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STUDY REPORT

These results concern only the samples tested in the laboratory which are defined here after.
The samples will be kept in our premises during 2 months from the date mentioned below.
The sample and the information regarding sample have been provided by the client. All information related to the sample are under liability of the client and have not been checked by the Eurofins ATS company.

CALYPSO MARKETING S.A.
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B1310 La Hulpe
BELGIUM

15/02/2017

EVALUATION OF THE LASTING OF AN EYELINER, BY IMAGE ANALYSIS UNDER UNCONTROLLED AND CONTROLLED CONDITIONS OVER A 24-HOUR PERIOD IN THE FEMALE ADULT SUBJECT: SINGLE USE TEST

Study sponsor: **Philippe NEVE, CALYPSO MARKETING S.A.**

Quotation n°: **2016/47749/v1**

Study manager: **Elise ABRIC**

Tested product:

- Name: eyeliner brown
- Product code: E136A-210814SP
- ATS reference: 601207
- Brand: -
- Product type: eyeliner

Study n°: **015TUE10V24H17**

The copy of this report is only authorized by unabridged edition.
It is made of 18 pages.

AUTHENTICITY OF THE STUDY REPORT

The study concerned by this report was carried out under my responsibility, according to the experimental protocol, the quality plan of EUROFINS ATS laboratory, and in accordance with the good clinical practices.
All observations and data taken during this study are reported in this report.

Study Manager, Elise ABRIC

I certify the rereading of this report and I agree with its content,

Quality Assurance Reader, Marion PAWLUK

STUDY SUMMARY

EVALUATION OF THE LASTING OF AN EYELINER, BY IMAGE ANALYSIS UNDER UNCONTROLLED AND CONTROLLED CONDITIONS OVER A 24-HOUR PERIOD IN THE FEMALE ADULT SUBJECT: SINGLE USE TEST

- **Tested product:** eyeliner brown, referenced E136A-210814SP

- **Study sponsor:** Philippe NEVE, CALYPSO MARKETING S.A.

- **Objective:** The aim of the study is to evaluate the lasting of an eyeliner after a single and standardized application to the eyelids, over a 24-hour period, under uncontrolled and controlled conditions, in the female adult healthy subject.

- **Place of the study:** EUROFINS ATS,
  505 rue Louis Berton
  CS 50550
  13594 Aix en Provence Cedex 3
  France

- **Study dates:** from 18/01/2017 to 19/01/2017

- **Method:**

✓ ***Directions for use:***

Application of the eyeliner:

The application is carried out at the investigational center. The product is applied to both eyelids, by a beautician in a quantity enabling make-up detection by image analysis (thick line).

✓ ***Assessment methods:***

➢ **Environmental conditions:**

Controlled conditions:

During 12 hours (from Timm to T12hrs), subjects stay in a room under controlled temperature (23°C +/- 2°C). Besides, the hygrometry is registered but not controlled.

Uncontrolled conditions:

After the assessment at T12hrs the study goes on out of the investigating center under real conditions without any temperature or hygrometry control until the T24hours.

Before T24hours measurement time, the subjects stay about 15 minutes in a room under controlled temperature (23°C +/- 2°C). Besides the hygrometry is registered but not controlled.

➢ **Pictures acquisition**

Front face pictures (closed eyes) are taken under crossed-polarized light (CPL) with the VISIA CR® imaging system immediately after application of the product (Timm), then 12 hours (T12hrs) and 24 hours (T24hrs) later.

➢ **Pictures analysis**

For each subject, a region of interest is delimited to the thick line of make-up. CPL-Pictures are then treated with the Kalliste® imaging software measuring the surface area A(TX) covered with product in the region of interest.

✓ ***Panel:***

10 healthy female adult volunteers aged from 30 to 55 years old.
For 2 volunteers (n°05 and 07) the analysis was performed on one eye only because the other eye was judged non-exploitable.
The assessment of the lasting until 24 hours after application was performed on 10 volunteers.

♦ **Results:**

- Assessment of the lasting by image analysis:

The mean decrease of the detected make-up area in the ROI (region of interest), at each kinetic, is presented in the following table.

Kinetic (Tx)	Surface decrease (Tx-Ti) – (%)
12hrs	-12.6%
24hrs	-19.8%

The results of the image analysis allow highlighting a satisfying lasting 12 hours after the application of the product on the basis of instrumental measurements.

24 hours after the application of the product, the results of the image analysis allow highlighting a satisfying lasting on the basis of instrumental measurements even if the overall satisfaction rate at this time is to be noticed, quite low.

♦ **Conclusion:**

In the experimental conditions, the results of the image analysis with Kalliste® software obtained on 10 healthy female adult volunteers, aged from 30 to 55 years old, allow to highlight a satisfying lasting of the eyeliner brown product, referenced E136A-210814SP, 24 hours after application, under controlled and uncontrolled conditions.

TABLE OF CONTENT

1 OBJECTIVE

The aim of the study is to evaluate the lasting of an eyeliner after a single and standardized application to the eyelids, over a 24-hour period, under uncontrolled and controlled conditions, in the female adult healthy subject, aged from 18 to 60 years old.

2 METHODOLOGY

	Controlled conditions			Uncontrolled conditions
	T0	Timm	T12hrs	T24hrs
Informed consent signature	X			
Checking inclusion Criteria / non-inclusion Criteria	X			
Final inclusion	X			
Product application by a beautician	X			
Pictures with VISIA CR® imaging system		X	X	X

3 ETHIC AND REGULATORY CONSIDERATIONS CONCERNING PROTECTION OF PERSONS

3.1 Legislative and regulatory references

The French law relative to the Public Health n° 2004-806 of August 9, 2004 (articles 88 to 97) applied by the French Decree n° 2006-477 of April 26, 2006 for the research integrates the dispositions regarding the biomedical researches and replaces the French law of December 20, 1988 relative to the protection of persons who take part in biomedical researches called Law “Huriet-Serusclat". All tests carried out within EUROFINS ATS, even if they are not submitted to this law, are carried out according to this law.
The studies are carried out according to the most recent recommendations of the World Medical Association (Helsinki Declaration 1964, in its current version), and to the AFSSAPS recommendations relative to the biomedical researches on cosmetic products entering in the application field of the French law relative to the Public Health n° 2004-806 of August 9, 2004.
However, no information is sent to the national folder of people who takes part in biomedical research and the opinion of the “Committee of Persons Protection” is not asked.
The studies follow the *“Guidelines for the Evaluation of the Efficacy of cosmetic Products”,* COLIPA, May 2008.

3.2 Ethic considerations

The ethic requirements, necessary to studies on Human, are respected:

- ✓ The volunteers are selected according to inclusion and non inclusion criteria.
- ✓ All volunteers are informed of the aim and the type of the study, of the possible risks they are taken by participating in this study and give their free and informed consent before the beginning of the study.
- ✓ Before volunteers are exposed to the product to be tested, minimum information regarding the safety of the product is asked to the sponsor.
- ✓ All care is taken in order to avoid excessive skin reactions or undesired effects on the volunteers' health during the study.
- ✓ Safety procedures are taken in case of bad reactions.
- ✓ The volunteers are paid in compensation for the time spent and the risks due to the study.

3.3 Confidentiality

The complete data regarding the health of the volunteers, collected during their final admittance in the volunteers database of EUROFINS ATS and necessary when recruiting and selecting them for the studies, are strictly confidential and submitted to the medical secret according to the article 4 of the "*Medical Ethics Code"* (R 4127-4 of the "Public Health Code", in its current version). The anonymity of the volunteers is respected within all studies carried out in our laboratories. However, each volunteer can be easily identified by the Investigator, the doctors and all the persons in charge of the study, thanks to its personal volunteer's code.
According to the article R. 5121-13 of the *"Public Health Code"*, in its current version, the product type studied, the trials, the volunteers, and the results are strictly confidential and the secret is respected by the Investigators and all the persons working with him.
EUROFINS ATS ensures not to divulge all the data and results collected during a study.
Treatment of personal data is declared to CNIL.

3.4 Archiving

All data related to the study will be stored in the archives of EUROFINS ATS (505 rue Louis Berton – CS 50550 - 13594 Aix-en-Provence Cedex 3 - France) and at a service provider's, Société Générale d'Archives (ZI Les Estroublans - 49 boulevard de l'Europe – 13127 VITROLLES), for 10 years.
At the end of this period, the study sponsor will have to specify whether the data related to the study should be thrown away or restored to him. Eurofins ATS can also consider extending the storage period of these documents, at the study sponsor's expenses.

4 QUALITY CONTROL AND INSURANCE

In order to meet client expectations and legal and regulatory requirements, EUROFINS ATS established all necessary resources for the management of its structural organizations and methods. With a constant client satisfaction policy, EUROFINS ATS chooses to follow the ISO 9001 requirements in order to establish the company organisation.

In this direction, this study was carried out in accordance with the procedures defined in the quality system. In order to insure results reliability, quality auto-controls are made all through the process.
Thus, during this study, all the documents, materials, environment and raw data were checked in order to avoid deviations from the protocol.

In the same way, under quality policy, the clinical tests laboratory is audited every year in order to assess that the procedures and instructions are well applied and to check their conformity with our internal requirements and process efficiency.

5 STUDIED PANEL

5.1 Number of volunteers

The product was tested on 10 volunteers. The study was carried out in open.

5.2 Recruitment, selection and final admittance of volunteers for a study

All volunteers recruited in this study come from the volunteers' data base of EUROFINS ATS, and answer the inclusion and non inclusion criteria presented in the paragraphs below.
Their final admittance was determined by the investigator from the answers given in a pre-study questionnaire and after a preliminary interview. During this interview, the following information are explained to the volunteers: title, objective, protocol, planning of the study, payment methods, as well as the possible effects expected and the study constraints. The admittance of the volunteers is validated by the signature of the Information Note and a free and informed consent, by the investigator and the volunteers.

5.3 Inclusion criteria

The volunteers corresponding to the following criteria are included:

- ✓ Healthy female subject.
- ✓ Age 18 to 60 years old included.
- ✓ Phototype (Fitzpatrick): I to IV.
- ✓ Face skin type: indifferent.
- ✓ Subject having received the information about the study modalities and having given his/her written consent and having signed the “informed consent form” specific for this study, in accordance with the corresponding procedure.
- ✓ Subject affiliated to a social security system according to the article L1121-11 from Public Health Code applying on biomedical research.
- ✓ Cooperative subject willing to comply with the study requirements.
- ✓ Women declaring committing themselves to use effective contraceptive method before and throughout the study (for the women of childbearing potential).
- ✓ Subject agreeing not to use any other cosmetic product or water to the face skin until the end of study.
- ✓ Certifying and signing not to take part in another clinical study in another investigating center in accordance with corresponding procedure.
- ✓ Certifying in writing the truth of the personal information declared to investigators.
- ✓ Free to ensure all the visits to the investigating center.

5.4 Non inclusion criteria

- ✓ Subject with wrinkles to eyelids or droopy eyelids.
- ✓ Subject with permanent make-up on the eyelids.
- ✓ Subject with personal history of allergy and/or particular reactivity to make-up products.
- ✓ Subject who has taken a drug containing lithium, corticoids, during the last month; anti-histaminic, anti-fungal, non-steroidal anti-inflammatory or immunosuppressive drugs during the last 7 days.
- ✓ Subject exposed to the sun or UV rays in an excessive way during the last month (according to the investigator).
- ✓ Subject with cutaneous affection of the face (psoriasis, atopic dermatitis, seborrheic dermatitis…).

- ✓ Subject affected by serious, non-stabilized or evolutive disease (according to the investigator) as diabetes, hypertension, hypothyroidism or hyperthyroidism which may influence the evolution of studied cutaneous state and morphology.
- ✓ Subject affected by serious pathology (cancer, immune-depressed)
- ✓ Subject who has undergone a surgical operation in the previous month of the study or having planned it during the study.
- ✓ Pregnancy or breastfeeding during the last 6 months, ongoing or planned during the study
- ✓ Subject placed in a social or sanitary establishment
- ✓ Subject deprived of liberty by adjunction or by official decision.
- ✓ Subject under legal protection or without the right to express her consent.
- ✓ Subject who is participating or who has participated to a clinical study for which exclusion period is not finished.
- ✓ Subject having applied a cosmetic to the eyelids in the morning of the study.

5.5 Banning and restrictions

For the whole length of the study, it was asked to volunteers:

- Not to take aspirin, anti-histamines, corticoids or anti-inflammatories that could interfere with the test results.
- Not to touch nor rub their eyes.
- Not to practice sport during the study.
- To respect of the date and hour of visits to the investigating center.
- Not to apply any product or water to the face skin and eyes during the whole study.
- Subject agreeing to sleep on the back before the T24hrs assessment.

5.6 Volunteers withdrawal

Volunteers may be excluded from the study for the following reasons:

- ✓ They no longer follow the requirements and constraints of the study, explained during the signing of the consent,
- ✓ They no longer wish to participate in the study.

6 TESTED PRODUCT

✓ Product name:	eyeliner brown
✓ Reference:	E136A-210814SP
✓ ATS reference:	601207
✓ Presentation (galenic, colour):	Brown pen
✓ Packaging:	Plastic pack
✓ Number of samples received:	25
✓ Use by date:	-
✓ Storage conditions:	room temperature, away from light and heat.

A sample of the tested product is kept in EUROFINS ATS laboratory, during 2 months after the end of the study. After this date and except contrary order from the study sponsor, the product will be destroyed.

7 CLINICAL STUDY

7.1 Environmental conditions

Controlled conditions:
During 12 hours (from Timm to T12hrs), subjects stay in a room under controlled temperature (23°C +/- 2°C). Besides, the hygrometry is registered but not controlled.

Uncontrolled conditions:
After the assessment at T12hrs the study goes on out of the investigating center under real conditions without any temperature or hygrometry control until the T24hours.

Before T24hours measurement time, the subjects stay about 15 minutes in a room under controlled temperature (23°C +/- 2°C). Besides the hygrometry is registered but not controlled.

7.2 Applying

Application of the eyeliner:
The application is carried out at the investigational center. The product is applied to both eyelids, by a beautician in a quantity enabling make-up detection by image analysis (thick line).

7.3 Study protocol

2 weeks before D0:

- ✓ Selection of the volunteers by the data base, an appointment is taken.

D0:

- ✓ The day of the study, volunteers came at the laboratory, with no make-up nor cosmetic product on the face,
- ✓ Welcoming of the volunteers, signature of the information and consent form, by the volunteers and the Investigator.
- ✓ The beautician checks the inclusion criteria on each volunteer.
- ✓ Application of the product at the laboratory by a beautician, according to the directions of use predefined with the study sponsor.
- ✓ Pictures of the volunteers' face are taken under cross-polarized light with the VISIA CR® system immediately after the application (Timm) and 12 hours (T12hrs) after the application.

D1:

- ✓ Welcoming of the volunteers.
- ✓ Pictures of the volunteers' face are taken under cross-polarized light with the VISIA CR® system 24 hours (T24hrs) after the application.

7.4 Clinical assessments of the lasting efficacy

Standardized pictures and treatment before analysis

Front face pictures (closed eyes) under crossed-polarized light (CPL), with the VISIA CR® imaging system (Canfield), before (T0), immediately after application of the product (Timm), 12 hours (T12hrs), and 24 hours (T24hrs) later.

Pictures are taken in the following standard and reproducible conditions:

- A headband is placed around the subjects' head to clear the face.
- Subjects wear a black cape.
- The VISIA CR® photo station is a device which allows obtaining high resolution standardized digital images of subjects' face.
- The VISIA CR® photo station fitted with a chin and forehead wedge, helps the subjects to position themselves.
- The Mirror® software (Canfield) allows showing by transparency the reference picture (T0), in order to re-position the subjects' face the best for each measurement time.

- The Colorskin® imaging software (Newtone technologies) allows adjusting the pictures spatially by taken checking points on the reference's image (T0).

Image analysis with the Kalliste® software

For each subject, a region of interest is delimited to the thick line of make-up on both eyes. CPL-Pictures are then treated with the Kalliste® imaging software measuring the surface area A(TX) covered with product in the region of interest.

7.5 Data analysis and results interpretation

Surface area covered

The lasting classification is determined according to the decrease variations of the detected surface area of make-up at each kinetic. Conclusions regarding the quality of the lasting are drawn based on the investigating team experience and history, including an overall analysis of the results obtained by image analysis.

8 RESULTS

8.1 Description of the panel

This study was carried out from 18/01/2017 to 19/01/2017 and includes 10 healthy female adult volunteers, whom characteristics are presented in *table 1:*

Table 1: Volunteers characteristics and events that occurred during the study

VOL	VOL CODE	Gender	Age (years)	No wrinkles to eyelids or droopy eyelids	Events occurred during the study
1	CHAMO	F	33	Yes	-
2	BELIS	F	46	Yes	-
3	SOUHA	F	34	Yes	-
4	DERMU	F	55	Yes	-
5	BAADJ	F	52	Yes	-
6	FAGMA	F	36	Yes	-
7	PESCA1	F	38	Yes	-
8	EL IB	F	53	Yes	-
9	HADNO	F	60	Yes	Excluded from the study on D0Timm (migration of the product after application)
10	ANDCH1	F	30	Yes	-
11	BARVÉ1	F	32	Yes	-
Average			43		

None of the volunteers selected took a treatment contraindicated with the study.

8.2 Study exits

10 healthy female adult volunteers participated to this study.
For 2 volunteers (n°05 and 07) the analysis was performed on one eye only because the other eye was judged non-exploitable.
The assessment of the lasting until 24 hours after application was performed on 10 volunteers.

8.3 Results analysis

- Assessment of the lasting by image analysis:

The mean decrease of the detected make-up area in the ROI (region of interest), at each kinetic, is presented in the following table.

Kinetic (Tx)	Surface decrease (Tx-Ti) – (%)
12hrs	-12.6%
24hrs	-19.8%

The results of the image analysis allow highlighting a satisfying lasting 12 hours after the application of the product on the basis of instrumental measurements.

24 hours after the application of the product, the results of the image analysis allow highlighting a satisfying lasting on the basis of instrumental measurements even if the overall satisfaction rate at this time is to be noticed, quite low.

Appendix I presents the individual results of the image analysis.

9 CONCLUSION

In the experimental conditions, the results of the image analysis with Kalliste® software obtained on 10 healthy female adult volunteers, aged from 30 to 55 years old, allow to highlight a satisfying lasting of the eyeliner brown product, referenced E136A-210814SP, 24 hours after application, under controlled and uncontrolled conditions.

APPENDIX I

✓ ***Individual results of the image analysis***

APPENDIX I **INDIVIDUAL RESULTS OF THE IMAGE ANALYSIS**

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Study code: 015TUE10V24H17
Product : eyeliner brown
Reference : E136A-210814SP

N° vol	Volunteers	S(Ti) (cm²)	S(T12) (cm²)	Mean decrease of the made-up surface area (S(T12)-S(Ti))	S(T24) (cm²)	Mean decrease of the made-up surface area (S(T24)-S(Ti))
1	**CHAMO**	0,353	0,351	**-0,6%**	0,350	**-1,0%**
2	**BELIS**	0,250	0,222	**-11,2%**	0,161	**-35,5%**
3	**SOUHA**	0,325	0,307	**-5,5%**	0,301	**-7,2%**
4	**DERMU**	0,280	0,273	**-2,4%**	0,270	**-3,6%**
5	**BAADJ**	0,168	0,166	**-1,0%**	0,156	**-7,1%**
6	**FAGMA**	0,321	0,295	**-8,3%**	0,278	**-13,4%**
7	**PESCA1**	0,154	0,097	**-36,8%**	0,073	**-52,8%**
8	**EL IB**	0,325	0,281	**-13,4%**	0,259	**-20,3%**
10	**ANDCH1**	0,248	0,233	**-6,0%**	0,218	**-12,1%**
11	**BARVÉ1**	0,202	0,069	**-65,9%**	0,040	**-80,2%**
	Mean	**0,263**	**0,229**	**-12,6%**	**0,211**	**-19,8%**
	Minimum	0,154	0,069	-65,9%	0,040	-80,2%
	Maximum	0,353	0,351	-0,6%	0,350	-1,0%
	Classification			**Satisfying**		**Satisfying**

APPENDIX II

✓ ***List of the personnel who participated in the study***

Beautician:
Name: Marie Béatrice AUDIBERT
Address: 505 Rue Louis Berton
CS 50550
13594 AIX EN PROVENCE cedex 3

Study manager:
Name: Elise ABRIC
Address: 505 Rue Louis Berton
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Phone: 04 42 37 14 25

Laboratory technician, production assistant:
Name: Laury ROSSETTI
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