

FINAL REPORT

IN USE TEST IN CONTROLLED CONDOTIONS TO ASSESS THE EFFICACY OF A COSMETIC PRODUCT

CUSTOMER	LABORATOIRE DR PAUL ET KARIN HERZOG SA Route de Tailleped, 1 1095 Lutry - SWITZERLAND
SPONSOR	LABORATOIRE DR PAUL ET KARIN HERZOG SA Route de Tailleped, 1 1095 Lutry - SWITZERLAND
SAMPLE	EE Express Effect - Crème pour le visage Batch: 4701355
REPORT DATE	10/06/2016
REPORT N.	REL/1213/2016/CLI/SAB

The results reported herein do exclusively refer to the tested sample

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Headquarters and laboratories

Via Quarantadue Martiri 213/B
28924 Verbania/VB
Italy

Pho. +39 0323 586239/496041
Fax +39 0323 496877
info@abich.it

CF/VAT/Reg. Imp. VCO: 01864020035
R.E.A.: 189901
Cap. Soc. € 116.000,00 i.v.

Clinical and cosmetic testing Center

Via Bruno Buozzi 4
20090 Vimodrone/MI
Italy

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Preliminary

This report contains the experimental data compiled during the in vitro studies of the test product. The test results are presented in a concise table format for easy interpretation. The first part provides information regarding sponsor and test product identifications, assay type, entrusted laboratory, study initiation and completion dates and supervisory personnel. The second part describes the study design, including materials and procedures. The test results are presented in the third part of the report. The bibliography and references are presented in the fourth and last part of the report.

Disclaimer

According to COLIPA guidelines, the test was performed with the assumption that the Sponsor under its responsibility provided to the personnel of the Abich Clinical study Center, truthful information on any ingredient of the test product endowed with potential toxicological relevance. On the basis of such information, a general assessment of the toxicological information concerning the product was preliminarily carried out and ethical implications as to its use during the present study have been considered.

Authenticity of Results

I hereby declare that the study concerned by this report was carried out under my responsibility, according to the experimental protocol and the quality plan of Abich S.r.l. I also state that, where applicable, all procedures were compliant with the principles of Good Clinical Practice. All relevant observations and data recorded during the test are reported in this study report. I certify the re-reading of this report and I do agree with its content.

Quality Assurance:

Roberta Cattaneo



Headquarters and laboratories

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1. **PART ONE – GENERAL INFORMATION**

1.1. **Customer**

LABORATOIRE DR PAUL ET KARIN HERZOG SA
Route de Taillepied, 1
1095 Lutry - SWITZERLAND

1.2. **Sponsor**

LABORATOIRE DR PAUL ET KARIN HERZOG SA
Route de Taillepied, 1
1095 Lutry - SWITZERLAND

1.3. **Tested Sample**

Name: **EE Express Effect - Crème pour le visage**

Batch: 4701355

Aspect: white cream

Abich sample code: 2963/16-01

INCI Composition: see annex

Pao / expiration date: n.a.

Storage conditions: room temperature

1.4. **Test / Assay**

In use test in controlled conditions to assess the efficacy and the tolerability of a cosmetic product.

1.5. **Entrusted Laboratory**

Abich S.r.l.- Clinical and Cosmetological Trials Center
Via Bruno Buozzi, 4
20090 - Vimodrone (MI) - Italy

Abich S.r.l.- Clinical and Cosmetological Trials Center
Via della Burrone, 51
20090 - Vimodrone (MI) - Italy

1.6. **Date dello studio / Study Date**

Inizio / *Start*: 21/04/2016

Fine / *End*: 31/05/2016

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Italy

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1.7. Direttore dello Studio/ Study Director:

Dr. Stefano Todeschi

Biologo e specialista in Patologia Clinica / *Biologist and Specialist in Clinical Pathology*

1.8. Assicurazione Qualità / Quality Assurance:

Roberta Cattaneo



1.9. Altri sperimentatori coinvolti nello studio / Other investigators involved in the study:

Dr Eleonora Spartà – Biologa / Biologist

Dr Giulia Caccia – Biologa / Biologist

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2. PART TWO –STUDY DESIGN

2.1. Aim of the test

This study was aimed to assess the efficacy of a cosmetic product, as perceived by the consumers. A self-assessment is full-filled after 10 and 20 days of product use, in controlled conditions and under medical supervision.

2.2. Panel characteristics

The study was performed on 40 female volunteers showing fine lines and wrinkles over the face, with age between 30 and 65 years, who have been identified from specified criteria of exclusion, from the database of volunteers of the Abich Test Centre, and who were evaluated as appropriate for participation in the study and not suffering from diseases to the skin areas to treat.

Before the beginning of the study each volunteer has read and signed an informative form (informed consent form, C.I.). Each volunteers has had the opportunity to ask any kind of questions regarding the study to which was given an exhaustive answer. The volunteer was explained the aim of the test, the procedure and the possible risks related.

Only after signature of the informed consent the participation in the study was permitted.

Only volunteers in good general health conditions were included in the study.

The originals of these informed consent forms were archived at the Abich Clinical and Cosmetological Trials Center. All patients signed a consent allowing to treat personal data according to the Italian law (Testo unico sulla privacy. D.Lgs 196/2003).

The following exclusion criteria were applied:

- Pregnant or lactating women;
- Persons below the age of consent;
- Subjects with discolorations, any kind of skin marks, including tattoos, scars, burns or their outcomes, which can interfere with the reading of the assay;
- Subjects taking medication that might interfere with the test results (i.e. photosensitising, anti-inflammatory drugs);
- Subjects having skin irritation at the application site;
- Subjects having skin diseases which could interfere with the aim of this study;
- Subjects with skin hyperpigmentation caused from exposure to solar radiation;
- Subjects with a history of adverse events related to sun exposure
- Subject participating in other simultaneous studies that might interfere with the test evaluation

2.3. Product application

Volunteers apply the product on face according to customer instructions during 20 days:

Day and night, clean well your face skin (with your usual cleansing product) and then rinse well. Apply your EE cream on the whole face and neck, in massaging and let it act. You can feel a fresh sensation which is normal, due to the ingredients inside this effective composition. You can, then, apply your usual protection cream or make-up on top (see annex 3).

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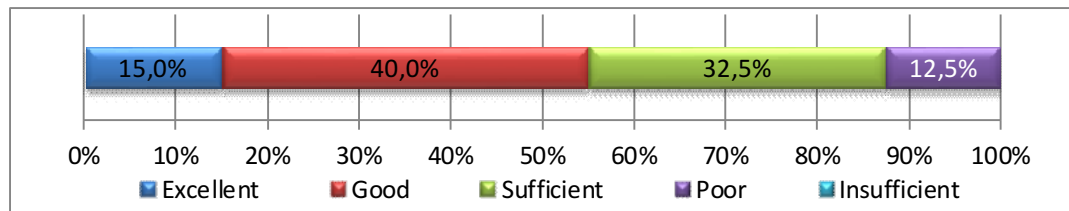
2.4. Self-assessment

After 10 and 20 days of product use, volunteers come back to the test facility in order to answer to a questionnaire, agreed with the customers. Some questions refer to product tolerability and someone to product efficacy.

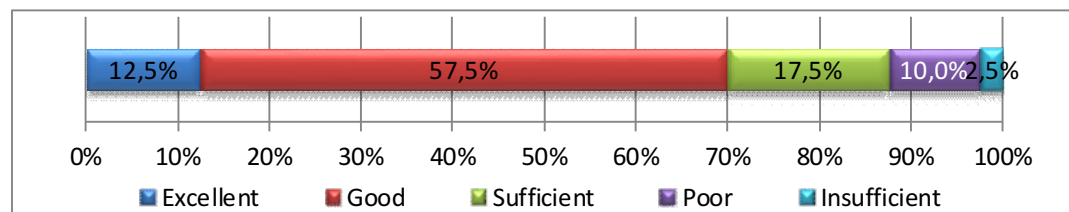
3. PART THREE – RESULTS AND CONCLUSIONS

3.1. T10 Results

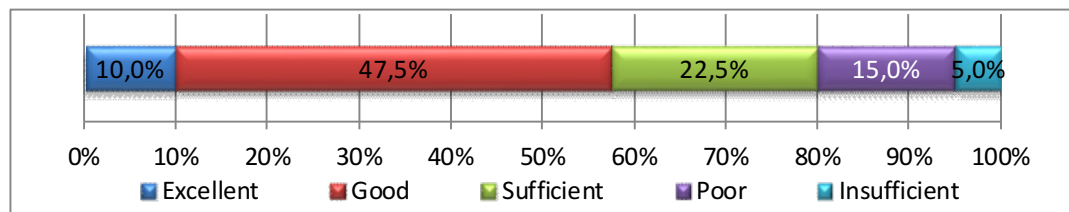
1. In your opinion, after 10 days of product use, tested product improves skin smoothness of fine lines and wrinkles in a manner:



2. In your opinion, after 10 days of product use, tested product improves skin radiance in a manner:



3. In your opinion, after 10 days of product use, tested product makes your skin complexion more uniform in a manner:



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28924 Verbania/VB
Italy

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info@abich.it

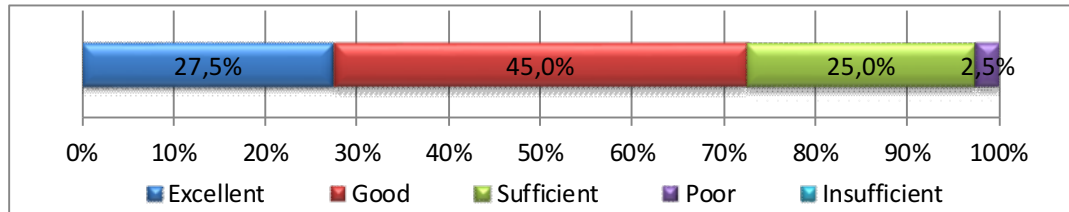
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4. In your opinion, after 10 days of product use, tested product has a mattifying* effect:



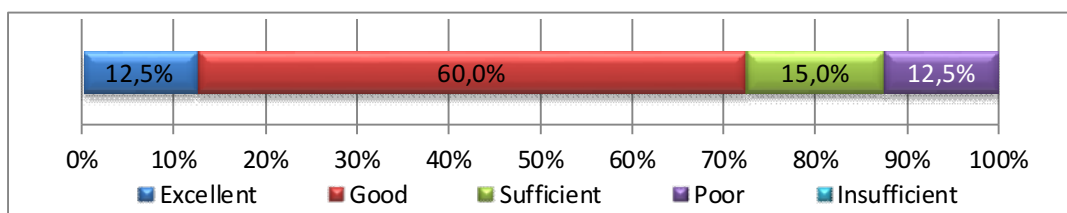
*there is a normal, shiny effect which is seen during the first 5 minutes after each application: these 5 first minutes are always necessary for the cream to be able to penetrate and to fit the skin. Therefore, this normal, shiny effect during the first 5 minutes does NOT concern question « 4. »

COMMENTS:

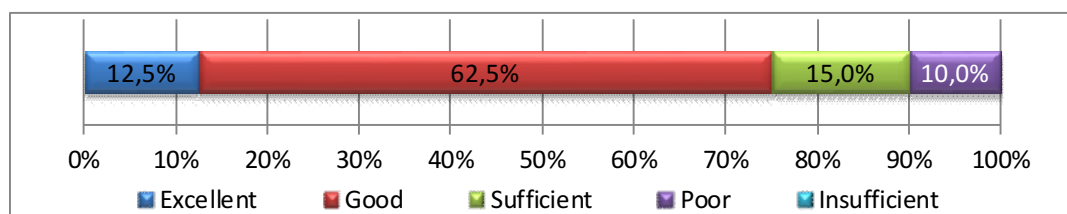
- One subject refers burning sensation if the product was applied too close to the eyes. Moreover, she refers that she has to wash finely her hands after product application, because if her hands come in contact with the eyes, even several minutes after product application, the burning sensation reappeared.
- One subject refers that the product provides a pleasant refreshing sensation.
- One subject refers that the product provides a severe skin tightening. The subject is carrying on the study applying the product just once a day.

3.2. T20 results

1. In your opinion, after 20 days of product use, tested product improves skin smoothness of fine lines and wrinkles in a manner:



2. In your opinion, after 20 days of product use, tested product improves skin radiance in a manner:



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 28924 Verbania/VB
 Italy

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 Fax +39 0323 496877
 info@abich.it

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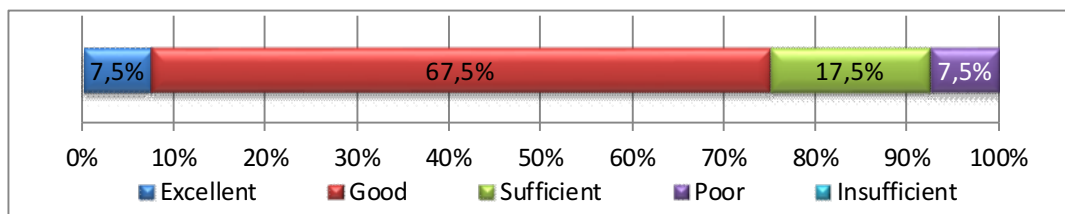
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 20090 Vimodrone/MI
 Italy

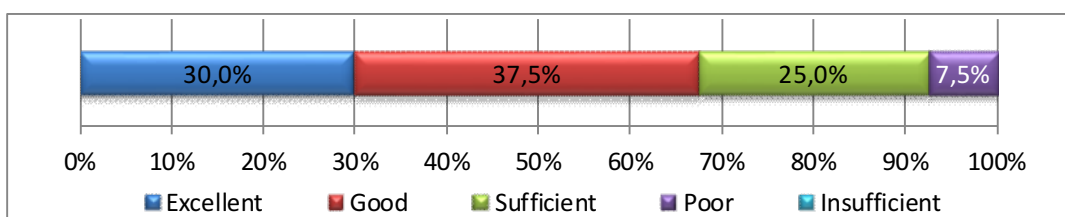
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Biological and chemical analysis

3. In your opinion, after 20 days of product use, tested product makes your skin complexion more uniform in a manner:

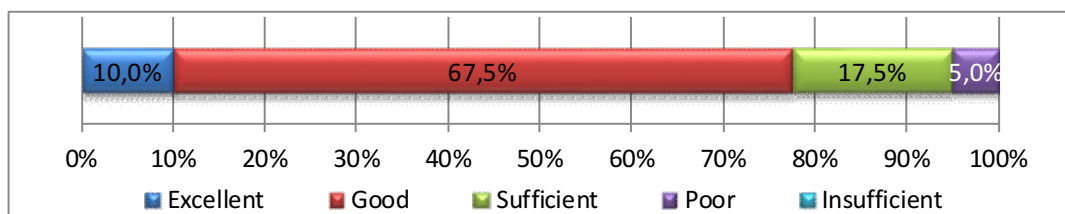


4. In your opinion, after 20 days of product use, tested product has a mattifying* effect:

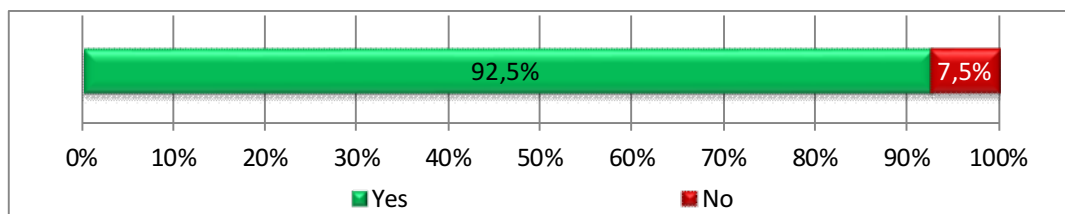


*there is a normal, shiny effect which is seen during the first 5 minutes after each application: these 5 first minutes are always necessary for the cream to be able to penetrate and to fit the skin. Therefore, this normal, shiny effect during the first 5 minutes does NOT concern question « 4. »

5. Please give a general judgement on the efficacy of tested product:



6. Would you suggest someone to buy the product?



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28924 Verbania/VB
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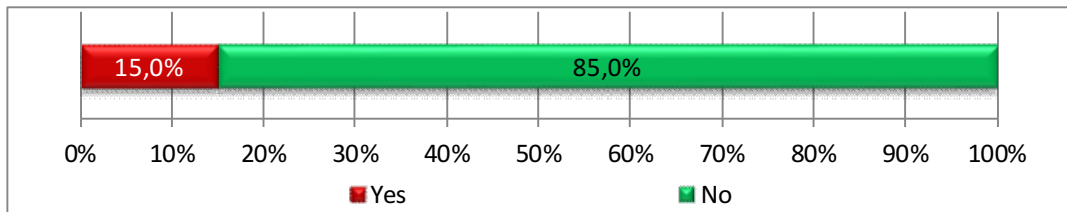
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Biological and chemical analysis

7. Due to product use, do you noticed any side effect (irritation, burning sensation, redness, dehydration/dryness, oily skin, etc)?



COMMENTS:

- One subject refers burning sensation if the product was applied too close to the eyes. Moreover, she refers that she has to wash finely her hands after product application, because if her hands come in contact with the eyes, even several minutes after product application, the burning sensation reappeared.
- Five subjects refer that the product dries the skin.

3.3. Conclusions

On the basis of the results obtained with the adopted experimental procedure it is allowed to conclude that the product under examination

**EE Express Effect - Crème pour le visage
Batch: 4701355**

Has been well tolerated by the most part of the enrolled subjects.
Moreover the most part of the volunteers positively judges the product.

The Study Director

Dr. Stefano Todeschi

**Headquarters
and laboratories**

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28924 Verbania/VB
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COLIPA guidelines for the evaluation of the efficacy of cosmetic products, May 2008.

Declaration WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects
Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Autori vari, "Manuale del cosmetologo" Tecniche Nuove, Milano 2007, pp.433-434, pp. 450-451,

Consensus documents Number 4.
OECD SERIES ON PRINCIPALES OF GLP AND COMPLIANCE MONITORING
"Quality assurance and GLP" 26 Oct. 1999.

OECD SERIES ON PRINCIPALES OF GLP AND COMPLIANCE MONITORING
"Compliance of laboratory suppliers with GLP principles" 28 Sept. 2000.

Consensus documents Number 7.
OECD SERIES ON PRINCIPALES OF GLP AND COMPLIANCE MONITORING
"The application of to GLP principles to short term studies" 15 Sept. 1999.

Consensus documents Number 8.
OECD SERIES ON PRINCIPALES OF GLP AND COMPLIANCE MONITORING
"The role and responsibility of the Study Director in the GLP studies" 15 Sept. 1999.

Headquarters and laboratories

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ANNEXES**ANNEX 1****Enrolled volunteers**

N°	VOL	AGE			
1	PAME698	37	21	ELSP047	31
2	PACA699	31	22	ROPA044	35
3	ROMI470	65	23	ELZA056	44
4	CRLU705	41	24	PAMA067	57
5	CABO441	56	25	ELSE077	52
6	NIMA410	52	26	CIBI010	52
7	VITCHI6	53	27	ANZA066	44
8	GIBA677	54	28	LOMA034	41
9	MOGI560	40	29	VASA068	35
10	ROCA554	36	30	LUMA028	39
11	BACR741	34	31	SILA060	43
12	DEBA748	36	32	ROCA045	48
13	STMI684	38	33	ISMA022	32
14	LICR740	62	34	ANBE020	40
15	ERGI544	36	35	MACE059	33
16	NAGR443	53	36	FAFR001	55
17	MAMA444	48	37	Lafa018	55
18	DOG1445	47	38	MATA062	36
19	LABE442	50	39	LARE036	60
20	ANPE440	63	40	NOLO052	33

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ANNEX 2

Inci list

Aqua, Rosa centifolia flower water, Citrus aurantium amara flower water, Alcohol denat, Polysorbate 80, Kaolin, Bisethylhexyl hydroxydimethoxy benzylmalonate, HDI/Trimethylol hexyllactone cross-polymer, Sodium polyacrylate, Potassium Cetyl phosphate, Sodium hyaluronate, Helianthus annuus seed oil, Arnica montana flower extract, Mentha piperita leaf oil, Boswellia carterii gum oil, Tocopherol, Citrus limon peel oil, Sodium bicarbonate, Silica, Limonene, Linalol, Citral

ANNEX 3

Way of use

Laboratoire Dr Paul et Karin Herzog SA

Application Protocol for efficiency test
Smoothing, Radiance, Moisturizing and Anti-spots effect



EE Express Effect

Day and Night :

Clean well your face skin (with your usual cleansing product) and then rinse well.

Apply your EE cream on the whole face and neck, in massaging in and let it act.

You can feel a fresh sensation which is normal, due to the ingredients inside this effective composition.

You can, then, apply your usual protection cream or make-up on top.

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