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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.
Avenue du Parc 23
B1310 La Hulpe
BELGIUM

08/02/2017

EVALUATION OF THE RESISTANCE OF A MAKE-UP PRODUCT TO SWEAT UNDER CONTROLLED CONDITIONS IN THE FEMALE ADULT SUBJECT: SWEATPROOF TEST

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

Quotation n°: **2016/47749/v1**

Study manager: **Elise ABRIC**

Tested product:

- Name: eyeliner black
- Product code: 92G4
- ATS reference: 601208
- Brand: -
- Product type: Eyeliner

Study n°: **013TUE10V17**

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

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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, Elisa FAGGIANELLI

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STUDY SUMMARY

EVALUATION OF THE RESISTANCE OF A MAKE-UP PRODUCT TO SWEAT UNDER CONTROLLED CONDITIONS IN THE FEMALE ADULT SUBJECT: SWEATPROOF TEST

- **Tested product:** eyeliner black, referenced 92G4

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

- **Objective:** The objective of the study is to evaluate the resistance of a cosmetic product to sweat after a single and standardized application on determined area, under controlled conditions, after exposure to 30-minute exercise period 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

- **Investigator:** Laury ROSSETTI, Beautician

- **Study dates:** Session 1: 10/01/2017
  Session 2: 12/01/2017
  Session 3: 18/01/2017

- **Method:**

✓ ***Directions for use:***

The application is carried out at the investigation center. The product is applied to the right or left eyelid, according to a randomization, by a beautician to obtain a normal make-up result, in a quantity enabling the assessment.
Before assessment, there is about a 15-minute of leave-on time eyes closed.
Then, the volunteer performs cardio-training exercise during about 30 minutes in order to expose the studied areas to sweat.

✓ ***Environmental conditions:***

The assessments are performed in a room under controlled temperature (23°C +/- 2°C). Besides the hygrometry is registered but not controlled.

✓ ***Assessment methods:***

Immediately after cardio-training exercise, the beautician judges the product resistance to sweat based on the following assessment:

- Scoring scale for the smudge:
  - 0 : Absence of smudge
  - 1 : Slightly visible smudge
  - 2: Visible smudge

- A cotton bud extremity is put in contact with the product, in a standardized way, and the beautician assesses the visual quantity of product on the cotton-bud, using a 3 point scale:
  - 0 : Absence of product
  - 1 : Slight presence of product
  - 2 : Clear presence of product

- The make-up is delicately wiped-off with a cotton bud and the beautician assesses the degradation of the make-up line, using a 3 point scale:
  - 0 : No degradation of the line
  - 1 : Slight degradation of the line
  - 2 : Clear degradation of the line

✓ ***Panel:***

10 healthy female adult volunteers aged from 25 to 37 years old.
The assessment of the sweatproof efficacy was carried out on 10 volunteers.

♦ **Results:**

The following table shows the mean score for the studied parameters, after cardio-training exercise:

Parameter	Mean score
Smudge	0.000
Product presence on the cotton bud after slight pressures	0.000
Degradation of the application after slight rubbing with a cotton bud	0.000

Based on these results and on the grading system used for the assessment:

- No smudge of the product was observed on the whole panel.
- No product transfert was observed on the whole panel after 3 slight pressures with a cotton-bud on the made-up area.
- No degradation of the made-up area was observed on the whole panel after slight rubbing with a cotton bud.

The mean scores obtained for the studied parameters allow highlighting a sweatproof efficacy of the tested product, according to the pre-defined scales.

♦ **Conclusion:**

To conclude, in the experimental conditions adopted and according to the pre-defined parameters, the results of the scoring obtained on 10 healthy female adult volunteers, aged from 25 to 37 years old, after a single and standardized application by a beautician, allow highlighting a sweatproof efficacy of the eyeliner black product, referenced 92G4, according to the pre-defined scales.

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TABLE OF CONTENT

1 OBJECTIVE

The objective of the study is to evaluate the resistance to sweat of the eyeliner black product after a single and standardized application to the eyelid, and after exposure to 30-minute exercise period, under controlled conditions on 10 healthy female adult volunteers, aged from 18 to 60 years old.

2 METHODOLOGY

	T0	Timm
Demographic data	X	
Informed consent signature	X	
Checking inclusion Criteria / non-inclusion Criteria	X	
Final inclusion	X	
Products application by a beautician	X	
Cardio-training exercise during 30 minutes	X	
Beautician assessment		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 Doctors 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 efficacy.

5 STUDIED PANEL

5.1 Number of volunteers

The product was tested by 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 study manager 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:

1. Healthy female subject.
2. Age 18 to 60 years old included.
3. Phototype (Fitzpatrick): I to IV.
4. Face skin type: indifferent.
5. Volunteers used to regularly practice sport.
6. 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.
7. Subject affiliated to a social security system according to the article L1121-11 from Public Health Code applying on biomedical research.
8. Cooperative subject willing to comply with the study requirements.
9. Women declaring committing themselves to use effective contraceptive method before and throughout the study (for the women of childbearing potential).
10. Subject agreeing not to use any other cosmetic product or water to the face skin until the end of study.
11. Certifying and signing not to take part in another clinical study in another investigating center in accordance with corresponding procedure.
12. Certifying in writing the truth of the personal information declared to investigators.
13. Free to ensure all the visits to the investigating center..

5.4 Non inclusion criteria

1. Subject with wrinkles to eyelids or droopy eyelids.
2. Subject with personal history of allergy and/or particular reactivity to make-up products.
3. 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.
4. Subject exposed to the sun or UV rays in an excessive way during the last month (according to the investigator).
5. Subject with cutaneous affection of the face (psoriasis, atopic dermatitis, seborrheic dermatitis…).

6. 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.
7. Subject affected by serious pathology (cancer, immune-depressed)
8. Subject who has undergone a surgical operation in the previous month of the study or having planned it during the study.
9. Pregnancy or breastfeeding during the last 6 months, ongoing or planned during the study
10. Subject placed in a social or sanitary establishment
11. Subject deprived of liberty by adjunction or by official decision.
12. Subject under legal protection or without the right to express her consent.
13. Subject having applied a cosmetic to Subject who is participating or who has participated to a clinical study for which exclusion period is not finished.
14. 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.

The study day, it was asked to the volunteers not to apply any product to the face and eyelids in the morning.

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 black
✓ Reference:	92G4
✓ ATS reference:	601208
✓ Presentation (galenic, colour):	Black pen
✓ Packaging:	Plastic pack
✓ Number of samples received:	15
✓ 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 Applying

The application is carried out at the investigation center. The product is applied to the right or left eyelid, according to a randomization, by a beautician to obtain a normal make-up result, in a quantity enabling the assessment.
Before assessment, there is about a 15-minute of leave-on time eyes closed.
Then, the volunteer performs cardio-training exercise during about 30 minutes in order to expose the studied areas to sweat.

7.2 Study protocol

2 weeks before D0:

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

D0:

- ✓ Welcoming of the volunteers, signature of the information and consent form, by the volunteers and the Investigator. The volunteers also complete the medical auto questionnaire confirmed by the Investigator.
- ✓ Volunteers came to the laboratory without applying any make-up or cosmetic product on the study area.
- ✓ Application of the product at the laboratory by a beautician, according to the directions of use predefined with the study sponsor.
- ✓ After 15 minutes of leave-on time, the volunteer performs cardio-training exercise during about 30 minutes in order to expose the studied areas to sweat.
- ✓ Assessment of the sweatproof efficacy by the beautician by clinical scoring.

7.3 Environmental conditions

The assessments are performed in a room under controlled temperature (23°C +/- 2°C). Besides the hygrometry is registered but not controlled.

7.4 Assessment of sweatproof efficacy

Immediately after cardio-training exercise, the beautician judges the product resistance to sweat based on the following assessment:

- Scoring scale for the smudge:
  - 0 : Absence of smudge
  - 1 : Slightly visible smudge
  - 2: Visible smudge

- A cotton bud extremity is put in contact with the product, in a standardized way, and the beautician assesses the visual quantity of product on the cotton-bud, using a 3 point scale:
  - 0 : Absence of product
  - 1 : Slight presence of product
  - 2 : Clear presence of product

- The make-up is delicately wiped-off with a cotton bud and the beautician assesses the degradation of the make-up line, using a 3 point scale:
  - 0 : No degradation of the line
  - 1 : Slight degradation of the line
  - 2 : Clear degradation of the line

7.5 Data analysis and results interpretation

The assessment of the sweatproof efficacy is made by the combined evaluation of the parameters named before.
Individual results are collected, analyzed and interpreted by the study manager. The mean scores obtained for each parameter allow to assess the efficacy of the tested product.
Conclusions regarding the resistance to sweat are drawn based on the investigating team experience and history.

8 RESULTS

8.1 Description of the panel

This study was carried out on from the 10/01/2017 to the 18/01/2017 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)	Events occurred during the study
1	DUSAN	F	29	-
2	VIDSA1	F	27	-
3	MIRCÉ	F	31	-
4	FOUCA1	F	37	-
5	HARSE1	F	36	-
6	COZST	F	30	-
7	GOBSA	F	37	-
8	DE MA6	F	25	-
9	LEBMA1	F	27	-
10	FRAEL	F	26	-
Average			**31**	

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

8.2 Study exits

10 healthy female adult volunteers participated to the study. No study withdrawal happened.
The assessment of the sweatproof efficacy was carried out on 10 volunteers.

8.3 Results analysis

The following table shows the mean score for the studied parameters, after cardio-training exercise:

Parameter	Mean score
Smudge	0.000
Product presence on the cotton bud after slight pressures	0.000
Degradation of the application after slight rubbing with a cotton bud	0.000

Based on these results and on the grading system used for the assessment:

- No smudge of the product was observed on the whole panel.
- No product transfert was observed on the whole panel after 3 slight pressures with a cotton-bud on the made-up area.
- No degradation of the made-up area was observed on the whole panel after slight rubbing with a cotton bud.

The mean scores obtained for the studied parameters allow highlighting a sweatproof efficacy of the tested product, according to the pre-defined scales.

Appendix I presents the individual data of the sweatproof efficacy assessed by a beautician.

9 CONCLUSION

To conclude, in the experimental conditions adopted and according to the pre-defined parameters, the results of the scoring obtained on 10 healthy female adult volunteers, aged from 25 to 37 years old, after a single and standardized application by a beautician, allow highlighting a sweatproof efficacy of the eyeliner black product, referenced 92G4, according to the pre-defined scales.

APPENDIX I

✓ ***Results of the clinical scoring***

APPENDIX I **CLINICAL ASSESSMENT OF THE RESISTANCE TO SWEAT**

Study N° **013TUE10V17**
Product 1 : eyeliner black

RESISTANCE TO SWEAT

Drying time: 15 minutes
Aspect of the product after 30 minutes of cardio-training

Scoring scale for the smudge:
0 : Absence of smudge
1 : Slightly visible smudge
2: Visible smudge

Scoring scale for the visual quantity of product on the cotton-bud after slight pressures:
0 : Absence of product
1 : Slight presence of product
2 : Clear presence of product

Scale of notation for the degradation of the make-up line after delicate rubbing:
0 : No degradation of the line
1 : Slight degradation of the line
2 : Clear degradation of the line

N°	Volunteer code	Smudge	Product's degradation after delicate rubbing	Product presence on the cotton bud after slight pressures	Comments
1	DUSAN	0	0	0	-
2	VIDSA1	0	0	0	-
3	MIRCÉ	0	0	0	-
4	FOUCA1	0	0	0	-
5	HARSE1	0	0	0	-
6	COZST	0	0	0	-
7	GOBSA	0	0	0	-
8	DE MA6	0	0	0	-
9	LEBMA1	0	0	0	-
10	FRAEL	0	0	0	-
N		10	10	10	
Mean		**0,0**	**0,0**	**0,0**	
Min		0,0	0,0	0,0	
Max		0,0	0,0	0,0	

APPENDIX II

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

Study manager:
Name: Elise ABRIC
Address: EUROFINS ATS
505 rue Louis Berton
CS 50550
13594 Aix en Provence Cedex 3 – France
Phone: +33 4 42 37 14 25

Laboratory technician, production assistant and Beautician:
Name: Laury ROSSETTI
Address: EUROFINS ATS
505 rue Louis Berton
CS 50550
13594 Aix en Provence Cedex 3 – France