n is the number of subjects participating in the study

3) The mean standard error of data is calculated as:

$$SEM. = \frac{\sqrt{\frac{\sum_{1}^{n}(p_i^2) - \frac{\sum_{1}^{n} p_i^2}{n}}{(n-1)}}}{\sqrt{n}}$$

where: p is the value of the parameter under; n is the number of subjects participating in the study

All the calculations are done using a Microsoft® Excel 2013 (vers. 15.0.4997.1000; Microsoft, USA) worksheet running on Microsoft® Windows 10 Professional (Microsoft, USA).

1.8.2. Statistical analysis

Data are submitted to both parametric (Wilcoxon and Mann-Whitney) and not parametric (t test of Student) statistical tests based on data normality. Statistical analysis is carried out using a Microsoft® Excel 2013 (vers. 15.0.4997.1000; Microsoft, USA worksheet running on Microsoft® Windows 10 Professional (Microsoft, USA).

1.9 Interpretation of results

The study here above reported was designed to demonstrate the test product claim(s) in the current framework proposed by Commission Regulation (EU) No 655/2013. Endpoints are measured using techniques currently accepted in the cosmetic field while biases are minimized by procedure(s) standardization according to ISO 9001 Quality Management System. Data are analyzed and interpreted by skilled technician according to both descriptive and inferential statistical analysis procedures. Due to the lack of reference values in the cosmetic field, statistical significance (for instrumental analysis) and percentage of subjects showing an effect (for clinical/sensorial endpoints) are the primary criterion to evaluate the correspondence between the proposed claim(s) and the study output(s). In

particular Intragroup (vs. T0) or intergroup (e.g. active vs. placebo, treated vs. non-treated) statistical analysis criterion to reject the null hypothesis (no product effect) is set at $p<0.05$. For clinical evaluations, the positive effect of the product on the measured parameter is confirmed if more than 50% of the subjects register an improvement. Finally, for the self-assessment questionnaires, the performance and the pleasantness of the product must be perceived by at least 60% of the subjects. Whenever reference values or threshold values exists that values are used to validate product claim(s).

1.10. Report change record

The table here below reports the change log of all approved changes made to the document that make up the course after initial approval.

Rev. no	Date	Description
00	05/09/2018	First release

RESULTS: PULL TEST

Table 1 The table here below reports the data obtained for each subject participating in the study. Data are reported as number of plucked hair.

Shampoo active

no.	Vol. ID	0	1	2	3	Variation vs. T0	1	2	3
01	R1784M	24	17	13	10		-29,2%	-45,8%	-58,3%
02	Z0418E	13	14	12	13		7,7%	-7,7%	0,0%
03	C0053D	15	13	12	8		-13,3%	-20,0%	-46,7%
04	G3555S	14	12	11	7		-14,3%	-21,4%	-50,0%
05	L2065A	14	11	9	4		-21,4%	-35,7%	-71,4%
06	M3661M	13	14	10	9		7,7%	-23,1%	-30,8%
07	P0290M	13	11	9	9		-15,4%	-30,8%	-30,8%
08	R3623F	12	9	8	6		-25,0%	-33,3%	-50,0%
09	A0966G	15	8	7	6		-46,7%	-53,3%	-60,0%
10	A0677G	18	11	9	10		-38,9%	-50,0%	-44,4%
11	R0446D	22	15	13	9		-31,8%	-40,9%	-59,1%
12	B2463I	13	10	10	8		-23,1%	-23,1%	-38,5%
13	S1258E	11	9	8	8		-18,2%	-27,3%	-27,3%
14	R1975R	11	9	10	9		-18,2%	-9,1%	-18,2%
15	V1064A	16	12	10	8		-25,0%	-37,5%	-50,0%
	Mean	**14,9**	**11,7**	**10,1**	**8,3**		**-20,3%**	**-30,6%**	**-42,4%**
	SE	1,0	0,7	0,5	0,5		3,8%	3,5%	4,8%
	p vs. T0	---	0,001	0,001	0,001				

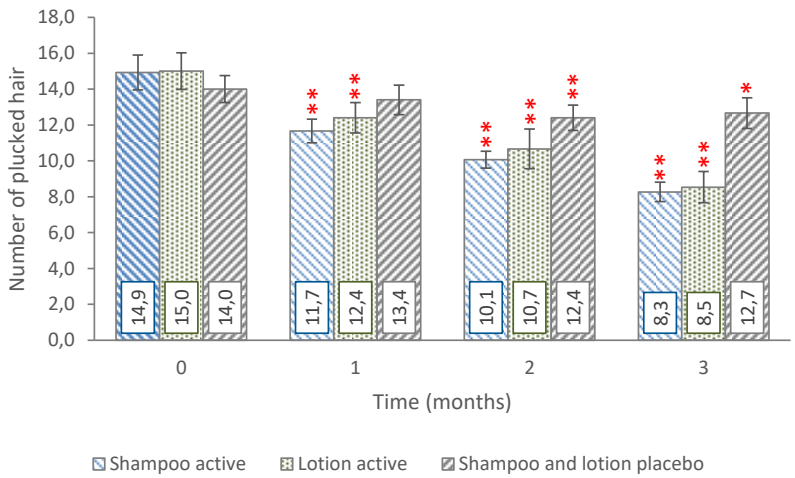
Lotion active

no.	Vol. ID	0	1	2	3	Variation vs. T0	1	2	3
01	R3160L	11	11	8	5		0,0%	-27,3%	-54,5%
02	M2000D	25	21	18	9		-16,0%	-28,0%	-64,0%
03	M2006A	17	11	6	9		-35,3%	-64,7%	-47,1%
04	M0218O	18	14	13	10		-22,2%	-27,8%	-44,4%
05	R0347R	11	10	9	6		-9,1%	-18,2%	-45,5%
06	Z3554A	21	17	22	19		-19,0%	4,8%	-9,5%
07	D0097E	12	8	7	5		-33,3%	-41,7%	-58,3%
08	B0021M	12	10	8	7		-16,7%	-33,3%	-41,7%
09	S2140I	12	10	9	8		-16,7%	-25,0%	-33,3%
10	C2155P	13	11	10	9		-15,4%	-23,1%	-30,8%
11	C1620T	15	12	9	6		-20,0%	-40,0%	-60,0%
12	C1099D	16	15	12	10		-6,3%	-25,0%	-37,5%
13	M1950M	13	11	10	8		-15,4%	-23,1%	-38,5%
14	S1741G	15	13	11	10		-13,3%	-26,7%	-33,3%
15	O0957S	14	12	8	7		-14,3%	-42,9%	-50,0%
	Mean	**15,0**	**12,4**	**10,7**	**8,5**		**-16,9%**	**-29,5%**	**-43,2%**
	SE	1,0	0,8	1,1	0,9		2,3%	3,9%	3,6%
	p vs. T0	---	0,001	0,001	0,001				

Shampoo and lotion placebo

no.	Vol. ID	0	1	2	3	Variation vs. T0	1	2	3
01	Q2899C	12	14	10	11		16,7%	-16,7%	-8,3%
02	D2313T	11	12	12	12		9,1%	9,1%	9,1%
03	F3716A	11	13	10	11		18,2%	-9,1%	0,0%
04	G3824D	12	11	14	14		-8,3%	16,7%	16,7%
05	C0074M	13	14	12	10		7,7%	-7,7%	-23,1%
06	P0840N	18	16	15	20		-11,1%	-16,7%	11,1%
07	R0813S	15	17	15	12		13,3%	0,0%	-20,0%
08	S2046S	16	15	10	14		-6,3%	-37,5%	-12,5%
09	E0537G	12	10	9	10		-16,7%	-25,0%	-16,7%
10	G1922I	15	15	14	14		0,0%	-6,7%	-6,7%
11	P1921V	11	8	10	10		-27,3%	-9,1%	-9,1%
12	R1975R	12	9	10	10		-25,0%	-16,7%	-16,7%
13	L1072P	15	12	12	11		-20,0%	-20,0%	-26,7%
14	C1934S	16	15	14	11		-6,3%	-12,5%	-31,3%
15	S1388A	21	20	19	20		-4,8%	-9,5%	-4,8%
	Mean	**14,0**	**13,4**	**12,4**	**12,7**		**-4,0%**	**-10,8%**	**-9,3%**
	SE	0,8	0,8	0,7	0,9		3,8%	3,4%	3,6%
	p vs. T0	---	0,238	0,008	0,032				

Figure 1 The graph here below shows the product effect on the measured parameter reported here above. Data are reported as mean ± SE. Upon the bars is reported the intragroup (vs. T0) statistical analysis. Statistical significance is reported as follows: * p<0.05, ** p<0.01, *** p<0.001.



Comment. The active ingredient formulated both in a rinse off (shampoo) and in a leave on (lotion) formulation is effective in decreasing the number of hair plucked during pull testing. The percentage variation of the decrease of the number of hair plucked, for both the shampoo and the lotion treated groups, is statistically significant when compared to the placebo product. The effect on pull testing output is comparable between the shampoo and the lotion formulations.

Table 1a. Intergroup statistical analysis output

	1	2	3
Pl vs. Sh	0.005	0.000	0.000
Pl vs. Lo	0.008	0.001	0.000
Sh vs. Lo	0.440	0.828	0.885

RESULTS: HAIR RADIANCE

Table 2 The table here below reports the data obtained for each subject participating in the study. Data are reported as gloss units.

Shampoo active

no.	Vol. ID	0	1	2	3		1	2	3
01	R1784M	3,02	4,40	4,49	5,12		45,7%	48,7%	69,5%
02	Z0418E	4,65	5,68	5,91	5,88		22,2%	27,1%	26,5%
03	C0053D	2,09	2,53	3,12	3,41		21,1%	49,3%	63,2%
04	G3555S	2,50	2,88	3,99	4,25		15,2%	59,6%	70,0%
05	L2065A	1,84	2,14	2,91	3,11		16,3%	58,2%	69,0%
06	M3661M	3,89	5,64	4,22	4,66		45,0%	8,5%	19,8%
07	P0290M	3,12	3,26	3,92	4,05		4,5%	25,6%	29,8%
08	R3623F	3,97	5,16	5,49	6,95		30,0%	38,3%	75,1%
09	A0966G	3,88	4,01	4,12	4,26		3,4%	6,2%	9,8%
10	A0677G	3,15	3,36	3,62	4,11		6,7%	14,9%	30,5%
11	R0446D	2,96	3,25	3,59	3,96		9,8%	21,3%	33,8%
12	B2463I	4,15	4,36	4,89	5,01		5,1%	17,8%	20,7%
13	S1258E	4,78	5,11	5,22	5,36		6,9%	9,2%	12,1%
14	R1975R	4,22	4,78	4,89	5,11		13,3%	15,9%	21,1%
15	V1064A	3,66	4,12	4,69	5,04		12,6%	28,1%	37,7%
	Mean	**3,46**	**4,05**	**4,34**	**4,69**		**17,2%**	**28,6%**	**39,2%**
	SE	0,23	0,29	0,22	0,25		3,5%	4,7%	6,0%
	p vs. T0	---	0,000	0,000	0,000				

Variation vs. T0

Lotion active

no.	Vol. ID	0	1	2	3		1	2	3
01	R3160L	3,96	5,20	5,73	6,08		31,3%	44,7%	53,5%
02	M2000D	2,66	2,77	4,06	4,18		4,1%	52,6%	57,1%
03	M2006A	3,54	5,73	5,52	5,65		61,9%	55,9%	59,6%
04	M0218O	2,89	3,96	5,14	4,89		37,0%	77,9%	69,2%
05	R0347R	3,67	3,89	3,82	5,84		6,0%	4,1%	59,1%
06	Z3554A	5,46	9,56	8,54	9,61		75,1%	56,4%	76,0%
07	D0097E	4,65	4,88	6,45	6,12		4,9%	38,7%	31,6%
08	B0021M	3,78	4,59	4,72	4,64		21,4%	24,9%	22,8%
09	S2140I	2,58	2,76	2,78	2,84		7,0%	7,8%	10,1%
10	C2155P	3,69	3,77	3,81	4,01		2,2%	3,3%	8,7%
11	C1620T	4,78	5,01	5,15	5,22		4,8%	7,7%	9,2%
12	C1099D	4,22	4,89	4,99	5,16		15,9%	18,2%	22,3%
13	M1950M	3,96	4,11	4,38	4,78		3,8%	10,6%	20,7%
14	S1741G	2,75	3,22	3,69	3,59		17,1%	34,2%	30,5%
15	O0957S	2,58	2,69	2,88	3,11		4,3%	11,6%	20,5%
	Mean	**3,68**	**4,47**	**4,78**	**5,05**		**19,8%**	**29,9%**	**36,7%**
	SE	0,23	0,44	0,38	0,42		5,8%	6,1%	6,0%
	p vs. T0	---	0,014	0,000	0,000				

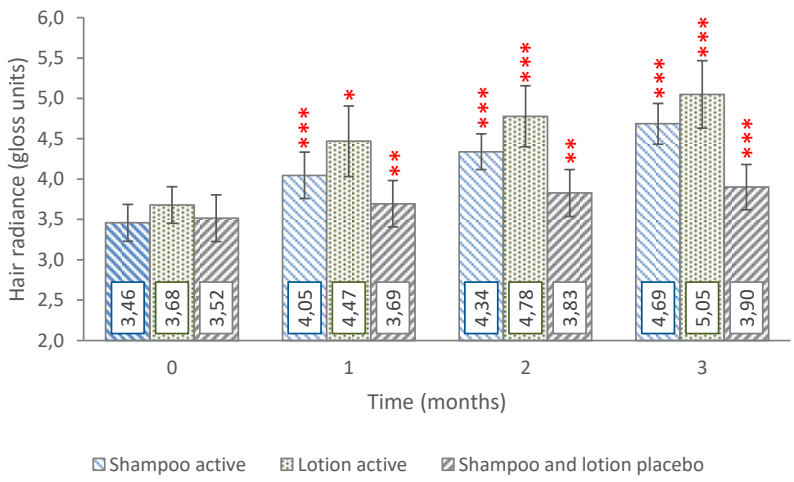
Variation vs. T0

Shampoo and lotion placebo

no.	Vol. ID	0	1	2	3		1	2	3
01	Q2899C	3,03	3,41	3,71	3,84		12,5%	22,4%	26,7%
02	D2313T	1,97	2,49	2,61	2,70		26,4%	32,5%	37,1%
03	F3716A	1,53	1,66	1,71	1,82		8,5%	11,8%	19,0%
04	G3824D	4,07	4,12	4,70	4,86		1,2%	15,5%	19,4%
05	C0074M	4,02	4,52	4,63	4,54		12,4%	15,2%	12,9%
06	P0840N	5,36	5,78	5,93	5,88		7,8%	10,6%	9,7%
07	R0813S	3,41	3,56	3,85	3,78		4,4%	12,9%	10,9%
08	S2046S	5,41	5,44	5,35	5,38		0,6%	-1,1%	-0,6%
09	E0537G	3,38	3,41	3,38	3,41		0,9%	0,0%	0,9%
10	G1922I	2,96	3,11	3,45	3,46		5,1%	16,6%	16,9%
11	P1921V	2,55	2,58	2,60	2,98		1,2%	2,0%	16,9%
12	R1975R	4,59	4,62	4,68	4,75		0,7%	2,0%	3,5%
13	L1072P	4,21	4,25	4,33	4,52		1,0%	2,9%	7,4%
14	C1934S	2,88	2,93	2,88	2,97		1,7%	0,0%	3,1%
15	S1388A	3,36	3,52	3,60	3,63		4,8%	7,1%	8,0%
	Mean	**3,52**	**3,69**	**3,83**	**3,90**		**5,9%**	**10,0%**	**12,8%**
	SE	0,29	0,29	0,29	0,28		1,8%	2,5%	2,6%
	p vs. T0	---	0,002	0,001	0,000				

Variation vs. T0

Figure 2 The graph here below shows the product effect on the measured parameter reported here above. Data are reported as mean ± SE. Upon the bars is reported the intragroup (vs. T0) statistical analysis. Statistical significance is reported as follows: * p<0.05, ** p<0.01, *** p<0.001.



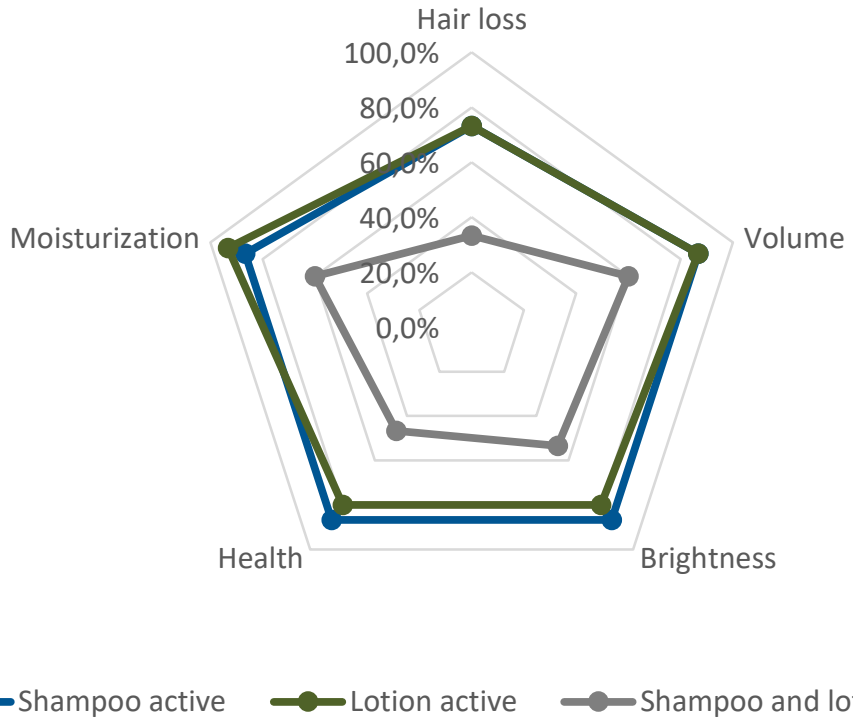
Comment. The active ingredient formulated both in a rinse off (shampoo) and in a leave on (lotion) formulation is effective in improving hair brightness. The percentage variation of hair brightness, for both the shampoo and the lotion treated groups, is statistically significant when compared to the placebo product. The effect on hair brightness is comparable between the shampoo and the lotion formulations.

Table 2a. Intergroup statistical analysis output

	1	2	3
Pl vs. Sh	0.008	0.002	0.000
Pl vs. Lo	0.031	0.005	0.001
Sh vs. Lo	0.703	0.863	0.771

RESULTS: SELF-ASSESSMENT QUESTIONNAIRE AFTER 3 MONTHS USE

Figure 3 The graph here below reports the self-assessment questionnaire output. Data are reported as % of subjects giving a positive response.



	Shampoo active	Lotion active	Shampoo and lotion placebo
The tested product decreases hair loss?	73.3%	73.3%	33.3%
My hair are more voluminous?	86.7%	86.7%	60.0%
My hair are brighter and less opaque?	86.7%	80.0%	53.3%
My hair are healthier?	86.7%	80.0%	46.7%
My hair are more moisturized	86.7%	93.3%	60.0%

CONCLUSIONS

According to the obtained results, elsewhere reported in this document, it is possible to preliminary conclude that the ingredient **CINATYNE® TOP** formulated both in a rinse-off (shampoo) and in a leave on (lotion) formulation is effective:

- ✓ In reducing hair loss. The following results were obtained:

	0	1m	2m	3m
Shampoo	14.9±1.0	11.7±0.7 (-20.3%)	10.1±0.5 (-30.6%)	8.3±0.5 (-42.4%)
Lotion	15.0±1.0	12.4±0.8 (-16.9%)	10.7±1.1 (-29.5%)	8.5±0.9 (-43.2%)
Placebo	14.0±0.8	13.4±0.8 (-4.0%)	12.4±0.7 (-10.8%)	12.7±0.9 (-9.3%)

- ✓ in increasing hair brightness. The following results were obtained:

	1m	2m	3m
Shampoo	+17.2%	+28.6%	+39.2%
Lotion	+19.8%	+29.9%	+36.7%
Placebo	+5.9%	+10.0%	+12.8%

Moreover the effects of the product were noted by the subjects participating in the study. The products were well tolerated. No significant adverse reactions were reported during the study period.

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