

STUDY REFERENCE : N°EternalSerCre.22I22.06-2I34.06/01.07.08

**SUBJECTIVE ASSESSMENT
OF THE EFFICACY
OF A COSMETIC PRODUCT AFTER
APPLICATION UNDER NORMAL CONDITIONS OF USE**

Consumer test

**TEST PRODUCT :
ETERNAL line products
ETERNAL INTENSIVE SERUM & ETERNAL CREAM**

Study report

Terrassa, July 30th, 2008

14 pages in this report including 6 in Appendices

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1 . AIM AND PRINCIPLE OF THE STUDY

This study intended to assess the efficacy of the **ETERNAL line** products (**ETERNAL CREAM & ETERNAL INTENSIVE SERUM**), after application for 21 days, under normal conditions of use on a panel of 31 volunteers.

The efficacy of the products was assessed **subjectively** using a target questionnaire, which was given to the volunteers at the beginning of the study.

2 . RELEVANCE OF THE STUDY

Ethics

The study aiming at a better knowledge of the efficacy of the test products and the foreseeable risk incurred by the volunteers who took part in the study being minor, there was a suitability between the aim of the study and its possible risks.

Methodological approach

The experimental conditions adopted (experimental area, quantity of product applied, frequency and duration of the applications...) exactly reproduced the normal conditions of use advocated and the test performed reflected the application by the future consumers.

The volunteers' opinion was taken into account since it could reflect that of the potential consumers.

Panel

The panel corresponded to the population likely to use the product : the inclusion criteria corresponded to the target market of the products.

The number of volunteers defined in the protocol was sufficient to assess the efficacy of the products.

Results

The subjective efficacy data were expressed in percentage of satisfied volunteers and were submitted to a suitable statistical treatment.

3 . STUDY TIME-TABLE

Beginning on : July 3rd, 2008

End on : July 24th, 2008

4 . TEST PRODUCT

The product was tested under two slightly different textures but with similar concentrations of active ingredients.

Denomination	ETERNAL Intensive serum or ETERNAL Cream	
Code	4131SM / 4130SM	
Reference / Batch number	2I22/06 (serum)	2I34/06 (cream)
Galenic form and organoleptic characteristics	Yellow pale serum / cream	
Number and type of samples	15 flasks	15 flasks
Content of samples	30 ml	50 ml

5 . VOLUNTEERS

5.1 . Number

The number of volunteers whose data had to be exploitable at the end of the study was 20.

31 volunteers were included in the study.

Four volunteers discontinued and 7 exclusions was decided by the investigator.

The efficacy of the test product were therefore assessed in 20 volunteers included in the study and who answered the questionnaire.

5.2 . Specific inclusion criteria

The specific inclusion criteria were the following ones :

- age : 20-65 years old,
- sex : female,
- having all skin types,
- regular or occasional users of facial care products.

All the volunteers corresponded to these specific inclusion criteria. Their typological characteristics are defined in **Appendix 1**.

5.3 . Specific non inclusion criteria

The specific non inclusion criteria defined in the protocol, were the following ones :

- allergy or reactivity to products of the same category to the tested one.

All the volunteers corresponded to these specific non inclusion criteria.

6 . METHODOLOGY

6.1 . Experimental conditions of use of the test product

The experimental conditions, defined in the protocol, were the following ones :

Experimental area	Product directions for use	Applications at home Frequency/duration
Face and eyes contour (avoiding the contact with eyes)	Application of the product as it is by gentle digital massage until its complete penetration	Application twice a day (morning and evening) during 21 ± 2 consecutive days of use

6.2 . Constraints of the study

The constraints imposed on the volunteers were the following ones:

- no application of products similar to the tested one to the experimental area,
- no change in hygiene / make-up habits.

6.3 . Control of the observance of the modalities of the protocol

The volunteers were **questioned at the end of the study about the way** they used the test product. The investigator assessed the importance of the possible deviations in comparison with the experimental conditions required at the beginning of the study.

The synthesis of the answers obtained is enclosed in **Appendix 2**.

In case of deviations from the protocol, those were analysed and the investigator assessed their effect on the validity of the results.

Deviations from the protocol concerning the experimental conditions of use at home were noticed by the investigator and are enclosed in **Appendix 2**.

6.4 . Assessment of the efficacy (self-assessment)

The volunteers had to answer a questionnaire at the end of the study, which gathered the items concerning the efficacy of the product. They had to send it to the investigator centre at the end of the study by mail.

These items were the following ones :

- Skin more younger, smoother and softer
- Wrinkle reduction
- Improvement of the firmness and elasticity of the skin
- More moisturized skin
- Brighter skin, lower spots appearance
- Improvement of the skin condition

Volunteers finally included in the study (see **Appendix 2**) were taken into account to assess the efficacy of the test product as long as they used the product and brought back the questionnaire duly completed.

For each item, the volunteers had to express their satisfaction :

- 0 = No, definitely not,
- 1 = Fairly not,
- 2 = Fairly yes,
- 3 = Yes, definitely.

and the results were expressed in percentage of satisfied volunteers (scores 2 and 3).

The results were submitted to a suitable statistical analysis (2-rank χ^2 test: comparison between 2 percentages – satisfied volunteers and non satisfied volunteers).

$$\chi^2 = \frac{\sum (|O_i - C_i|^2)}{C_i}$$

O_i = strength observed
 C_i = strength calculated
 α = 5 % risk

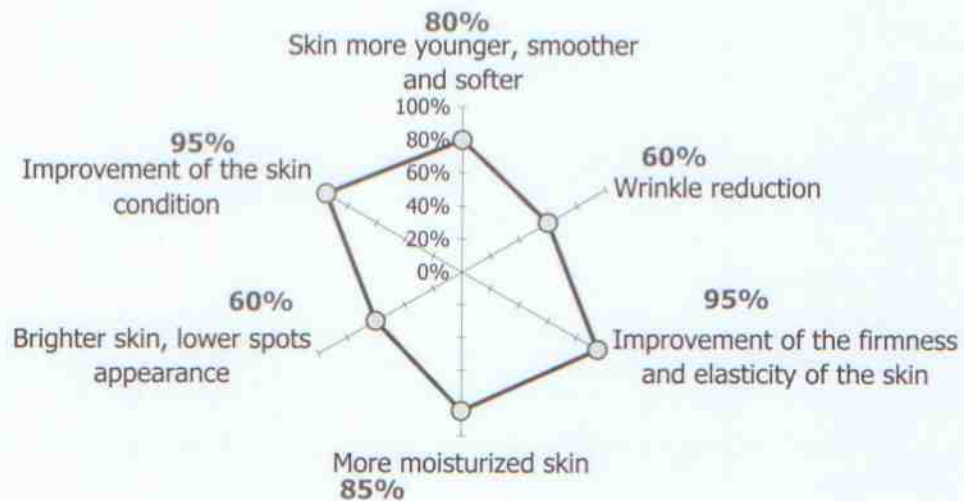
Significant difference if $\chi^2 > 3,84$ (for $\alpha = 5 \%$)

Non significant difference if $\chi^2 \leq 3,84$

7 . RESULTS / DISCUSSION

Assessment of the efficacy (self-assessment)

For each item, the percentage of satisfied volunteers is enclosed in **Appendix 3** and is reported in the graphics below :



For a significant percentage of volunteers, the product was judged that:

- Skin more younger, smoother and softer
- Wrinkle reduction*
- Improvement of the firmness and elasticity of the skin
- More moisturized skin
- Brighter skin, lower spots appearance*
- Improvement of the skin condition

*Items that are not statistically significant (see **Appendices 3/1 & 3/2**)

8. CONCLUSIONS

With regard to the results obtained after 21 days of application on a panel of 31 volunteers (20 exploitable results), we are able to conclude that the **ETERNAL line** products (**ETERNAL Cream & ETERNAL Intensive serum**) according to volunteer's opinion:

- leaves the skin smoother and softer, looking more younger: 80%
- improves of the firmness and elasticity of the skin: 95%
- leaves the skin more moisturized: 85%
- improves the skin condition: 95%

The product can claim the "global anti-aging" label, and a "quicker efficacy".

Signatures

Investigator:

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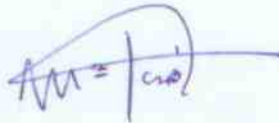
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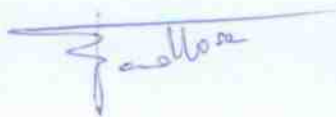
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This study was designed and developed by the International Beauty Training Centre researchers for an internal purposes, in accordance with the principles of Good Clinical Practices as well as the recommendations of the COLIPA accounting for the assessment of the efficacy in cosmetic products. Its free distribution is forbidden without permission of the authors, which don't assume any responsibility about its wrong use or diffusion.

APPENDICES

Appendix 1/1

TYPOLGICAL CHARACTERISTICS OF THE VOLUNTEERS

Volunteers		DNI	Age (years)	Sex F=female	Type of skin*	Regular or occasional user of facial care products
Ref.	Surname/ name					
1	PARE/DO	39.186.741	40	F	O	X
2	GUTI/RO	45.492.891	28	F	C	X
3	PLAN/PI	39.098.896	63	F	C	X
4	MONT/AN	39.159.021	45	F	D	X
5	CAST/DO	45.637.927	27	F	C	X
6	GUTI/MA	45.482.663	33	F	C	X
7	VALL/SO	75.262.634	26	F	C	X
8	BERN/AN	44.182.667	34	F	C	X
9	PERE/IR	39.114.052	59	F	D	X
10	PARD/LA	45.471.444	31	F	N	X
11	VIDA/CR	45.473.853	35	F	N	X
12	VALL/MA	45.478.392	36	F	C	X
13	RODR/MO	45.467.390	35	F	C	X
14	REYE/SI	46.803.396	31	F	C	X
15	PALA/YO	45.466.236	38	F	C	X
16	VIÑA/NU	39.112.086	60	F	D	X
17	PLAN/PI	39.098.896	63	F	C	X
18	MONT/AN	39.159.021	45	F	D	X
19	COLL/MA	39.137.487	52	F	D	X
20	MOLI/JU	39.161557	45	F	D	X
21	MOLI/EM	39.166.156	44	F	D	X
22	PAGE/ME	39.124.771	56	F	D	X
23	FERN/DO	39.167.160	45	F	D	X
24	POLO/MA	39.174.344	42	F	N	X
25	MERI/AL	77.099.242	49	F	C	X

Legends : / = no x = yes

* D = dry, N = normal, C = combined normal/oily, O = oily

TYOLOGICAL CHARACTERISTICS OF THE VOLUNTEERS

Volunteers		DNI	Age (years)	Sex F=female	Type of skin*	Regular or occasional user of facial care products
Ref.	Surname/ name					
26	PERE/IR	39.114.052	59	F	D	X
27	VIDA/CR	45.473.853	35	F	D	X
28	SANC/DO	39.178.534	42	F	C	X
29	COLO/CA	39.142.700	52	F	D	X
30	PERE/SO	39.107.177	61	F	D	X
31	VIÑA/NU	39.112.086	60	F	D	X

Legends : / = no x = yes

* D = dry, N = normal, C = combined normal/oily, O = oily

Appendix 2

CONTROL OF THE OBSERVANCE
Modalities of use

Modalities of use (31 raw results)	Number of volunteers who respected the modalities	Percentage of volunteers who respected the modalities
<p>Frequency of application at home : Twice a day (morning and evening)</p> <p>Deviations : 14 volunteers</p> <ul style="list-style-type: none"> - Volunteer ref. 3, 11, 17, 19, 27 & 29 applied the product once to twice a day during the period of the study. - Volunteers ref. 2, 8, 12, 13, 15 and 21 applied the product once a day during the period of the study. - Volunteer ref. 23 applied the product twice to three times per day during the period of the study. 	17	55%
<p>Duration of application at home : 21 ± 2 consecutive days</p> <p>Deviations : 9 volunteers</p> <ul style="list-style-type: none"> - Volunteers ref. 2, 8, 14, 16 & 31 applied the product below to 14 consecutive days. - Volunteer ref. 19 applied the product above to 28 consecutive days. - Volunteers ref. 7 and 23 applied the product during 25 consecutive days. 	22	71%
<p>Withdrawals & exclusions:</p> <p>Deviations : 11 volunteers</p> <ul style="list-style-type: none"> - Volunteer ref. 28 discontinued the study. - Volunteers ref. 2, 16 and 31 manifest some uncomfortable feelings associated to the product use. They discontinued the study. - Volunteers ref. 8, 12, 13, 14, 15, 19 and 21 were excluded from the study by decision of the investigator, according the non acceptable deviations registered in their modalities of use. 	20 exploitable results	65%
<p>Volunteers opinion:</p> <p>At least, one every two volunteers that finally participates in the study noted the efficacy of the product in the first week of treatment.</p>		

Appendix 3/1

COSMETIC EFFICACY

Items (20 exploitable results)	Number of satisfied volunteers	Percentage of satisfied volunteers
Skin more younger, smoother and softer.	16	80%
Wrinkle reduction	12	60%
Improvement of the firmness and elasticity of the skin	19	95%
More moisturized skin	17	85%
Brighter skin, lower spots appearance.	12	60%
Improvement of the skin condition	19	95%

STATISTICAL ANALYSIS

Test of χ^2

$$\chi^2 = \frac{\sum(|o_i - c_i|^2)}{c_i}$$

O_i = strength observed
 C_i = strength calculated
 α = 5 % risk

Significant difference (S) si $\chi^2 > 3,84$ (for $\alpha = 5 \%$)

Non significant difference (NS) if $\chi^2 \leq 3,84$

Item 1 : Skin more younger, smoother and softer

Repartition	yes	no	Total	Value χ^2	Significance of the difference
Theoretical proportion	50%	50%	100%	7.2	S
Strength calculated (c_i)	10	10	20		
Strength observed (o_i)	16	4	50		

Item 2 : Wrinkle reduction

Repartition	yes	no	Total	Value χ^2	Significance of the difference
Theoretical proportion	50%	50%	100%	0.8	NS
Strength calculated (c_i)	10	10	20		
Strength observed (o_i)	12	8	20		

