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CLINICAL EVALUATION OF THE OCULAR TOLERANCE OF A COSMETIC PRODUCT

- USE TEST UNDER OPHTHALMOLOGICAL CONTROL -

Draft (version 1):	**#12E0847, May 18, 2012**
Price proposal:	**#12E0847-3**
Product:	**EYELASH &EYEBROW CARE SERUM**
Galenic form:	**Transparent gel**
Packaging:	**40 transparent glass small bottles**
Application zone:	**Eyelids**
Sponsor:	**EEOSE LABORATUARLARI KOZMETIK VE ILAC. SAN Feneryolu Mah. Fahrettin Kerim Gökay Cad. No: 92 3 KADIKÖY INSTANBUL TURKEY**
Study monitor:	**Ms Eda CICEKCI**
Study site:	**DERMSCAN POLAND**
Project Manager :	**Ms Mariola FISCHBACH-KARGUL** mafi@dermscan.pl
Investigator (ophthalmologist):	**Ewa PAW**

Certified ISO 9001 : 2008

Document: 1/1
(document including 28 pages)

TABLE OF CONTENTS

CERTIFICAT DE CONTROLE QUALITE....4

RESUME DU RAPPORT D'ETUDE N°12E0847....5

SUMMARY OF THE STUDY REPORT #12E0847....6

1.AIMS....7

1.1.Primary objective....7

1.2.Secondary objective....7

2.METHODS....7

2.1.Trial period....7

2.2.Experimental plan....7

2.3.Assessment criteria....7
2.3.1.Primary criterion....7
2.3.2.Secondary criterion....7
2.3.3.Principles....8
2.3.3.1.Ocular tolerance....8
2.3.3.2.Subjective evaluation questionnaire....8

2.4.Method pertinence....8
2.4.1. Ocular tolerance....8
2.4.2.Subjective evaluation questionnaire....9

2.5.Subject selection....9
2.5.1.Number of subjects....9
2.5.2.Inclusion criteria....9
2.5.3.Non-inclusion criteria....9
2.5.4.Compliance assessment....9
2.5.5.Associated treatment during the study....10

2.6.Operational aspect....10
2.6.1.Trial schedule....10
2.6.2.Adverse Events/Serious Adverse Events....10
2.6.2.1.Definitions....10
2.6.2.2.Documentation....11
2.6.2.3.Notification....11
2.6.2.4.Follow-up....11
2.6.2.5.Occurrence of pregnancy....11
2.6.2.6.Early termination of the study....12
2.6.3.Collection and validation of data....12
2.6.4.Audit and trial monitoring visit....12
2.6.5.Quality assurance and quality control....13

2.7.Studied product....13
2.7.1.Confidentiality procedure....13

2.7.2.Storage....13
2.7.3.Reference....13
2.7.4.Aspect....13
2.7.5.Packaging....13
2.7.6.Labeling....13
2.7.7.Dosage....14
2.7.8.Application site and method....14
2.7.9.Product issue....14
2.7.10.Product future....14

2.8.Method of product attribution to the subjects....14
2.8.1.Randomization method for the application zones....14
2.8.2.Product attribution....14

2.9.Data analysis....14
2.9.1.Calculation formulas....14
2.9.2.Statistical methods....14
2.9.3.Statistical software....15

2.10.Archives....15

3.STUDY FOLLOW-UP....16

3.1.Population....16

3.2.Protocol non-adherences....16

3.3.Audit / Trial monitoring visit....16

4.SUBJECT CHARACTERISTICS....17

5.CONCOMITANT TREATMENTS....18

6.RESULTS....19

6.1.Ocular tolerance....19

6.2.Subjective evaluation questionnaire....20

7.CONCLUSION....22

8.CERTIFICATION....23

9.BIBLIOGRAPHY....24

9.1.Regulatory....24

9.2.Ocular tolerance....24

10.APPENDICES....25

10.1.Daily log (translation)....25

10.2.Subjective evaluation questionnaire....26

CERTIFICAT DE CONTROLE QUALITE

RESUME DU RAPPORT D'ETUDE N°12E0847

<table>
<tr><td colspan="2">Promoteur : EEOSE LABORATUARLARI KOZMETIK VE ILAC. SAN

Adresse :
Feneryolu Mah. Fahrettin Kerim
Gökay Cad. No: 92
3 KADIKÖY
INSTANBUL
TURQUIE</td><td colspan="3">Investigateur : DERMSCAN POLAND

Adresse :
Ul. Kruczkowskiego 12
80-288 GDANSK
POLOGNE</td></tr>
<tr><td>Titre de l'étude</td><td colspan="4">EVALUATION CLINIQUE DE LA TOLERANCE OCULAIRE D'UN PRODUIT COSMETIQUE
- TEST D'USAGE SOUS CONTROLE OPHTALMOLOGIQUE -</td></tr>
<tr><td>Produit</td><td colspan="2">Référence :
EYELASH &EYEBROW CARE SERUM.</td><td colspan="2">Forme galénique :
Gel transparent.</td></tr>
<tr><td>Dates de l'étude</td><td colspan="4">Du 23 avril 2012 au 14 mai 2012.</td></tr>
<tr><td>Objectifs</td><td colspan="4">- Evaluer la tolérance oculaire du produit étudié.
- Evaluer subjectivement ses caractéristiques, son efficacité, sa tolérance et son utilisation ultérieure.</td></tr>
<tr><td>Plan expérimental</td><td colspan="4">Etude en ouvert et en intra-individuel.</td></tr>
<tr><td rowspan="4">Critères d'évaluation</td><td rowspan="4">- Tolérance oculaire (examen clinique),

- Evaluation subjective (questionnaire).</td><td>Cinétique</td><td>J0-J21.</td></tr>
<tr><td>Méthodologie</td><td>Avant / Après.</td></tr>
<tr><td>Zone d'application</td><td>Paupières.</td></tr>
<tr><td>Fréquence d'application</td><td>Une fois par jour (le soir).</td></tr>
<tr><td rowspan="3">Population étudiée</td><td colspan="4">Nombre de volontaires analysés : 22.</td></tr>
<tr><td colspan="4">Age moyen : 33 ± 3 ans (entre 20 et 61 ans).</td></tr>
<tr><td colspan="4">Critères principaux d'inclusion :
Sexe : féminin.
Age : 18 ans ou plus.</td></tr>
<tr><td>Résultats - Conclusion</td><td colspan="4">Dans les conditions expérimentales retenues, le produit "EYELASH &EYEBROW CARE SERUM" :

• a été très bien toléré sur le plan oculaire,
• a été apprécié par les volontaires pour ses caractéristiques et pour son efficacité.

Le produit "EYELASH &EYEBROW CARE SERUM" peut porter la mention "TESTE SOUS CONTROLE OPHTALMOLOGIQUE".</td></tr>
<tr><td colspan="2">Investigateur :

Ewa PAW
Ophtalmologiste</td><td colspan="3">Date et signature :</td></tr>
</table>

SUMMARY OF THE STUDY REPORT #12E0847

Sponsor: **EEOSE LABORATUARLARI KOZMETIK VE ILAC. SAN** **Address**: Feneryolu Mah. Fahrettin Kerim Gökay Cad. No: 92 3 KADIKÖY INSTANBUL TURQUIE	**Investigator**: **DERMSCAN POLAND** **Address**: Ul. Kruczkowskiego 12 80-288 GDANSK POLAND

Study Title	**CLINICAL EVALUATION OF THE OCULAR TOLERANCE OF A COSMETIC PRODUCT - USE TEST UNDER OPHTHALMOLOGICAL CONTROL -**		
Product	**Reference:** EYELASH &EYEBROW CARE SERUM.	**Galenic form:** Transparent gel.	
Study dates	From April 23, 2012 to May 14, 2012.		
Objectives	- To evaluate the ocular tolerance of the studied product. - To evaluate, subjectively, its properties, efficacy, tolerance and the future use.		
Experimental plan	Open and intra-individual study.		
Assessment criteria	- Ocular tolerance (clinical examination), - Subjective evaluation (questionnaire).	**Kinetics**	D0-D21.
		Methodology	Before / After.
		Application zone	Eyelids.
		Application frequency	Once daily (in the evening).
Studied population	Number of subjects analyzed: 22.		
	Average age: 33 ± 3 years (between 20 and 61).		
	Main inclusion criteria: Sex: female. Age: 18 years old or above.		
Results - Conclusion	**Under these study conditions, the product "EYELASH &EYEBROW CARE SERUM":** • **was very well tolerated on the ocular level,** • **was appreciated by a majority of the subjects for its properties and for its efficacy.** **The product "EYELASH &EYEBROW CARE SERUM" can claim the label "TESTED UNDER OPHTHALMOLOGICAL CONTROL".**		

Investigator: **Ewa PAW** **Ophthalmologist**	**Date and signature:**

1. AIMS

1.1. Primary objective

The primary objective of this study was to evaluate the ocular tolerance of the product “EYELASH &EYEBROW CARE SERUM” after 21 days of use.

1.2. Secondary objective

The secondary objective of this study was to evaluate, for the studied product, the subjective appreciation of its properties, efficacy, tolerance and the future use.

2. METHODS

2.1. Trial period

Product reception at Dermscan Poland:	April 12, 2012.
Beginning of the study:	April 23, 2012.
End of the study:	May 14, 2012.
Preliminary report by e-mail:	May 18, 2012.

2.2. Experimental plan

This was an open, intra-individual study; each subject was its own control.

2.3. Assessment criteria

2.3.1. Primary criterion

Evaluation of the ocular tolerance by clinical examination by ophthalmologist in charge of the study.

2.3.2. Secondary criterion

Analysis of the subjects' answers to a subjective evaluation questionnaire.

2.3.3. Principles

2.3.3.1. Ocular tolerance

Before using the product, the ophthalmologist, using a slit lamp, clinically observed the state of the:

- cornea,
- bulbar conjunctiva,
- palpebral conjunctiva,
- eyelids,
- eye contour.

After 21 days of use, a new examination was done, by the same ophthalmologist, in order to note any change.
Evaluation of the sensations felt in intensity and duration:

- watering,
- itching of eyes and eyelids,
- tingling of eyes and eyelids,
- stinging of eyes and eyelids,
- dryness of eyes and eyelids,
- eyelid swelling.

The ocular tolerance of the product (ref: 1. 2 in §8.2) was assessed by taking into account elements reported by the subjects (functional and physical signs) and those noticed by the ophthalmologist (clinical signs). The global tolerance is defined as the least favourable result.

Unpleasant sensations were considered "relevant" if the ophthalmologist declared they were possibly, probably or certainly related to the use of the studied product. The minor signs occurred during the very first days will be considered "not relevant"; the signs occurred during the last days will be considered "relevant" as they could be the beginning of a reaction that might last in case of a longer use.

The clinical signs not related to the studied product were not taken into account for the tolerance assessment.

2.3.3.2. Subjective evaluation questionnaire

A subjective evaluation questionnaire, prepared by the clinical trial center and submitted to the sponsor, was filled in by the subjects on D21 to subjectively evaluate the properties of the studied product, its efficacy, tolerance and the future use.

2.4. Method pertinence

2.4.1. Ocular tolerance

Repeated use every day on the eyes and their contours (use test) with ocular examination provides an accurate evaluation of the tolerance and acceptance of a cosmetic product.

The clinical examination by the ophthalmologist at the beginning and at the end of the test was used to detect any signs of intolerance to the product (ocular modifications and subjective functional signs).

2.4.2. Subjective evaluation questionnaire

Answers given by the subjects to a subjective evaluation questionnaire are used to evaluate the properties, the efficacy, the tolerance and the future use of a studied product. These subjective criteria give, in particular, accurate information regarding product appreciation.

2.5. Subject selection

2.5.1. Number of subjects

The study was conducted on 20 subjects minimum, at the sponsor's request.

2.5.2. Inclusion criteria

General criteria
Healthy subject.
Subject gave its informed, written consent.
Cooperative subject, aware of the necessity and duration of controls so that perfect adhesion to the protocol established by the clinical trial center could be expected.
Specific criteria
Sex: female.
Age: 18 years old or above.

2.5.3. Non-inclusion criteria

Pregnant or nursing woman or woman planning a pregnancy during the study.
Use of topical or systemic treatment during the previous weeks liable to interfere with the assessment of the ocular tolerance of the studied product according to the investigator's advice.
Subject having an ophthalmological pathology in the six previous months (glaucoma, keratitis, conjunctivitis…).
Subject with make-up or uses some cosmetics on the days of the visit at the laboratory.
Subject wearing their contact lenses the days of the visit at the laboratory.
Excessive exposure to sunlight or UV-rays within the previous month.
Subject enrolled in another clinical trial during the study period (concerns the studied zone).
Subject, who, according to the investigator's assessment, could not follow the protocol.

2.5.4. Compliance assessment

If the protocol was not respected and if the deviation was minor, the technician or the investigator in charge of the study warned the subject of the importance of respecting the prescribed protocol. If the subject persisted or if the deviation was major, the subject was declared non-compliant. In this case, the subject was removed from the study for non-compliance.

Under normal conditions of use (utilisation of the product at home), no compliance control could be carried out during the study. However the subjects completed the daily log by indicating the number of applications.

2.5.5. Associated treatment during the study

The subjects kept their usual hygiene and care habits on the face and eyes (soap, gel, make-up and make-up remover products,...) during the study.
The studied product replaced the product usually used with the same expected effects.
No excessive exposure to sunlight or UV-rays was authorized during the study.

2.6. Operational aspect

2.6.1. Trial schedule

On D0

- The subjects came to the laboratory without applying any product on the eyes and their contour since the previous evening and without wearing their contact lenses.
- They read, signed and dated the information sheet (instructions on the product use and restrictions related to the study) and informed consent forms in duplicate. These documents were also signed and dated by the person who conducted the informed consent discussion. The subjects received a copy.
- Verification of inclusion and non-inclusion criteria.
- Initial clinical examination of the cornea, bulbar conjunctiva, palpebral conjunctiva, eyelids and eye contour of the subjects by the ophthalmologist in charge of the study.
- Distribution of the studied product to the subjects who used it once daily (in the evening) for 21 days.
- The subjects received a daily log in order to write down their potential intolerance sensations or others felt and observed during the study (see the **Appendix 10.1**).

On D21 (the last application was done the evening before the visit):

- The subjects returned to the laboratory without applying any product on the eyes and their contour since the previous evening and without wearing their contact lenses.
- The subjects brought back their daily log and the remaining product.
- New clinical examination of the cornea, bulbar conjunctiva, palpebral conjunctiva, eyelids and eye contour of subjects by the ophthalmologist in charge of the study and interrogation of the subjects about any signs of intolerance felt or observed during the study to assess the ocular tolerance.
- The subjects filled in the subjective evaluation questionnaire (see the **Appendix 10.2**).

2.6.2. Adverse Events/Serious Adverse Events

During the study, the following rules were applied:

2.6.2.1. Definitions

An Adverse Event (AE) is defined as any noxious symptom, temporarily linked to the use of a study product, occurring in a subject taking part in a clinical trial, whether or not this symptom is related to the studied product(s).

An adverse reaction is defined as any noxious and unexpected reaction that might be related to the studied product(s).
All adverse events judged, by the investigator, as being possibly, probably or certainly related to the studied product are considered as adverse reactions.

A Serious Adverse Event (SAE) is defined as an adverse event or effect that:

- results in death (note: death is the outcome, not the event),
- is life threatening,
- requires in-patient hospitalization (at least one night) or prolongation of existing hospitalization (does not include hospitalization scheduled before the inclusion),
- results in persistent or significant disability or incapacity,
- is a congenital anomaly/birth defect,
- is considered like by the investigator.

The severity/intensity of adverse events can be graded on a three-point scale:

- **Mild** or *Grade 1*: discomfort noted, but does not disturb normal daily activities.
- **Moderate** or *Grade 2*: discomfort sufficient to reduce or affect normal daily activities.
- **Severe** or *Grade 3*: inability to work or have normal daily activities.

2.6.2.2. Documentation

All Adverse Events are reported in the Case Report Form (CRF).
All concomitant treatments are reported in the CRF and the study report.
All Adverse Events related to the studied product (adverse effect) are reported in the CRF and the study report.
All Serious Adverse Events are reported in the CRF and the study report.

2.6.2.3. Notification

The investigator declares to the sponsor, by fax or e-mail, the occurrence of adverse reactions according to their severity and their unexpectedness (according to the investigator's advice).

All Serious Adverse Events will be transmitted by e-mail to the sponsor without delay, at the latest 24 hours after knowledge of their occurrence.
A SAE declaration form signed by a physician are sent, within 48 hours, by fax or e-mail with acknowledgement of receipt.

2.6.2.4. Follow-up

When an Adverse Effect persists at the end of the study, the Investigator ensures that the subject is followed up until total resolution without taking off the application of the obligations and the responsibilities of the sponsor.

2.6.2.5. Occurrence of pregnancy

The occurrence of a pregnancy (reported or diagnosed) after inclusion in the study is considered as an intercurrent event not related to the studied product(s) nor the protocol and induces the immediate dropping out of the subject.
A follow-up will be done according to the current internal procedures up to the end of the pregnancy or to its interruption.

2.6.2.6. Early termination of the study

♦ **Study exit conditions**

- In compliance with the Helsinki Declaration (1964) and its successive updates (ref: 1 to 2 in §8.1), subjects have the right to exit from the study at any time and for any motive.
- The investigator can also interrupt the subject participation in the study prematurely in the case of an intercurrent disease or adverse effect.
- The sponsor can demand that any subject be excluded from the study for major infringements to the protocol, for administrative reasons or any other motive.
- Nevertheless, premature removal of a high percentage of subjects from the study can make the study difficult or impossible to interpret. Consequently, any premature exit without valid motives should be avoided as much as possible and is carefully documented in the case report form, the final report and, if necessary, in the Adverse Event form.
- Every premature exit must be classified under one of the following headings:
- Adverse Event occurrence,
- Serious Adverse Event occurrence,
- withdrawal of consent,
- untraceable panelist,
- appearance of non-inclusion criteria,
- non-adherence to the protocol,
- other reason.

♦ **Replacement conditions**

No replacement is foreseen as 10% additional subjects are planned to be included in the study.

2.6.3. Collection and validation of data

An identification code was attributed to each subject in purpose to keep his identity confidential. This code consists of: the first three letters of the subject's name and the first two letters of his first name.

The personnel in charge of the study (technician, physician,…) added data to subject case report form and to a computerized data base.
Data were validated by Dermscan's study manager.

2.6.4. Audit and trial monitoring visit

An audit and/or trial monitoring visit might be carried out at the sponsor's request or by the appropriate regulatory authority. The aim of the monitoring visit is to verify that the study is conducted according to the determined protocol and current regulations.

2.6.5. Quality assurance and quality control

In order to ensure the conformity of the clinical trials to the study sponsor's requirement, DERMSCAN has implemented a quality management system which has been certified ISO 9001: 2008 by AFNOR certification.
This quality assurance system includes Good Clinical Practices (GCP) and regulation requirements.

Each study report is the subject of a quality control by a member of the DERMSCAN Proofreading Committee. The proofreader is chosen because he(she) is not involved in the audited study. The inspection of the study report allows to confirm that the results reflect exactly the study raw data.

A certificate of quality control, signed by the person who checked the report is enclosed in each study report to certify that the study report reflects the study raw data and fulfils any standard and regulatory requirements.

2.7. Studied product

2.7.1. Confidentiality procedure

The products supplied by the sponsor were encoded.

2.7.2. Storage

Before the beginning of the study, the products were kept at room temperature in a dedicated room. This room was locked and access controlled.

2.7.3. Reference

EYELASH &EYEBROW CARE SERUM**.**

2.7.4. Aspect

Transparent gel.

2.7.5. Packaging

40 transparent glass small bottles.

2.7.6. Labeling

Example of translation of labeling of each product by the clinical trial center:

DERMSCAN Badanie nr	DERMSCAN Study #
Nr Ochotnika: …… W naglej potrzebie: ……	Subject#:…… Emergency telephone number: ……...
Warunki przechowywania: ……	Conservation: ……..
Przechowywac z dala od dzieci. Stosowac pod kontrola medyczna tylko dla potrzeb badania.	Keep out of reach of children. For clinical trial: to be used only under strict medical supervising.

2.7.7. Dosage

Once daily (in the evening) during 21 days.

2.7.8. Application site and method

- Application site: eyelids
- Application method: apply a small amount of the product with an included applicator on the eyelids close to bottom of the eyelashes.

2.7.9. Product issue

The products were delivered to the subjects by the technician in charge of the study with an explanation of the application conditions.

2.7.10. Product future

A sample of the studied product will be kept by the laboratory for a period of one year after the sending of the report.
By default, the remaining products will be destroyed according to the current internal procedures.

2.8. Method of product attribution to the subjects

2.8.1. Randomization method for the application zones

Not applicable.

2.8.2. Product attribution

Not applicable. All the subjects received the same reference of product.

2.9. Data analysis

2.9.1. Calculation formulas

Not applicable.

2.9.2. Statistical methods

Only the descriptive statistic (Mean, SEM,…) were realized.

2.9.3. Statistical software

The software used was EXCEL 10.1.

2.10. Archives

Data will be securely archived digitally and on paper for ten years from the date of dispatch of the final report. At the end of this period, the study archives will be destroyed unless otherwise stipulated in writing by the sponsor.

All the documents related to this study are archived during one year maximum at Dermscan before being sent to the company PIKA Sp. z o.o. (ul. Matejki 11, 80-283, Gdansk, POLAND).

3. STUDY FOLLOW-UP

3.1. Population

	Number of subjects		
	Included subjects	**Subjects who completed the study**	**Analyzed subjects**
Ocular tolerance / Questionnaire	*22*	*22*	*22*

3.2. Protocol non-adherences

No protocole non-adherence took place during the study.

3.3. Audit / Trial monitoring visit

No monitoring visit took place.

4. SUBJECT CHARACTERISTICS

The table below presents the observations concerning the subjects included to the study.

Subject	Last name	First name	Age	Sex	Phototype	Sensitive eyes	Contact lenses wearer	Comments	Inclusion date	End date
1	ZIM	IW	46	F	III	No	No	None	April 23, 2012	May 14, 2012
2	OST	BO	56	F	II	No	No	None	April 23, 2012	May 14, 2012
3	BIS	IW	30	F	I	Yes	No	None	April 23, 2012	May 14, 2012
4	GOŚ	MA	34	F	III	Yes	No	None	April 23, 2012	May 14, 2012
5	BOJ	MA	22	F	II	No	No	None	April 23, 2012	May 14, 2012
6	BUD	KA	24	F	II	Yes	Yes	None	April 23, 2012	May 14, 2012
7	SCH	KA	24	F	I	Yes	No	None	April 23, 2012	May 14, 2012
8	JAN	KA	23	F	III	Yes	No	None	April 23, 2012	May 14, 2012
9	SKU	MA	21	F	II	No	Yes	None	April 23, 2012	May 14, 2012
10	BAC	EW	20	F	I	No	No	None	April 23, 2012	May 14, 2012
11	GŁU	JA	61	F	II	No	No	None	April 23, 2012	May 14, 2012
12	KŁO	KA	22	F	II	No	No	None	April 23, 2012	May 14, 2012
13	BOR	AG	35	F	II	Yes	Yes	None	April 23, 2012	May 14, 2012
14	KUL	EL	58	F	III	Yes	No	None	April 23, 2012	May 14, 2012
15	SMU	MA	23	F	III	Yes	No	None	April 23, 2012	May 14, 2012
16	MYS	JO	39	F	III	Yes	Yes	None	April 23, 2012	May 14, 2012
17	KOZ	IR	52	F	II	No	No	None	April 23, 2012	May 14, 2012
18	KUR	BA	22	F	II	Yes	No	None	April 23, 2012	May 14, 2012
19	LUB	LU	22	F	II	Yes	No	None	April 23, 2012	May 14, 2012
20	RAD	MA	49	F	II	No	No	None	April 23, 2012	May 14, 2012
21	KAS	MA	22	F	II	Yes	No	None	April 23, 2012	May 14, 2012
22	KOT	MA	23	F	III	Yes	No	None	April 23, 2012	May 14, 2012

Moyenne	**33**	**F**	22	**I**	3	**Yes**	13	**Yes**	4
Médiane	24	**M**	0	**II**	12	**No**	9	**No**	18
Minimum	20			**III**	7				
Maximum	61			**IV**	0				
SEM	3								
IC 95%	6								

Legend: F: female
M: male

5. CONCOMITANT TREATMENTS

The table below presents the treatment taken by the subjects during the study.

Subject	Last name	First name	Medication (sales name)	Indication	Start date	End date or ongoing
1	ZIM	IW	None	None	None	None
2	OST	BO	None	None	None	None
3	BIS	IW	None	None	None	None
4	GOŚ	MA	None	None	None	None
5	BOJ	MA	None	None	None	None
6	BUD	KA	None	None	None	None
7	SCH	KA	None	None	None	None
8	JAN	KA	None	None	None	None
9	SKU	MA	None	None	None	None
10	BAC	EW	Luteina®	menstrual disorders	April 30, 2012	May 5, 2012
11	GŁU	JA	None	None	None	None
12	KŁO	KA	None	None	None	None
13	BOR	AG	None	None	None	None
14	KUL	EL	None	None	None	None
15	SMU	MA	Flondan®	allergy with pollens	May 1, 2012	May 1, 2012
16	MYS	JO	Efferalgan Codeine®	headache	May 13, 2012	May 13, 2012
			Tramal®	headache	May 13, 2012	May 14, 2012
17	KOZ	IR	None	None	None	None
18	KUR	BA	None	None	None	None
19	LUB	LU	None	None	None	None
20	RAD	MA	None	None	None	None
21	KAS	MA	Ibuprom®	menstrual pain	May 3, 2012	May 5, 2012
22	KOT	MA	None	None	None	None

6. RESULTS

6.1. Ocular tolerance

The individual results are presented in the table below (eventual relevant signs are in bold type):

Subject #	Signs reported by the subject		Clinical signs observed on D21
	Functional signs	Physical signs	
1	None	None	None
2	None	None	None
3	None	None	None
4	None	None	None
5	Slight itching of the eyelids five minutes after the product aplication during 30 minutes on D0 (possible imputability).	None	None
6	None	None	None
7	None	None	None
8	None	None	None
9	None	None	None
10	None	None	None
11	None	None	None
12	None	None	None
13	None	None	None
14	None	None	None
15	None	None	None
16	None	None	None
17	None	None	None
18	None	None	None
19	None	None	None
20	None	None	None
21	None	None	None
22	None	None	None

After 21 days of use, one subject (#5) reported functional sign judged not relevant. However, no clinical signs were observed on D21.

Under these study conditions, the product "EYELASH &EYEBROW CARE SERUM" was very well tolerated on the ocular level.

6.2. Subjective evaluation questionnaire

The subjects' answers to the subjective evaluation questionnaire are presented in the **Appendix 9.2**.
To be easier to read, the percentages were rounded off. The sum of these percentages may be different from 100%.
In this study (n= 22), one subject represents 4.5%.
A synthesis of the answers is presented in the following tables.

AFTER 21 DAYS OF USE	
GLOBAL APPRECIATION OF THE PRODUCT AND ITS PROPERTIES	
General appreciation	**77%**
Very pleasant	18%
Pleasant	59%
Aspect	**95%**
Very pleasant	50%
Pleasant	45%
Texture	**95%**
Very pleasant	50%
Pleasant	45%
Color	**86%**
Very pleasant	59%
Pleasant	27%
Fragrance	**77%**
Very pleasant	41%
Pleasant	36%
Easy application	**87%**
Agree	64%
Agree somewhat	23%

PRODUCT'S EFFICACY	
Improved eyelashes condition	**68%**
Stimulated eyelashes growth	**59%**
Strengthened eyelashes	**77%**
Agree	50%
Agree somewhat	27%
Thicker eyelashes	**54%**
Agree	36%
Agree somewhat	18%
Longer eyelashes	**41%**
Agree	14%
Agree somewhat	27%
More nourished eyelashes	**90%**
Agree	45%
Agree somewhat	45%
Softer eyelashes	**87%**
Agree	32%
Agree somewhat	55%
More supple eyelashes	**95%**
Agree	27%
Agree somewhat	68%
Eyelashes with more volume	**50%**
Agree	18%
Agree somewhat	32%
Eyelashes do not fall out	**91%**
Agree	36%
Agree somewhat	55%
TOLERANCE	
Ocular irritation sensations	**5%**
FUTURE USE OF THE PRODUCT	
Would like to continue to use the product	**64%**
Would like to buy the product	**59%**

7. CONCLUSION

The primary objective of this study was to evaluate the ocular tolerance of the product “EYELASH &EYEBROW CARE SERUM” after 21 days of use.

The secondary objective of this study was to evaluate for the studied product, the subjective appreciation of its properties, efficacy, tolerance and the future use.

Study conditions:

<table>
<tr><td>Product</td><td colspan="2">Reference:
EYELASH &EYEBROW CARE SERUM.</td><td>Galenic form:
Transparent gel.</td></tr>
<tr><td>Experimental plan</td><td colspan="3">Open and intra-individual study.</td></tr>
<tr><td rowspan="4">Assessment criteria</td><td rowspan="4">- Ocular tolerance (clinical examination),
- Subjective evaluation (questionnaire).</td><td>Kinetics</td><td>D0-D21.</td></tr>
<tr><td>Methodology</td><td>Before / After.</td></tr>
<tr><td>Application zone</td><td>Eyelids.</td></tr>
<tr><td>Application frequency</td><td>Once daily (in the evenig).</td></tr>
<tr><td rowspan="3">Studied population</td><td colspan="3">Number of subjects analyzed: 22.</td></tr>
<tr><td colspan="3">Average age: 33 ± 3 years (between 20 and 61).</td></tr>
<tr><td colspan="3">Main inclusion criteria:
Sex: female.
Age: 18 years old or above.</td></tr>
</table>

Under these study conditions, the product "EYELASH &EYEBROW CARE SERUM":

- **was very well tolerated on the ocular level,**
- **was appreciated by a majority of the subjects for its properties (pleasant general appreciation, aspect, texture, color and fragrance, easy application) and for its efficacy (the product leaves the eyelashes strengthened, more nourished, softer, suppler and not falling out).**

The product "EYELASH &EYEBROW CARE SERUM" can claim the label "TESTED UNDER OPHTHALMOLOGICAL CONTROL.

8. CERTIFICATION

The study was conducted according to Helsinki Declaration (1964) and its successive updates. Data were obtained using the study protocol, current internal procedures and in the spirit of the note for guidance on Good Clinical Practice CPMP / ICH / 135 / 95, January 1997 (ref: 1 and 2 in §8.1).

Any modifications are the sole responsibility of the author of the modification, whether he/she is acting for the sponsor or independently. Any partial or total reproduction of this study report requires prior written agreement from Dermscan.

This study was totally performed under the responsibility of Dermscan.

The quality system of Dermscan is certified ISO 9001: 2008.

All the observations and numerical data collected throughout the study are reported in this document. We certify that these data are in accordance with the obtained results.

Date and signature:

Name **Ewa PAW**
Function Ophthalmologist

Date and signature:

Name **Mariola FISCHBACH-KARGUL**
Function Project Manager

9. BIBLIOGRAPHY

9.1. Regulatory

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2. WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI/ Ethical Principles for Medical Research Involving Human Subjects- Helsinki Declaration (1964) and its successive updates.

9.2. Ocular tolerance

1. RIGAL D. et coll./ L'épithélium cornéen- Rapport de la société française d'ophtalmologie, 1993.

2. LIOTET S. et coll./ L'œil sec- Rapport de la société française d'ophtalmologie, 1987.

10. APPENDICES

10.1. Daily log (translation)

KARTA BIEŻĄCEJ OBSERWACJI (miejscowo) / *DAILY LOG*

PONIŻSZA TABELA MUSI BYĆ WYPEŁNIANA KAŻDEGO DNIA / *THIS TABLE MUST BE COMPLETED EVERY DAY*

W przypadku dyskomfortu i/lub nietolerancji, prosimy zanotować **objaw** (ściąganie, mrowienie, swędzenie, pieczenie,…), **miejsce**, **intensywność** (lekkie, średnie, ostre, bardzo ostre), **czas trwania** oraz czas pojawienia się od momentu użycia produktu (zaraz po aplikacji, 5 min po aplikacji …)
***In case of discomfort and/or intolerance**, please note the **nature** (skin tension, stinging, itching, burning sensations,…), the **zone**, the **intensity** (slight, moderate, severe, very severe) and **duration** of these sensations as well as the time of appearance regarding product application (immediately after application, 5 minutes after…)*

DZIEŃ *DAY*	DATA *DATA*	ILOSC UŻYĆ PRODUKTU NA DZIEŃ / *Number of use per day*	ODCZUWALNY DYSKOMFORT I/LUB OZNAKI NIETOLERANCJI */ DISCOMFORT AND/OR INTOLERANCE SENSATIONS FELT*	UŻYCIE LEKÓW (dlaczego?, jaki?, jaka dawka?, jak długo?) *MEDICATION (why?, which one? which dosage? how long?)*
D0			☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:*	☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:* .....
D1			☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:*	☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:* .....
D2			☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:*	☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:* .....
D3			☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:*	☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:* .....
D4			☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:*	☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:* .....
D5			☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:*	☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:* .....
D6			☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:*	☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:* .....
D7			☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:*	☐ NIE / *NO* ☐ TAK / *YES* Jeśli tak, opisać/ *if yes, define:* .....

…/…
D21

10.2. Subjective evaluation questionnaire

To be easier to read, the percentages were rounded off. The sum of these percentages may be different from 100%.
In this study, one subject (n=22) represents 4.5%.

APRES 21 JOURS D'UTILISATION */ AFTER 21 DAYS OF USE*

APPRECIATION GLOBALE ET CARACTERISTIQUES DU PRODUIT /
GENERAL APPRECIATION OF THE PRODUCT AND ITS PROPERTIES

1. Quelle est votre appréciation globale de ce produit ? */ What is your general appreciation of this product?*

très agréable / *very pleasant*	agréable / *pleasant*	ni agréable ni désagréable / *neither pleasant nor unpleasant*	désagréable / *unpleasant*	très désagréable / *very unpleasant*
18%	59%	18%	5%	0%

Que pensez-vous de ce produit ? */ What do you think about this product?*

	très agréable / *very pleasant*	agréable / *pleasant*	ni agréable ni désagréable / *neither pleasant nor unpleasant*	désagréable / *unpleasant*	très désagréable / *very unpleasant*
2. son aspect */ its aspect*	50%	45%	5%	0%	0%
3. sa texture */ its texture*	50%	45%	5%	0%	0%
4. sa couleur */ its color*	59%	27%	14%	0%	0%
5. son parfum */ its fragrance*	41%	36%	23%	0%	0%

Qu'avez-vous pensé de l'utilisation de ce produit ? */ What did you think about the use of this product?*

	d'accord / *agree*	plutôt d'accord / *agree somewhat*	plutôt pas d'accord / *disagree somewhat*	pas d'accord / *disagree*
6. application facile */ easy application*	64%	23%	5%	9%

EFFICACITE DU PRODUIT APRES 21 JOURS D4APPLICATION */ PRODUCT EFFICACY AFTER 21 DAYS OF USE*

7. Trouvez-vous que le produit a amélioré l'état de vos cils ? */ Do you find the product improved the condition of your lashes?*

oui / *yes*	68%
non / *no*	32%

8. Trouvez-vous que le produit stimulait la croissence de vos cils ? */ Do you find the product stimulated the growth of your lashes ?*

oui / *yes*	59%
non / *no*	41%

Quel est votre avis concernant l'état et l'aspect des vos cils, après 21 jours d'utilisation quotidienne ? */ What is your opinion concerning your lashes state after 21 days of once-daily use?*

	d'accord/ *agree*	plutôt d'accord/ *agree somewhat*	plutôt pas d'accord / *disagree somewhat*	pas d'accord / *disagree*
9. cils renforcés */ strengthened eyelashes*	50%	27%	23%	0%
10. cils plus épais */ thicker eyelashes*	36%	18%	45%	0%
11. cils plus longs */ tlonger eyelashes*	14%	27%	50%	9%
12. cils plus nourris */ more nourished eyelashes*	45%	45%	9%	0%
13. cils plus doux */ softer eyelashes*	32%	55%	9%	5%
14. cils plus souples */ more supple eylashed*	27%	68%	5%	0%
15. cils avec plus de volume */ eyelashes with more volume*	18%	32%	41%	9%
16. les cils ne chute pas */ eyelashes do not fall out*	36%	55%	9%	0%

TOLERANCE / *TOLERANCE*

17. Au cours de cette utilisation, avez-vous eu des sensations d'irritation oculaire ? / *During this study, did you feel any ocular irritation sensations ?*

oui / *yes*	5%
non / *no*	95%

Si oui, veuillez voir §6.1.*/ If yes, please see §6.1.*

18. L'utilisation a-t-elle été interrompue ? *I Did you stop using this product*?

oui / *yes*	0%
non / *no*	100%

Si oui, durée de l'interruption */ If yes, how long did you stop for?* ----------

Si elle a été interrompue, l'a-t-elle été */ If you stopped, what was the reason?*

19. Suite à une réaction d'intolérance ? *I Because of an intolerance reaction*?

oui / *yes*	0%
non / *no*	0%

20. Pour d'autres raisons ? *I For other reasons?*

oui / *yes*	0%
non / *no*	0%

Si oui, précisez */ If yes, why ?*: ----------

UTILISATION ULTERIEURE DU PRODUIT / *FUTURE USE OF THE PRODUCT*

21. Souhaiteriez-vous poursuivre l'utilisation de ce produit ? *I Would you like to continue to use this product?*

oui / *yes*	64%
non / *no*	36%

22. A l'issue de cette étude achèteriez-vous ce produit (indépendamment de son prix) ? *I At the end of this study would you like to buy this product (regardless of the price)?*

oui / *yes*	59%
non / *no*	41%

Commentaires : *I Comments*

Subject #	Comments
1	The eyelashes are more nourished and look better.
4	The eyelashes are nourished well and eyes were not swollen.
5	I am satisfied with the tested product. The eyelashes' condition is improved.
10	I would change the application's method.
12	Pleasant product.
15	Unpleasant and difficult application.
16	I would buy the product if my eyelashes were in very bad condition. I prefer to use the mascara for making the eyelashes thicker and longer.
19	Difficult application. No improvement.