

# **Evaluation of the efficacy of a cleansing product on a panel of volunteers**

**STUDY 18E4141**

**Quote D18-324**

## **Study performed on:**

✚ 40 Caucasian women

✚ Reference :

Le Démaquillant Gel Nettoyant Extra  
Lab-01133.4  
18.05.2018

## SUMMARY

<b>1</b>	<b>AIM OF THE STUDY</b>	<b>7</b>
<b>2</b>	<b>EXPERIMENTAL DESIGN</b>	<b>7</b>
2.1	Study design	7
2.2	Volunteers selection and method	8
<b>3</b>	<b>VOLUNTEERS</b>	<b>9</b>
3.1	Inclusion and non-inclusion criteria	9
3.1.1	Inclusion criteria	9
3.1.2	Non-inclusion criteria	9
3.2	Volunteers included in the study	9
3.2.1	Demographic characteristics	9
3.2.2	Schedule compliance	9
3.2.3	Concomitant treatments	9
<b>4</b>	<b>PRODUCTS</b>	<b>10</b>
4.1	Study product	10
<b>5</b>	<b>METHODS</b>	<b>11</b>
5.1	Photographies by VISIA®	11
5.2	Assessment of the cutaneous hydration through Corneometer®	11
<b>6</b>	<b>RESULTS</b>	<b>12</b>
6.1	Atmospheric conditions around Paris	12
6.2	Statistical method	12
6.3	Protocol deviation	12
6.4	Undesirable events	12
6.5	Results of the volume of the eyelashes by VISIA®	13
6.5.1	Make up removal with cotton	13
6.5.1.1	Waterproof mascara	13
6.5.1.2	No waterproof mascara	14
6.5.1	Make up removal with fingers and rinsing	15
6.5.1.1	Waterproof mascara	15
6.5.1.2	No Waterproof mascara	16
6.5.2	Comparison according to the type of mascara apply	17
6.5.1	Comparison according to the type of make-up removal	17
6.6	Moisturizing assessment by Corneometer®	18
6.6.1	Make up removal with cotton	18
6.6.1	Make up removal with fingers + rinsing	18
6.7	Adhesion of particles	19
6.7.1	Cleansing with cotton	19
6.7.2	Cleansing with fingers and rinsing	21
6.7.3	Comparison of cleansing with cotton and fingers	23
<b>7</b>	<b>CONCLUSION</b>	<b>24</b>
<b>9</b>	<b>STUDY REPORT ARCHIVING</b>	<b>26</b>

<b>STUDY 18E4141</b>	
<b>QUOTE D18-324</b>	
<b>Sponsor</b>	<b>TEMMENTEC</b> Mrs BARUCHET Gwendoline Lütoldstrasse 6 CH-3454 Sumiswald SWITZERLAND Tél : +41 (0) 75 429 7335 Mail : gbaruchet@temmentec.ch
<b>Test facility</b>	<b>Laboratoire BIO-EC</b> 1 chemin de Saulxier 91 160 LONGJUMEAU Tel : 01 69 41 47 68 Mail : e.lati@bio-ec.fr
<b>Director of the test facility</b>	<b>M. Elian LATI</b>
<b>In vivo Manager</b>	<b>Mrs Magalie DANIEL</b>
<b>Studies Engineer</b>	<b>Mrs Enora DOULS</b>
<b>Delegate quality assurance</b>	<b>M. Laurent PENO-MAZZARINO</b>

## Summary of the study

### ▪ **TITLE:**

Evaluation of the efficacy of a cleansing product on a panel of volunteers.

### ▪ **AIM OF THE STUDY:**

The aim of the study is to assess on a panel of 40 volunteers older than 18 years old, the efficacy of a cleansing product on normal and waterproof mascara and on polluting particles by performing 2 types of makeup removal.

This efficacy will be measured through:

- Moisturizing assessment by Corneometer®
- Face photography by VISIA®
- Adhesion of polluting particles

The 40 volunteers were divided into 4 groups:

- 1- Make-up with normal mascara and application of the product with fingers with rinsing
- 2- Make-up with waterproof mascara and application of the product with fingers with rinsing
- 3- Make-up with normal mascara and application of the product with cotton without rinsing
- 4- Make-up with waterproof mascara and application of the product with cotton without rinsing

The various measurements were recorded during the first visit.

The makeup removal efficacy has been tested on eyes for normal and waterproof mascara.

The removing of polluting particles has been evaluated on forearms.

### ▪ **PROGRESS OF THE STUDY:**

40 women, older than 18 years old, meeting the inclusion and non-inclusion criteria defined by the promoter were included in the study.

▪ **RESULTS AND CONCLUSION:**

The aim of the study was to assess on a panel of 40 volunteers, the efficacy of a cleansing product on normal and waterproof mascara and on polluting particles by performing 2 types of makeup removal (cotton or fingers+rinsing);

- ❖ Concerning the make-up remover effect, we can conclude that:
  - ✓ after make-up with a waterproof mascara and then application of the product with cotton, the product has a make-up remover effect.
  - ✓ after make-up with a no waterproof mascara and then application of the product with cotton, the product has a make-up remover effect.
  - ✓ after make-up with a waterproof mascara and then application of the product with fingers and rinsing, the product has a make-up remover effect.
  - ✓ after make-up with a no waterproof mascara and then application of the product with fingers and rinsing, the product has a make-up remover effect.

Furthermore:

- ✓ The type of mascara doesn't have a significative effect on make-up remover, whether with cotton application or application with fingers + rinsing
- ✓ The make-up remover effect is significantly better ( $p=0,0307$ ) with cotton than with fingers + rinsing when apply no waterproof mascara.

- ❖ **Concerning the skin hydration, we can conclude that:**
  - ✓ The application of the product with a cotton increase significantly the skin hydration.
  - ✓ The application of the product with fingers + rinsing doesn't improve the skin hydration.
  
- ❖ **Concerning the antipollution effect, we can conclude to:**
  - ✓ An antipollution effect of the product and the water when applied with cotton. There is no significative difference on anti-pollution effect between product and water when applied with a cotton.
  - ✓ An antipollution effect of the product and the water when applied with fingers and rinsing. There is a tendency ( $p < 0,1$ ) for the product to have a better anti-pollution effect than water.

**Furthermore:**

- ✓ There is a significative difference ( $p < 0,001$ ) on anti-pollution effect with the product between application with cotton or fingers. The anti-pollution effect is better when the product is applied with a cotton.

## **1 AIM OF THE STUDY**

The aim of the study is to assess on a panel of 40 volunteers older than 18 years old, the efficacy of a cleansing product on normal and waterproof mascara and on polluting particles by performing 2 types of makeup removal.

This efficacy will be measured through:

- Moisturizing assessment by Corneometer®
- Face photography by VISIA®
- Adhesion of polluting particles

The 40 volunteers were divided into 4 groups:

- 5- Make-up with normal mascara and application of the product with fingers with rinsing
- 6- Make-up with waterproof mascara and application of the product with fingers with rinsing
- 7- Make-up with normal mascara and application of the product with cotton without rinsing
- 8- Make-up with waterproof mascara and application of the product with cotton without rinsing

The various measurements were recorded during the first visit.

The makeup removal efficacy has been tested on eyes for normal and waterproof mascara.

The removing of polluting particles has been evaluated on forearms.

## **2 EXPERIMENTAL DESIGN**

### **2.1 Study design**

The efficacy of the product was assessed on 40 women meeting the inclusion and non-inclusion criteria previously defined by the promoter. The measurements were taken in a controlled-atmosphere room ( $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ), after stabilization of the volunteers for at least 10 minutes.

Each volunteer was asked to notify Laboratory BIO-EC of any discomfort or undesirable event that would occur. They did not stop or change the frequency of application without prior notice.

During each visit, assessments were done using the same method.

## 2.2 Volunteers selection and method

**Recruitment** (Week 21, 22): Women older than 18 years with a dry and sensitive skin.

▪ **T0:** (Week 23), the technician in charge of the study:

- Makes stabilize the volunteer on a control-atmosphere room during 10 minutes,
- Checks out of the criteria of inclusion and non-inclusion,
- Checks out of the well understanding of the study,
- Signing of the agreement by the volunteers,

### **Evaluation of the make-up removal efficacy:**

- The technician in charge of the study makes initial biometrical measurements on face:
  - VISIA photography
  - Corneometer®
- Volunteers apply the mascara (20 passages per eye)
- The technician in charge of the study makes VISIA photography
- Volunteers apply the cleansing product according to the recommendations given by the promotor
- The technician in charge of the study makes:
  - VISIA photography
  - Corneometer®

### **Evaluation of the cleansing efficacy:**

The technician in charge of the study

- Delimits 2 areas (16cm<sup>2</sup>) on the forearms (4\*4 latin square zones)
- Makes initial photography of the 2 areas
- Applies 7 mg of coal particles on each zones
- Makes photography of the 2 areas
- Applies 2mg/cm<sup>2</sup> of the cleansing product on one of the area and water on the other area
- Makes photography of the 2 areas
- Gives compensation to volunteers



### 3 VOLUNTEERS

#### 3.1 Inclusion and non-inclusion criteria

##### 3.1.1 Inclusion criteria

- Caucasian women
- Having between more than 18 years old,
- With dry and sensitive skin,

The volunteers should commit themselves to:

- Use the product in conformity with the recommendation use
- Not using any other product on the studied zone

##### 3.1.2 Non-inclusion criteria

- Pregnancy or breast feeding women,
- Persons having dermatological problems and/or know allergy to cosmetic products.
- Persons under medical treatment potentially capable of influencing the measured parameters

#### 3.2 Volunteers included in the study

Overall, 40 Caucasians women meeting the inclusion and non-inclusion criteria defined in the protocol were included in the study. They were informed of the possible adverse effects from using the product and the technical conditions in which the assessment is performed. They willingly signed the consent form which was written in compliance with the Declaration of Helsinki and the December 20th, 1988 act of the Code de la Santé Publique.

##### 3.2.1 Demographic characteristics

The demographic characteristics of the volunteer group (mean  $\pm$  SD) are as follows:

<b>Le Demaquillant Gel Nettoyant Extra</b> <b>Lab-01133.4</b> <b>18.05.2018</b>	N = 40 women
	Age : 32 $\pm$ 5 years old

##### 3.2.2 Schedule compliance

No volunteer left the study prematurely. All volunteers returned for their appointments.

##### 3.2.3 Concomitant treatments

The volunteers included in the study did not take any concurrent treatment likely to induce a modification of the cutaneous state.

## **4 PRODUCTS**

### **4.1 Study product**

The product was identified as:

**Le Demaquillant Gel Nettoyant Extra**

**Lab-01133.4**

**18.05.2018**

The product was a transparent gel packed by the promoter in vials.

## **5 METHODS**

### **5.1 Photographies by VISIA®**

With VISIA® 6th generation, numeric photographs were performed at T0, Tafter make-up (TM) and Tafter make-up removal (TD).

- Different parameters can be analysed with the VISIA®: Spots, Wrinkles, Texture, Pores, UV Spots, Brown spots, Red areas and Porphyrines.
- The VISIA® gives 3 types of results :
  - The Lineaments Count gives a count of the number of lesions evaluate by the dispositive, with no concern of the size or the lesion intensity. The lineaments count can be used to see a treatment progress when the decrease of the lesions number for one or many skin features.
  - The Absolute Grades give a complete and comprehensive measure of the lesion impact on the subject skin. They totally consider the size, the surface and the analysed lesions intensity. The absolute grade can also be used to detect a treatment improvement when the lesion size and intensity are the most appropriate to evaluate the treatment efficacy.
  - The Centiles gives a context in which the subject results analysis are compared to the Absolute grades of other subjects who have similar characteristics. Centiles can also be used to give a comparative assessment of the subject's general state.

### **5.2 Assessment of the cutaneous hydration through Corneometer®**

The stratum corneum hydration causes changing in its electrical characteristics. The stratum corneum is like a dielectric corps. Any modifications of its hydration statement cause a variation of the electric capacity measured by a condenser. Higher is the hydration, higher is the electric capacity because its dipolar nature increases the electric permittivity of the environment and its conductivity.

Measurement is realized by the Corneometer CM825TM (Courage & Khazaka electronics). The probe linked to a condenser allows applying at all the time the same pressure on the tegument in order to not disturb the measures and to obtain good experimental conditions reproducibility.

## **6 RESULTS**

### **6.1 Atmospheric conditions around Paris**

Maximal and minimal temperatures around Paris during the study were:

- 04 – 08 June (T0): 14.8 °C to 26.5°C

### **6.2 Statistical method**

The basic statistical parameters (mean and standard deviation) were calculated for each data point and recorded. Then, the assessment of the overall effect of the test product was made by calculating the variation of percentage compared to the initial measurement.

In order to determine whether the identified changes were significant or not, a Student's t-test was performed. The statistical analysis (through Prism v5.04 software by GraphPad) was made with Student's t-test on paired samples. The assumptions were the randomness and normal distribution of the samples.

### **6.3 Protocol deviation**

All inclusion and evaluation criterion were respected.

### **6.4 Undesirable events**

No adverse effects occurred during the study.

## 6.5 Results of the volume of the eyelashes by VISIA®

Means of volume of the eyelashes parameter for the global population are gathered in the table below. Individual values for each volunteer are presented in the appendixes.

### 6.5.1 Make up removal with cotton

#### 6.5.1.1 Waterproof mascara

N = 10	Values			Delta of variations	
	T0	T after make up (TM)	T after make up removal (TD)	T after make up – T0	T after make up removal – T after make up
Cleansing product	53,80 ± 8,97	59,10 ± 9,88	51,1 ± 10,46	5,30 ± 3,02	-8,00 ± 5,75

N = 10	% of variation	
	T after make up - T0	T after make up removal – T after make up
Cleansing product	10 % ***	-15 % **

# Significant p<0.1

\* Significant p<0.05

\*\*Significant p<0.01

\*\*\*Significant p<0.001

After application of the waterproof mascara, we can observe:

→ A significant increase by **10 %** of the volume of the eyelashes (p=0.0004)

After make-up removal with the cleansing product, we can observe:

→ A significant decrease by **15 %** of the volume of the eyelashes (p=0.0017)

### Illustrations:

T0

Tafter make-up

Tafter make-up removal



→ We can conclude that after make-up with a waterproof mascara and then application of the product with cotton, the product has a make-up remover effect.

### 6.5.1.2 No waterproof mascara

N = 10	Values			Delta of variations	
	T0	T after make up (TM)	T after make up removal (TD)	T after make up – T0	T after make up removal – T after make up
Cleansing product	50,30 ± 3,74	59,10 ± 4,31	48,30 ± 4,69	8,80 ± 3,33	-10,80 ± 4,16

N = 10	% of variation	
	T after make up – T0	T after make up removal – T after make up
Cleansing product	17 % ***	-21% ***

# Significant p<0.1

\* Significant p<0.05

\*\*Significant p<0.01

\*\*\*Significant p<0.001

After application of the waterproof mascara, we can observe:

→ A significant increase by **17 %** of the volume of the eyelashes (p<0.001)

After make-up removal with the cleansing product, we can observe:

→ A significant decrease by **21 %** of the volume of the eyelashes (p<0.001)

#### Illustrations:

T0



Tafter make-up



Tafter make-up removal



→ We can conclude that after make-up with a no waterproof mascara and then application of the product with cotton, the product has a make-up remover effect.



## 6.5.1 Make up removal with fingers and rinsing

### 6.5.1.1 Waterproof mascara

N = 10	Values			Delta of variations	
	T0	T after make up (TM)	T after make up removal (TD)	T after make up – T0	T after make up removal – T after make up
Cleansing product	55,40 ± 9,28	59,20 ± 9,38	51,90 ± 9,93	3,80 ± 2,97	-7,30 ± 3,47

N = 10	% of variation	
	T after make up – T0	T after make up removal – T after make up
Cleansing product	6,9 % **	-13,2% ***

# Significant p<0.1

\* Significant p<0.05

\*\*Significant p<0.01

\*\*\*Significant p<0.001

After application of the waterproof mascara, we can observe:

→ A significant increase by **6,9%** of the volume of the eyelashes (p=0.0029)

After make-up removal with the cleansing product, we can observe:

→ A significant decrease by **13,2%** of the volume of the eyelashes (p<0.001)

#### Illustrations:

T0



Tafter make-up



Tafter make-up removal



→ We can conclude that after make-up with a waterproof mascara and then application of the product with fingers and rinsing, the product has a make-up remover effect.

### 6.5.1.2 No Waterproof mascara

N = 10	Values			Delta of variations	
	T0	T after make up (TM)	T after make up removal (TD)	T after make up – T0	T after make up removal – T after make up
Cleansing product	55,80 ± 13,22	58,90 ± 12,73	52,00 ± 11,93	3,10 ± 2,92	-6,90 ± 3,11

N = 10	% of variation	
	T after make up – T0	T after make up removal – T after make up
Cleansing product	5,6 % **	-12,4% ***

# Significant p<0.1

\* Significant p<0.05

\*\*Significant p<0.01

\*\*\*Significant p<0.001

After application of the waterproof mascara, we can observe:

→ A significant increase by **5,6%** of the volume of the eyelashes (p=0.0085)

After make-up removal with the cleansing product, we can observe:

→ A significant decrease by **12,4%** of the volume of the eyelashes (p<0.001)

### Illustrations:

T0



Tafter make-up



Tafter make-up removal



→ We can conclude that after make-up with a no waterproof mascara and then application of the product with fingers and rinsing, the product has a make-up remover effect.



### 6.5.2 Comparison according to the type of mascara apply

Student test				Student test			
		p-value	Significativity			p-value	Significativity
Cotton WP vs Cotton NWP	TD/TM	0,2840	ns	Fingers WP vs Fingers NWP	TD/TM	0,7957	ns

We can observe:

- ➔ No significant difference of the make-up remover effect between application of waterproof and no waterproof mascara, whether with cotton or finger 's + rinsing application.
- ➔ **We can conclude that the type of mascara doesn't have a significative effect on make-up remover, whether with cotton application or application with fingers + rinsing.**

### 6.5.1 Comparison according to the type of make-up removal

Student test				Student test			
		p-value	Significativity			p-value	Significativity
Cotton WP vs Fingers WP	TD/TM	0,7796	ns	Cotton NWP vs Fingers NWP	TD/TM	0,0307	*

We can observe:

- ➔ No significant difference of the make-up remover effect between application of the product with a cotton and with fingers and rinsing, when apply a waterproof mascara
- ➔ A significative difference ( $p < 0,05$ ) of the make-up remover effect between application of the product with a cotton and with fingers and rinsing, when apply a no waterproof mascara.
- ➔ **We can conclude that the make-up remover effect is significantly better ( $p=0,0307$ ) with cotton than with fingers + rinsing when apply no waterproof mascara.**

## 6.6 Moisturizing assessment by Corneometer®

Means of skin moisturizing values for the global population are gathered in the table below. Individual values for each volunteer are presented in the appendixes.

### 6.6.1 Make up removal with cotton

N = 20	Values		Delta of variation T after make up removal	% of variation T after make up removal
	T0	T after make up removal		
Cleansing product	62,61 ± 9,71	67,62 ± 10,07	5,01 ± 8,91	8 % *

# Significant p<0.1      \* Significant p<0.05      \*\*Significant p<0.01      \*\*\*Significant p<0.001

We can observe a significant increase by **8%** (p=0,0211) of the corneometry after application of the product with a cotton.

→ **We can conclude that the application of the product with a cotton increase significantly the skin hydration.**

### 6.6.1 Make up removal with fingers + rinsing

N = 20	Values		Delta of variation T after make up removal	% of variation T after make up removal
	T0	T after make up removal		
Cleansing product	65,96 ± 8,69	66,93 ± 7,26	0,96 ± 7,68	1 % ns

# Significant p<0.1      \* Significant p<0.05      \*\*Significant p<0.01      \*\*\*Significant p<0.001

We can observe a no significant increase by **1%** (p=0,5809) of the corneometry after application of the product with a cotton.

→ **We can conclude that the application of the product with fingers + rinsing doesn't improve the skin hydration.**

## 6.7 Adhesion of particles

Percentages of the surface occupy by particles are gathered in the table below. Individual values for each volunteer are presented in the appendixes.

### 6.7.1 Cleansing with cotton

n= 20	T after pollution(TP)	T after cleansing(TC)	Delta of variation T after pollution removal – T after cleansing	% of variation
<b>Cleansing product</b>	22,31 ± 5,93	0,53 ± 0,53	-21,78 ± 5,86	-97,62% ***
<b>Control</b>	21,84 ± 5,66	0,75 ± 1,26	-21,09 ± 5,90	-96,57% ***

# Significant p<0.1

\* Significant p<0.05

\*\*Significant p<0.01

\*\*\*Significant p<0.001

After application of coal particles and then make-up removal with a cotton+product, we can observe:

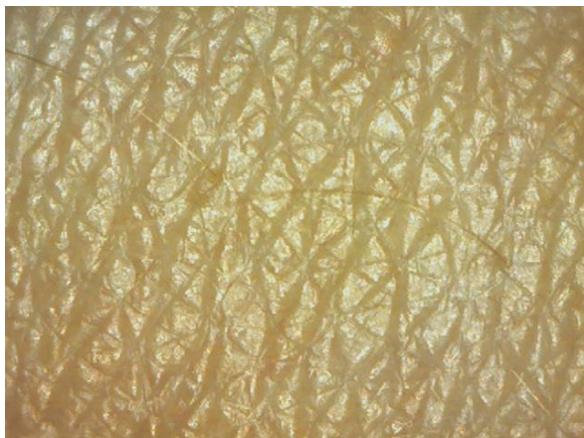
➔ A significant decrease (p<0,001) of **97,62%** of the particles on the skin

After application of coal particles and then make-up removal with a cotton+water, we can observe:

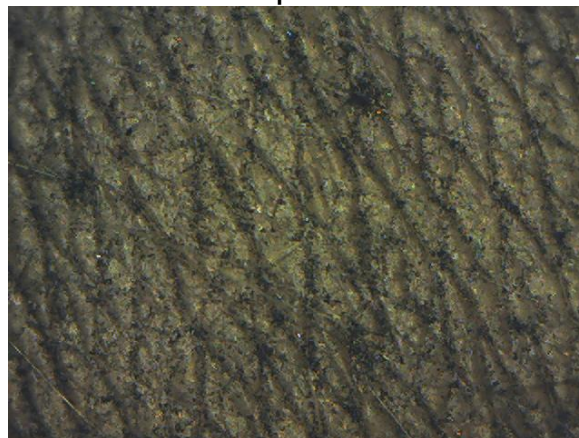
➔ A significant decrease of (p<0,001) **96,57%** of the particles on the skin

### Images for cleansing with the Product :

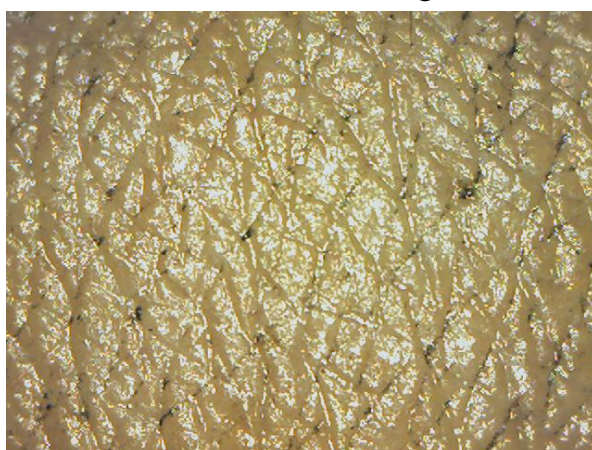
T0



Tafter pollution

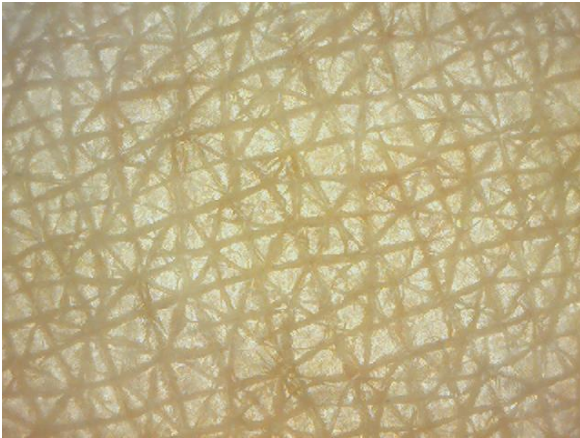


Tafter cleansing

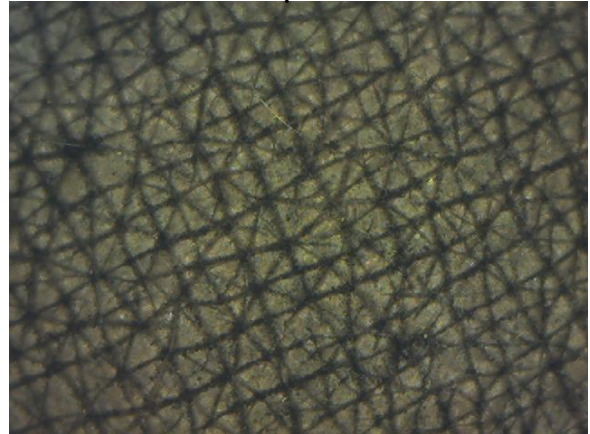


**Images for cleansing with water:**

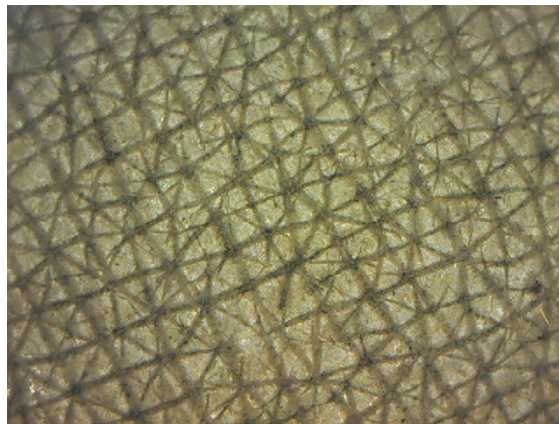
T0



Tafter pollution



Tafter cleansing



**Comparison product vs Control :**

Student test			
		p-value	Significativity
Product vs Control	TP/TC	0,6945	ns

→ We can conclude to an antipollution effect of the product and the water when applied with cotton. There is no significative difference on anti-pollution effect between product and water when applied with a cotton.



### 6.7.2 Cleansing with fingers and rinsing

n= 29	T after pollution (TP)	T after cleansing (TC)	Delta of variation T after pollution – T after cleansing	% of variation
<b>Cleansing product</b>	11,95 ± 3,33	0,90 ± 1,15	-11,05 ± 3,47	-92,50% ***
<b>Control</b>	13,89 ± 3,71	1,43 ± 1,41	-12,46 ± 3,75	-89,72% ***

# Significant p<0.1      \* Significant p<0.05      \*\*Significant p<0.01      \*\*\*Significant p<0.001

After application of coal particles and then make-up removal with application of the product with fingers and rinsing, we can observe:

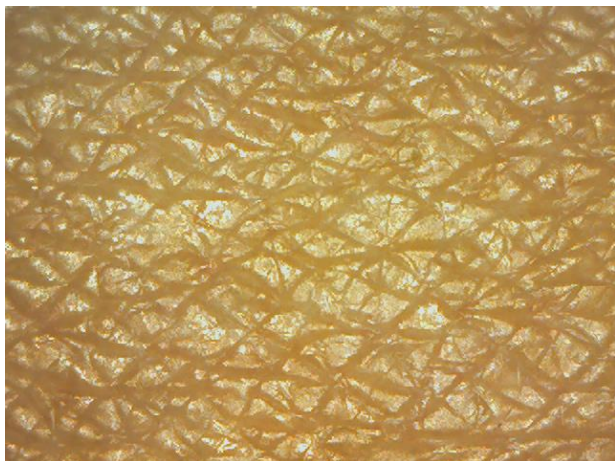
➔ A significant decrease (p<0,001) of **92,50%** of the particles on the skin

After application of coal particles and then make-up removal with application of water with fingers and rinsing, we can observe:

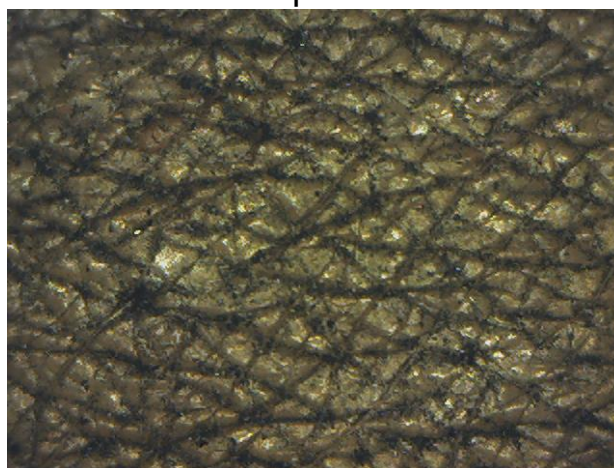
➔ A significant decrease of (p<0,001) **89,72%** of the particles on the skin

#### Images for cleansing with product:

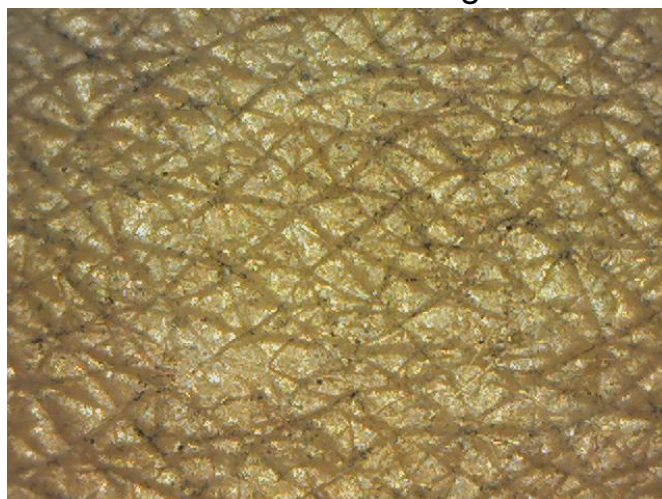
T0



Tafter pollution

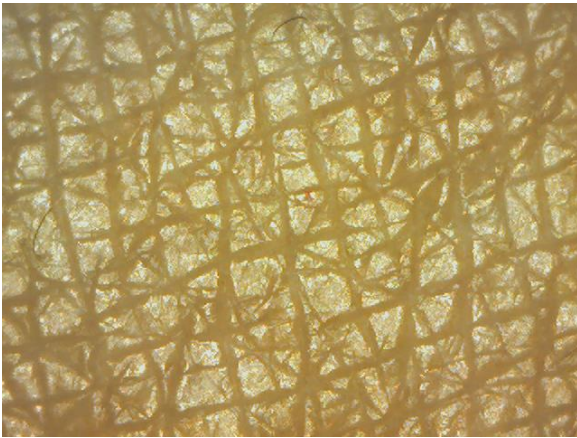


Tafter cleansing

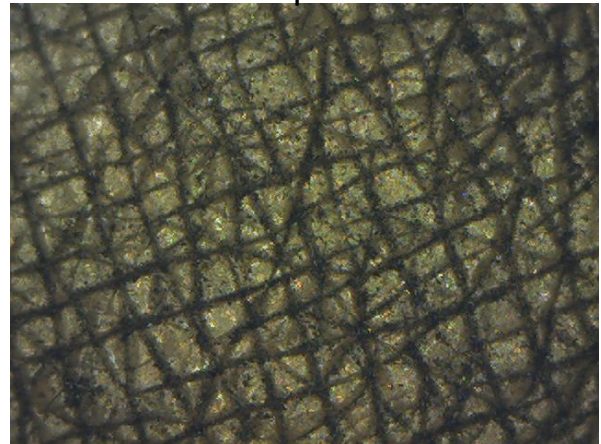


**Images for cleansing with water:**

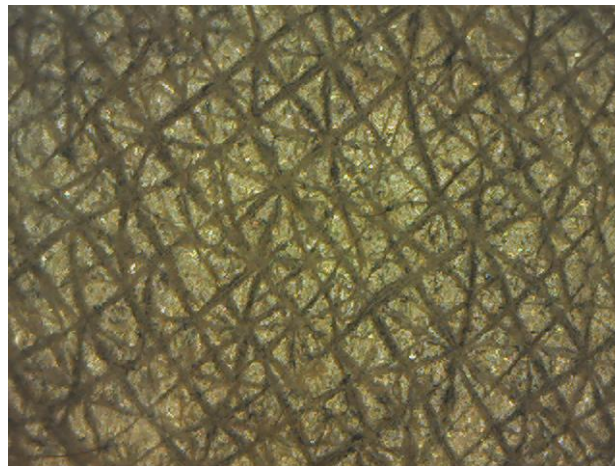
T0



Tafter pollution



Tafter cleansing



**Comparison product vs Control:**

Student test			
		p-value	Significativity
Product vs Control	TP/TC	0,0854	#

→ We can conclude to an antipollution effect of the product and the water when applied with fingers and rinsing. There is a tendency ( $p < 0,1$ ) for the product to have a better anti-pollution effect than water.

### 6.7.3 Comparison of cleansing with cotton and fingers

Student test			
Product (Cotton vs Fingers)	TP-TC	p-value	Significativity
		1,1656E-06	***

- ➔ There is a significative difference ( $p < 0,001$ ) on anti-pollution effect with the product between application with cotton or fingers. The anti-pollution effect is better when the product is applied with a cotton.

## 7 CONCLUSION

The aim of the study was to assess on a panel of 40 volunteers, the efficacy of a cleansing product on normal and waterproof mascara and on polluting particles by performing 2 types of makeup removal (cotton or fingers+rinsing);

- ❖ Concerning the make-up remover effect, we can conclude that:
  - ✓ after make-up with a waterproof mascara and then application of the product with cotton, the product has a make-up remover effect.
  - ✓ after make-up with a no waterproof mascara and then application of the product with cotton, the product has a make-up remover effect.
  - ✓ after make-up with a waterproof mascara and then application of the product with fingers and rinsing, the product has a make-up remover effect.
  - ✓ after make-up with a no waterproof mascara and then application of the product with fingers and rinsing, the product has a make-up remover effect.

Furthermore:

- ✓ The type of mascara doesn't have a significative effect on make-up remover, whether with cotton application or application with fingers + rinsing
- ✓ The make-up remover effect is significantly better ( $p=0,0307$ ) with cotton than with fingers + rinsing when apply no waterproof mascara.



- ❖ **Concerning the skin hydration, we can conclude that:**
  - ✓ The application of the product with a cotton increase significantly the skin hydration.
  - ✓ The application of the product with fingers + rinsing doesn't improve the skin hydration.
  
- ❖ **Concerning the antipollution effect, we can conclude to:**
  - ✓ An antipollution effect of the product and the water when applied with cotton. There is no significative difference on anti-pollution effect between product and water when applied with a cotton.
  - ✓ An antipollution effect of the product and the water when applied with fingers and rinsing. There is a tendency ( $p < 0,1$ ) for the product to have a better anti-pollution effect than water.

**Furthermore:**

- ✓ There is a significative difference ( $p < 0,001$ ) on anti-pollution effect with the product between application with cotton or fingers. The anti-pollution effect is better when the product is applied with a cotton.

## 9 STUDY REPORT ARCHIVING

### + Raw data filing

The raw data consists of:

- Image analysis results
- Assays results
- Biometrological results using devices

All the raw data is kept in a paper file and a backup is saved when it is possible (depending on the used device).

### + Products ; samples ; blocks and blades filing

The products entrusted to BIO-EC are preserved one year after using the tested product.

The blocs, the stained and immunostained slides revealed by alkaline phosphatase and peroxidase are kept at BIO-EC's for fifteen years.

The frozen blocs will stay in possession of BIO-EC for two years at minus 80°C. If the culture media are harvested during the study, they will be stored for two years at minus 80°C.

After that, and without any other instructions from the client, they will all be destroyed.

### + Final report filing

The paper file is archived and kept for 20 years

The study report (raw data, images, preliminary reports, final report) and all the computer data are saved thanks to a double internal backup (KERTEL BOX2CLOUD, RAID 1) and by an automated and daily external system, Backupia (KERTEL Group).

Our computer system is protected by the anti-viruses Microsoft Security Essential, F-Secure and McAfee Saas.



# Appendixes

## RESULTS OF CORNEOMETER

### Make-up removal with cotton

Volunteers	Cornéomètre			
	T0	Taprès démaq	Taprès démaqu - T0	%
1	69,50	80,00	10,50	15,11%
2	45,40	46,65	1,25	2,75%
3	62,65	69,70	7,05	11,25%
4	69,55	69,95	0,40	0,58%
5	57,45	61,65	4,20	7,31%
6	50,45	64,25	13,80	27,35%
7	48,60	69,15	20,55	42,28%
8	53,45	61,10	7,65	14,31%
9	73,20	74,70	1,50	2,05%
10	69,50	76,95	7,45	10,72%
11	79,65	78,95	-0,70	-0,88%
12	67,90	77,20	9,30	13,70%
13	61,75	83,80	22,05	35,71%
14	56,50	57,80	1,30	2,30%
15	65,05	55,50	-9,55	-14,68%
16	71,05	54,40	-16,65	-23,43%
17	53,05	59,60	6,55	12,35%
18	62,35	71,70	9,35	15,00%
19	77,90	76,90	-1,00	-1,28%
20	57,30	62,45	5,15	8,99%
<b>MEAN</b>	62,61	67,62	5,01	<b>8%</b>
<b>SD</b>	9,71	10,07	8,91	

	Student test (p-value)	Significativité
Taprès démaquillage/ T0	0,0211	Study ID: E4141- TEMMENTEC*

### Make-up removal with fingers + rinsing

Volunteers	Cornéomètre			
	T0	Taprès démaq	Taprès démaqu - T0	%
21	67,95	63,35	-4,60	-6,77%
22	81,50	80,00	-1,50	-1,84%
23	58,00	52,25	-5,75	-9,91%
24	68,65	71,10	2,45	3,57%
25	58,55	56,45	-2,10	-3,59%
26	55,85	69,10	13,25	23,72%
27	70,75	69,55	-1,20	-1,70%
28	47,25	69,20	21,95	46,46%
29	63,80	72,95	9,15	14,34%
30	70,10	65,70	-4,40	-6,28%
31	51,30	52,00	0,70	1,36%
32	63,20	63,10	-0,10	-0,16%
33	69,70	63,20	-6,50	-9,33%
34	73,40	69,85	-3,55	-4,84%
35	71,15	73,60	2,45	3,44%
36	66,90	64,95	-1,95	-2,91%
37	69,15	73,40	4,25	6,15%
38	81,10	70,70	-10,40	-12,82%
39	67,40	64,10	-3,30	-4,90%
40	63,50	73,95	10,45	16,46%
<b>MEAN</b>	65,96	66,93	0,96	<b>1%</b>
<b>SD</b>	8,69	7,26	7,68	

	Student test (p-value)	Significativity
Tafter make-up removal/T0	0,5809	ns

	Student test (p-value)	
	p-value	Significativity
Cotton vs fingers	0,1466	ns

## RESULTS OF VISIA

Cotton + mascara waterproof							
Volontaires	T0	TM	TD	DELTA		% VARIATION	
				TM-T0	TD-TM	TM-T0/T0	TD-TM/T0
8	56	63	51	7	-12	13%	-21%
12	42	43	40	1	-3	2%	-7%
13	55	67	50	12	-17	22%	-31%
14	51	58	49	7	-9	14%	-18%
15	68	71	63	3	-8	4%	-12%
16	38	43	32	5	-11	13%	-29%
17	55	60	47	5	-13	9%	-24%
18	52	55	51	3	-4	6%	-8%
19	64	70	64	6	-6	9%	-9%
20	57	61	64	4	3	7%	5%
MEAN	53,80	59,10	51,10	5,30	-8,00	10%	-15%
SD	8,97	9,88	10,46	3,02	5,75		

cotton + mascara No waterproof							
Volontaires	T0	TM	TD	DELTA		% VARIATION	
				TM-T0	TD-TM	TM-T0/T0	TD-TM/T0
1	48	52	44	4	-8	8%	-17%
2	54	63	56	9	-7	17%	-13%
3	44	52	44	8	-8	18%	-18%
4	46	59	46	13	-13	28%	-28%
5	51	57	47	6	-10	12%	-20%
6	51	63	54	12	-9	24%	-18%
7	49	60	43	11	-17	22%	-35%
9	56	63	47	7	-16	13%	-29%
10	54	59	54	5	-5	9%	-9%
11	50	63	48	13	-15	26%	-30%
MEAN	50,30	59,10	48,30	8,80	-10,80	17%	-21%
SD	3,74	4,31	4,69	3,33	4,16		

	Student test	
	p-value	Significativity
TM/TD	0,0017	**
TM/T0	0,0004	***

	Student test	
	p-value	Significativity
TM/TD	1,7920E-05	***
TM/T0	1,5469E-05	***

Fingers + mascara waterproof							
Volontaires	T0	TM	TD	DELTA		% VAR	
				TM-T0	TD-TM	TM-T0/T0	TD-TM/T0
21	50	53	45	3	-8	6%	-16%
22	56	61	51	5	-10	9%	-18%
23	75	78	75	3	-3	4%	-4%
24	49	50	45	1	-5	2%	-10%
25	49	50	45	1	-5	2%	-10%
26	41	49	40	8	-9	20%	-22%
27	58	61	57	3	-4	5%	-7%
28	54	59	49	5	-10	9%	-19%
30	61	70	56	9	-14	15%	-23%
31	61	61	56	0	-5	0%	-8%
MEAN	55,40	59,20	51,90	3,80	-	6,9%	-13,2%
SD	9,28	9,38	9,93	2,97	3,47		

Fingers + mascara No waterproof							
Volontaires	T0	TM	TD	DELTA		% VARIATION	
				TM-T0	TD-TM	TM-T0/T0	TD-TM/T0
29	54	55	47	1	-8	2%	-15%
32	51	54	52	3	-2	6%	-4%
33	74	76	71	2	-5	3%	-7%
34	36	41	37	5	-4	14%	-11%
35	60	69	56	9	-13	15%	-22%
36	41	46	39	5	-7	12%	-17%
37	64	65	60	1	-5	2%	-8%
38	64	69	60	5	-9	8%	-14%
39	42	43	36	1	-7	2%	-17%
40	72	71	62	-1	-9	-1%	-13%
MEAN	55,80	58,90	52,00	3,10	-	5,6%	-12,4%
SD	13,22	12,73	11,93	2,92	3,11		

	Student test	
	p-value	Significativity
TM/TD	9,2579E-05	***
TM/T0	0,0029	**

	Student test	
	p-value	Significativity
TM/TD	6,1732E-05	***
TM/T0	0,0085	**

## RESULTS OF ANTIPOLLUTION

### Application of product with a cotton

Zone traitée (Produit)				
volontaire			Delta of variations	% Variation
	TM	TD	TD-TM	TM
1	20,291	0,076	-20,215	-99,63%
2	25,416	0,097	-25,319	-99,62%
3	25,907	0,620	-25,287	-97,61%
4	24,149	0,191	-23,958	-99,21%
5	21,413	1,544	-19,869	-92,79%
6	36,709	0,682	-36,027	-98,14%
7	22,825	0,695	-22,130	-96,96%
9	14,952	1,210	-13,743	-91,91%
10	30,343	0,345	-29,998	-98,86%
11	19,257	0,183	-19,074	-99,05%
8	18,37	1,16	-17,20	-93,66%
12	18,43	0,10	-18,32	-99,44%
13	18,80	0,99	-17,81	-94,72%
14	21,39	0,24	-21,14	-98,86%
15	23,14	0,21	-22,93	-99,08%
16	31,61	1,71	-29,91	-94,60%
17	24,05	0,06	-23,99	-99,76%
18	10,27	0,04	-10,23	-99,62%
19	21,16	0,34	-20,82	-98,41%
20	17,71	0,10	-17,61	-99,43%
Mean	22,31	0,53	-21,78	-97,62%
SD	5,93	0,53	5,86	

Zone contrôle (Eau)				
		Delta of variations		% Variation
TM	TD	TD-TM	TM	
18,37	0,10	-18,27	-99,45%	
21,47	0,04	-21,43	-99,83%	
28,03	0,09	-27,93	-99,66%	
21,09	0,16	-20,93	-99,23%	
20,29	5,78	-14,52	-71,54%	
26,74	1,50	-25,25	-94,39%	
35,80	0,57	-35,23	-98,41%	
23,40	1,00	-22,40	-95,73%	
18,43	0,10	-18,32	-99,44%	
18,80	0,99	-17,81	-94,72%	
25,15	0,10	-25,04	-99,59%	
14,95	1,21	-13,74	-91,91%	
30,34	0,34	-30,00	-98,86%	
19,26	0,18	-19,07	-99,05%	
20,63	0,21	-20,42	-99,00%	
15,85	0,94	-14,91	-94,05%	
27,97	0,43	-27,53	-98,45%	
16,97	0,35	-16,62	-97,91%	
13,32	0,55	-12,77	-95,87%	
19,86	0,33	-19,54	-98,35%	
21,84	0,75	-21,09	-96,57%	
5,66	1,26	5,90		



### Application of product with a cotton

Student test			
		p-value	Significativity
ZT	TD/TM	8,80739E-13	***
ZNT	TD/TM	1,76542E-12	***
ZT vs ZNT	TD/TM	0,6945	ns

### Application of product with fingers

Zone traitée (Produit)				
volontaire			Delta of variations	% Variation
	T1	T2	T2-T1	TM
21	15,73	0,07	-15,66	-99,54%
22				
23	9,25	0,12	-9,13	-98,70%
24	14,20	0,25	-13,95	-98,24%
25	15,42	0,08	-15,34	-99,47%
26	14,62	0,25	-14,36	-98,27%
27	15,03	0,15	-14,88	-98,98%
28	12,20	0,45	-11,75	-96,33%
29	13,45	2,34	-11,11	-82,58%
30	16,41	1,42	-14,99	-91,33%
31	11,66	0,12	-11,54	-99,01%
32	13,60	3,93	-9,67	-71,07%
33	16,25	1,79	-14,46	-88,98%
34	10,36	0,45	-9,90	-95,65%
35	9,78	0,19	-9,59	-98,10%
36	9,78	0,20	-9,58	-97,97%
37	8,53	2,68	-5,86	-68,64%
38	7,33	0,07	-7,26	-99,08%
39	6,37	0,22	-6,15	-96,49%
40	7,02	2,23	-4,79	-68,20%
Mean	11,95	0,90	-11,05	-92,50%
SD	3,33	1,15	3,47	

Zone contrôle (Eau)				
				% Variation
T1	T2	T2-T1	TM	
16,97	0,06	-16,91	-99,63%	
20,29	0,15	-20,14	-99,24%	
15,95	0,07	-15,88	-99,57%	
14,65	0,61	-14,03	-95,81%	
14,47	2,50	-11,97	-82,71%	
15,62	2,36	-13,26	-84,88%	
11,10	1,84	-9,26	-83,45%	
10,05	0,76	-9,30	-92,47%	
19,09	2,57	-16,52	-86,53%	
18,17	0,07	-18,09	-99,59%	
14,50	3,00	-11,50	-79,31%	
16,32	1,15	-15,17	-92,98%	
15,43	4,00	-11,43	-74,06%	
10,84	0,99	-9,85	-90,85%	
7,66	0,08	-7,58	-98,95%	
14,13	4,41	-9,72	-68,76%	
9,33	0,18	-9,15	-98,08%	
7,75	0,08	-7,67	-99,01%	
11,56	2,23	-9,33	-80,70%	
13,89	1,43	-12,46	-89,72%	
3,71	1,41	3,75		

### Application of product with fingers

Student test			
		p-value	Significativity
ZT	TD/TM	4,77916E-11	***
ZNT	TD/TM	2,3367E-11	***
ZT vs ZNT	TD/TM	0,0854	#



**DERMSCAN TUNISIA**

E2, Centre Esthétique  
Avenue Tahar Ben Ammar  
El Menzah 9  
1013 – TUNIS  
TUNISIA

Tel. + 216 71 87 35 77  
[www.dermscan.com](http://www.dermscan.com)

**RIVOLI**

**Samira ALTIN**  
Temmentec AG  
Lütoldstrasse 6  
3454 Sumiswald  
SUISSE

Tunis, April 16, 2018

**Preliminary results# 18E0573 (version 1.0) /**  
Related to quote# 18D0573

---

## **EVALUATION OF THE OCULAR ACCEPTABILITY OF A COSMETIC PRODUCT**

### **-USE TEST UNDER OPHTHALMOLOGICAL CONTROL-**

---



**RIVOLI Huile Demaquillant BATCH # lab-01133.9 .15.02.18**

**DermScan Project Manager**

**Houneida BOUSSETTA:** [hbo@dermscan.com](mailto:hbo@dermscan.com)

**Investigator (ophthalmologist)**

**Dr. Imen LETAIF**

Document 1/1 including 22 pages

---

## TABLE OF CONTENTS

---

<b>1. STUDY PROCESS</b>	<b>3</b>
1.1. POPULATION	3
1.2. INVESTIGATIONAL PRODUCT	4
1.3. DATA ANALYSIS	5
<b>2. PRINCIPLES AND RESULTS</b>	<b>6</b>
2.1. UNDESIRABLE EFFECTS / ADVERSE EVENTS	6
2.2. OCULAR ACCEPTABILITY	6
2.3. SUBJECTIVE EVALUATION QUESTIONNAIRE	9
<b>3. CONCLUSION</b>	<b>14</b>
<b>4. APPENDICES – STUDY DOCUMENTS / DETAILED RESULTS</b>	<b>16</b>
4.1. SUBJECTS' CHARACTERISTICS	16
4.2. RANDOMIZATION LIST	17
4.3. DAILY LOG	18
4.4. CONCOMITANT TREATMENTS	18
4.5. OCULAR ACCEPTABILITY	19
4.6. SUBJECTIVE EVALUATION QUESTIONNAIRE	20

## 1. STUDY PROCESS

### 1.1. POPULATION

#### 1.1.1. Protocol non-adherence

- No protocol non-adherence was observed during the study.

#### 1.1.2. Concomitant treatments

- None of the new concomitant medications invalidated the data obtained for the subjects in question.  
✚ See the concomitant medications in **Appendix 4.4**.

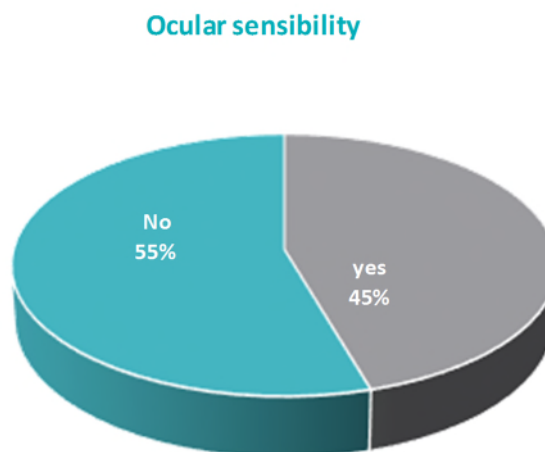
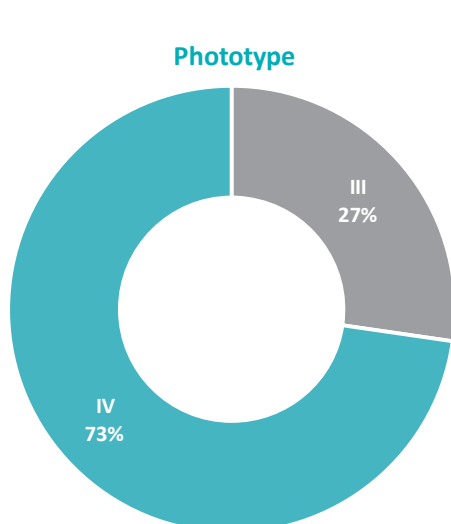
#### 1.1.3. Follow-up

	Number of SUBJECTS				
	INCLUDED	COMPLETING THE STUDY	ANALYZED	NOT COMPLETING THE STUDY	NOT-ANALYZED
Ocular acceptability / Questionnaire	22	22	22	0	0

✚ See observations detailed in **Appendix 4.1**.

#### 1.1.4. Demographic data

ANALYZED SUBJECTS	SEX	AGE (IN YEARS)			COMMENTS AND DETAILED DATA
		Mean ± SEM	Min.	Max.	
22	Female	35±2	20	52	See <b>Appendix 4.1</b>



## 1.2. INVESTIGATIONAL PRODUCT

### 1.2.1. Description

Reference	Batch#	Form	Packaging	Confidentiality procedure	Storage temperature
RIVOLI Huile Demaquillant	lab – 01133.9 .15.02.18	White emulsion	22 samples	Encoded	Room temperature

### 1.2.2. Application

Zones	Frequency	Mode
Eyes, face and lips	Once a day, in the evening.	<p><u>Method 1:</u></p> <ul style="list-style-type: none"> <li>Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth</li> </ul> <p><u>Method 2:</u></p> <ul style="list-style-type: none"> <li>Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water</li> </ul> <p>The application method of the study product is randomized according to the list presented in <b>Appendix 4.2.</b></p>

**1.2.3. Attribution to the subjects**

➔ *Product*

All the subjects receive the same product reference.

➔ *Application zone*

All the subjects apply the product to the same zone.

---

**1.3. DATA ANALYSIS**

---

The following data are analyzed:

	Parameters	Units	Variation(s) D21/D0	Statistical analysis (tick if yes)	Expected result(s)
<b>Ocular acceptability</b>	Clinical signs observed  Functional and physical signs reported by the subjects	/	No worsening between D0 and D21		
<b>Subjective evaluation</b>	Questionnaire	%	D21		Majority of positive answers



---

## 2. PRINCIPLES AND RESULTS

---

---

### 2.1. UNDESIRABLE EFFECTS / ADVERSE EVENTS

---

No Serious Adverse Event was reported during the study.

No Undesirable Effect was observed during the study.

---

### 2.2. OCULAR ACCEPTABILITY

---

#### 2.2.1. Principle

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

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

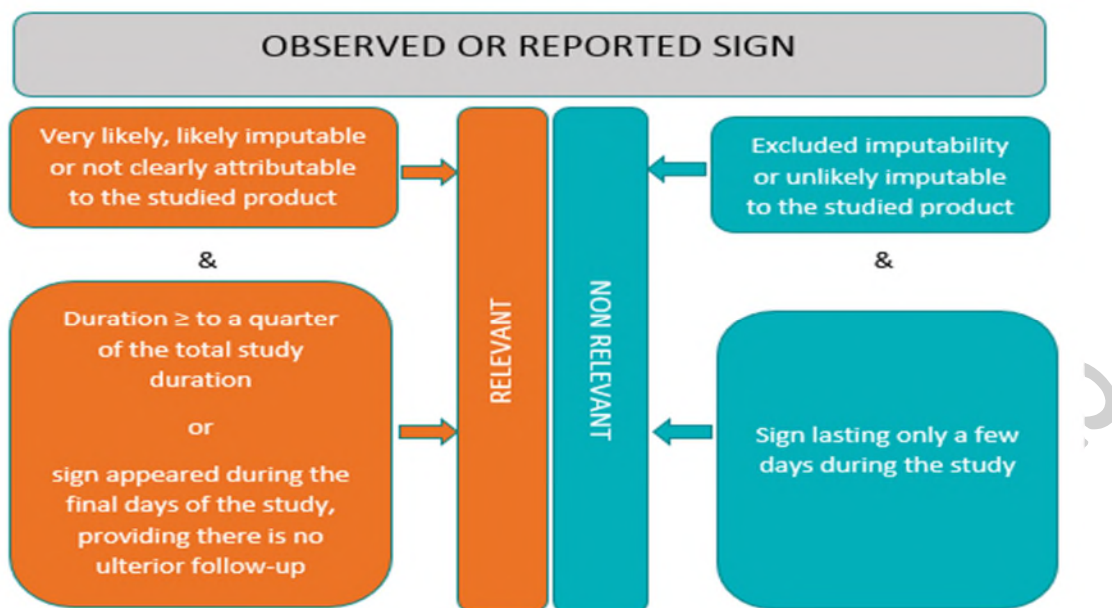
After 21 days of use, a new examination is done, by the same ophthalmologist.

Evaluation of the sensations felt in intensity and duration:

- watering,
- blurred vision,
- itching of eyes and eyelids,
- stinging of eyes and eyelids,
- dryness of eyes and eyelids,
- eyelid swelling,
- sensation of foreign body.

The ocular acceptability of the product is assessed by taking into account elements reported by the subjects (functional and physical signs) and those noticed by the ophthalmologist (clinical signs).

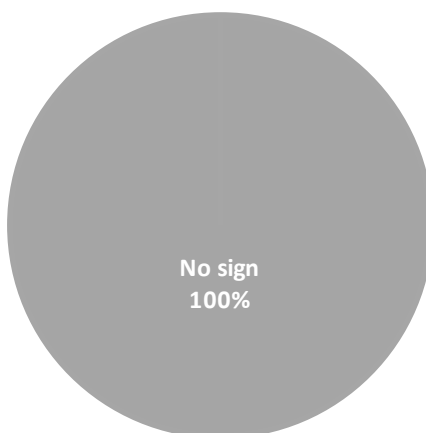
The global ocular acceptability is defined as the least favourable result.

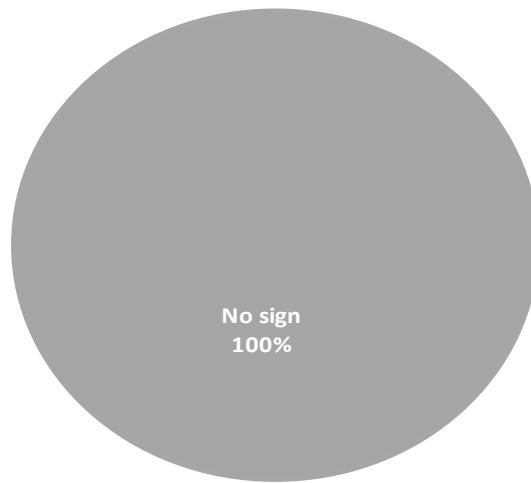


### 2.2.2. Summary of the results

- ❖ Clinical signs observed by the ophthalmologist on D21

#### PERCENTAGE OF SUBJECTS PRESENTING CLINICAL SIGNS



❖ **Functional and physical signs reported by the subjects on D21****PERCENTAGE OF SUBJECTS REPORTING FUNCTIONAL & PHYSICAL  
SIGNS**

+ See details in Appendix 4.5.



None of the subjects reported relevant functional or physical signs nor presented relevant clinical signs on D21.

So, product " RIVOLI Huile Demaquillant BATCH # lab – 01133.9 .15.02.18" is very well-tolerated on the ocular level.

## 2.3. SUBJECTIVE EVALUATION QUESTIONNAIRE

### 2.3.1. Principle

A subjective evaluation questionnaire, prepared by the clinical trial center and submitted to the sponsor, is filled in by the subjects on D21 at the end of the study to subjectively evaluate the global appreciation, the properties, the efficacy and the future use of the studied product.

### 2.3.2. Summary of the results

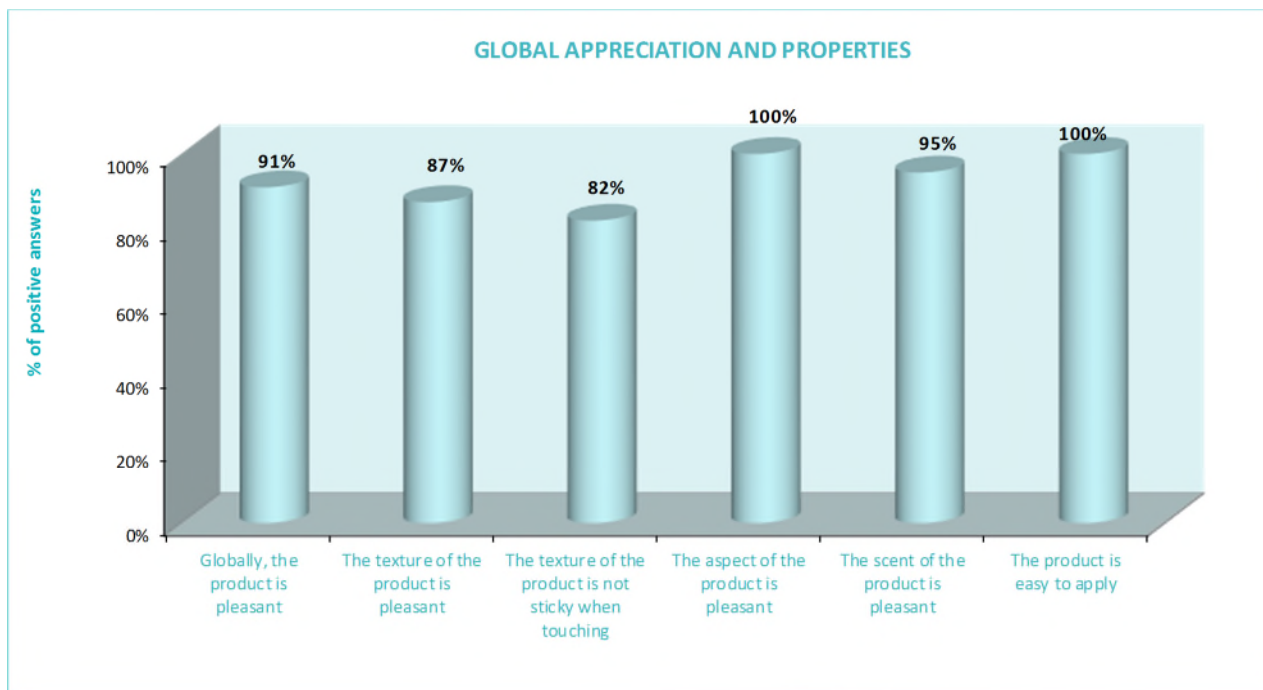
To be easier to read, the percentages are rounded off. The sum of these percentages may be different from 100%.

- In this study (n=22), one subject represents 4.5%.

#### AFTER 21 DAYS OF USE

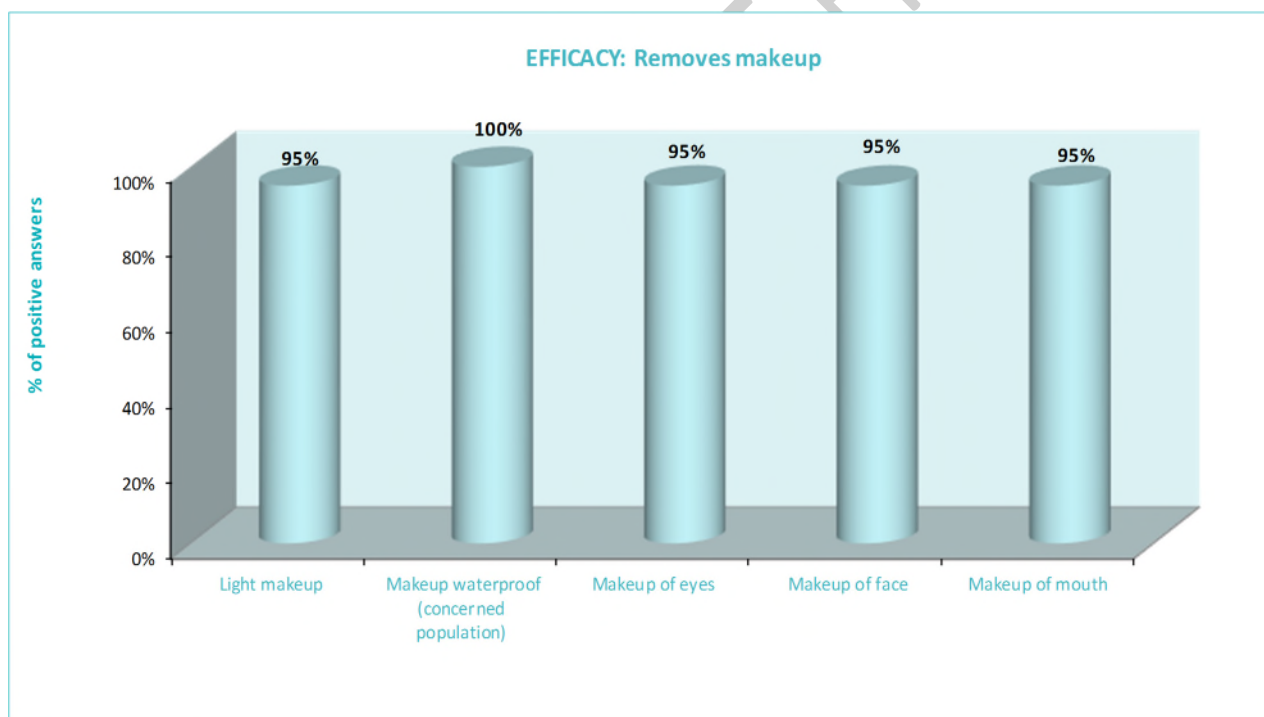
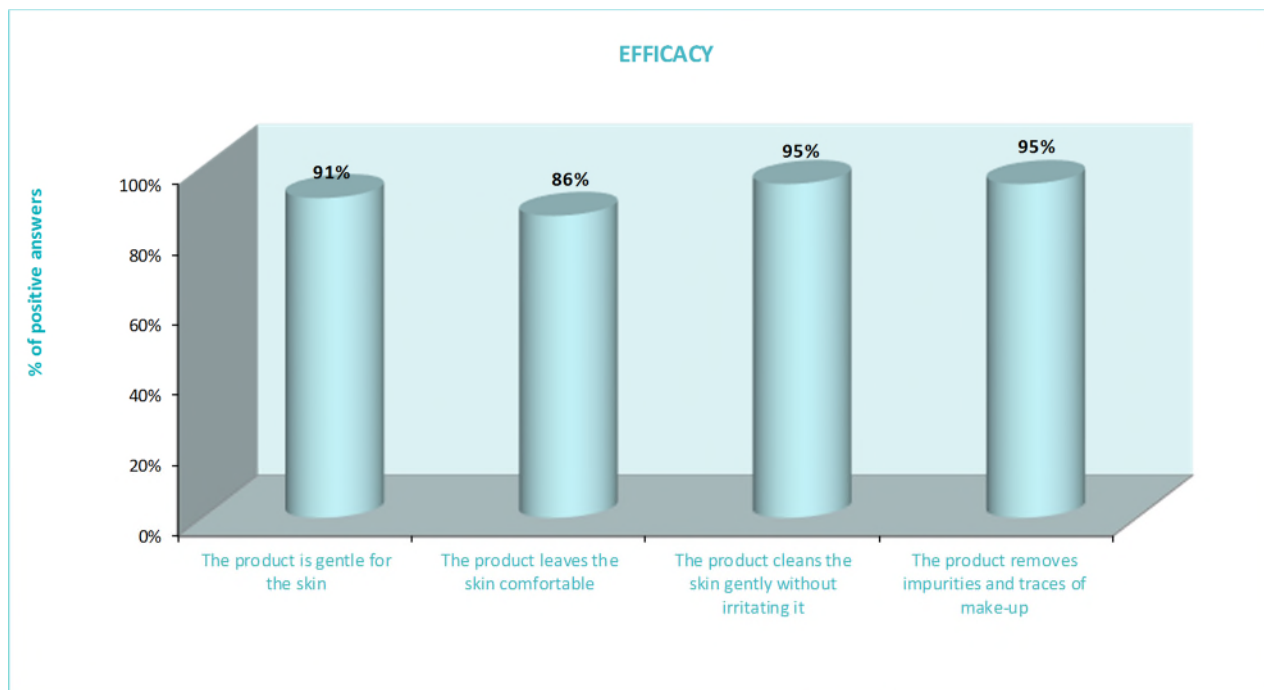
#### GLOBAL APPRECIATION AND PROPERTIES

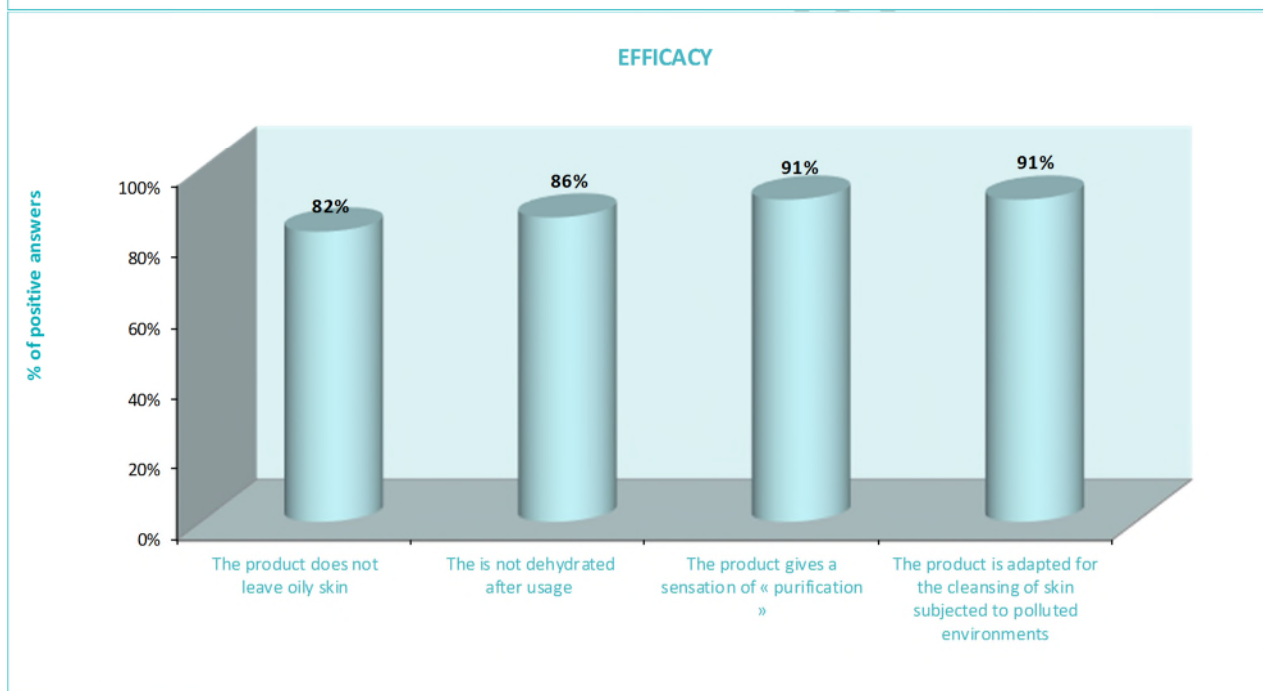
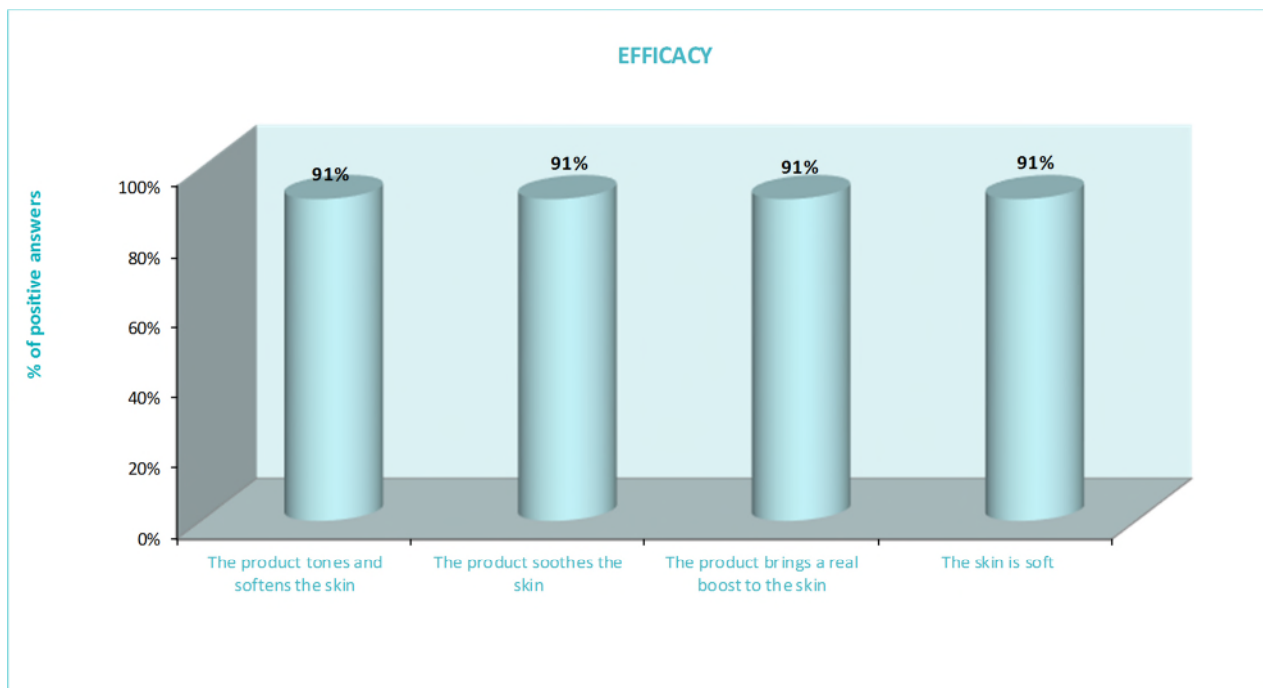
	% of subjects (agree / somewhat agree)	agree	somewhat agree
Globally, the product is pleasant	91%	86%	5%
The texture of the product is pleasant	87%	82%	5%
The texture of the product is not sticky when touching	82%	77%	5%
The aspect of the product is pleasant	100%	91%	9%
The scent of the product is pleasant	95%	86%	9%
The product is easy to apply	100%	100%	0%



### EFFICACY

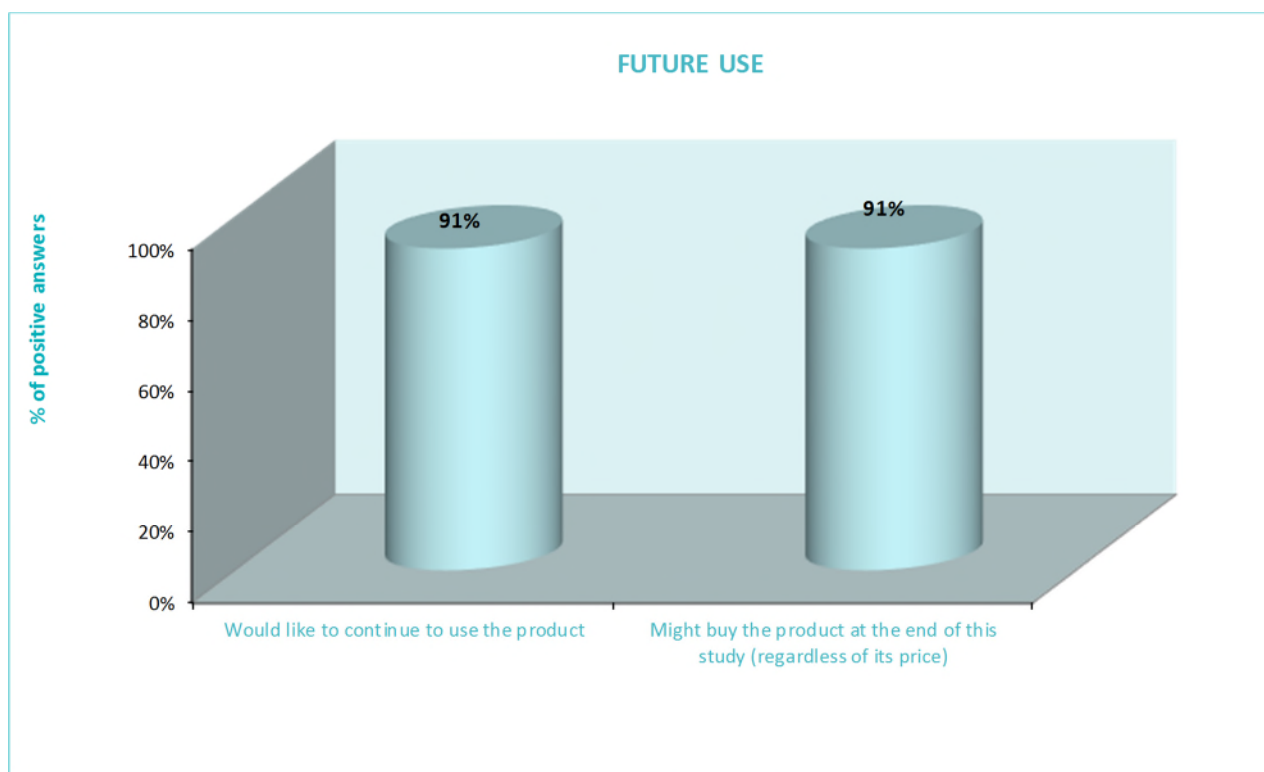
	% of subjects (agree / somewhat agree)	agree	somewhat agree
The product is gentle for the skin	91%	82%	9%
The product leaves the skin comfortable	86%	86%	0%
The product cleans the skin gently without irritating it	95%	95%	0%
The product removes impurities and traces of make-up	95%	95%	0%
The product removes makeup with efficacy:			
Light makeup	95%	95%	0%
Makeup waterproof (concerned population)	100%	100%	0%
Makeup of eyes	95%	95%	0%
Makeup of face	95%	95%	0%
Makeup of mouth	95%	95%	0%
The product tones and softens the skin	91%	91%	0%
The product soothes the skin	91%	91%	0%
The product brings a real boost to the skin	91%	91%	0%
The skin is soft	91%	91%	0%
The product does not leave oily skin	82%	82%	0%
The skin is not dehydrated after usage	86%	86%	0%
The product gives a sensation of « purification »	91%	91%	0%
The product is adapted for the cleansing of skin subjected to polluted environments	91%	91%	0%





**FUTURE USE**

	% of subjects (yes)
Would like to continue to use the product	91%
Might buy the product at the end of this study (regardless of its price)	91%



✚ See details in **Appendix 4.6.**



### 3. CONCLUSION



Under the conditions of this study conducted under ophthalmological control, the product:

**"RIVOLI Huile  
Demaquillant  
BATCH #  
lab-01133.9  
.15.02.18"**

- is very well-tolerated on the ocular level;

- is appreciated by subjects for its properties and its efficacy. 91% of subjects would like to continue its use and might buy it at the end of the study.

CONTROLE QUALITE

---

## APPENDICES:

### STUDY DOCUMENTS & DETAILED RESULTS

---



## 4. APPENDICES – STUDY DOCUMENTS / DETAILED RESULTS

### 4.1. SUBJECTS' CHARACTERISTICS

Subject#	Last name	First name	Age	Sex	Phototype	Contact lenses wearers	Ocular sensibility		Comments	Inclusion date	End date
1	ME	F	31	F	IV	No	No	None	None	March 12, 2018	April 2, 2018
2	IB	Y	28	F	IV	No	yes	Watering : without factors	None	March 12, 2018	April 2, 2018
3	AB	S	31	F	III	No	No	None	None	March 12, 2018	April 2, 2018
4	ME	R	20	F	IV	No	No	None	None	March 12, 2018	April 2, 2018
5	JA	I	41	F	IV	No	yes	Watering , stinging eyes , swelling eyelids, eyelid pruritus , stinging eyelids and dryness eyelids : pollen	None	March 12, 2018	April 2, 2018
6	AL	S	38	F	III	No	yes	Watering: high concentration of near Pruritus eyes and swelling eyelids : dust	None	March 12, 2018	April 2, 2018
7	BH	E	39	F	IV	No	yes	Eyelids dryness: without factors	None	March 12, 2018	April 2, 2018
8	FA	R	50	F	IV	No	yes	Watering : hot weather Pruritus eyes : hot	None	March 12, 2018	April 2, 2018
9	TR	A	28	F	IV	No	No	None	None	March 13, 2018	April 3, 2018
10	BO	I	32	F	IV	No	No	None	None	March 13, 2018	April 3, 2018
11	AY	Z	51	F	IV	No	yes	Dryness eyes : without factors	None	March 13, 2018	April 3, 2018
12	GA	J	33	F	IV	No	No	None	None	March 13, 2018	April 3, 2018
13	RI	K	52	F	IV	No	yes	Eyes and eyelids pruritus : strong smells	None	March 13, 2018	April 3, 2018
14	BS	N	41	F	IV	No	yes	Watering : wind	None	March 13, 2018	April 3, 2018
15	BE	A	24	F	III	No	yes	Pruritus eyes : dust	None	March 13, 2018	April 3, 2018
16	LA	M	28	F	IV	No	No	None	None	March 13, 2018	April 3, 2018
17	JE	A	35	F	III	No	No	None	None	March 13, 2018	April 3, 2018
18	JB	K	25	F	IV	yes (soft)	yes	Watering and burning : cosmetic products	None	March 13, 2018	April 3, 2018
19	ME	M	26	F	III	No	No	None	None	March 13, 2018	April 3, 2018
20	ME	R	37	F	IV	No	No	None	None	March 13, 2018	April 3, 2018
21	BA	N	26	F	IV	No	No	None	None	March 13, 2018	April 3, 2018
22	AR	K	51	F	III	yes (soft)	No	None	None	March 13, 2018	April 3, 2018
Mean			35	F	22	I	0	yes	2	yes	10
Median			33	M	0	II	0	No	20	No	12
Minimum			20			III	6				
Maximum			52			IV	16				
SEM			2			V	0				
95% CI			4			VI	0				

Legend: F: female  
M: male

## 4.2. RANDOMIZATION LIST

Sujet	Groupe
1	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
2	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
3	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water
4	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water
5	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
6	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water
7	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water
8	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
9	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
10	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water
11	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water
12	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
13	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
14	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water
15	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water
16	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
17	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water
18	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water
19	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
20	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
21	Apply the equivalent of a nut of gel to cotton, after apply to eyes, face and mouth
22	Apply the equivalent of a nut of gel on fingertips, gently massage on eyes, face and mouth. Rinse off with lukewarm water

...../ D21

Subject#	Medication (sales name)	Indication	Beginning of treatment (compared to the kinetics)	End of treatment (compared to the kinetics)
4	Panadol <sup>®</sup>	Headache	D 6	D 6
7	Grippex <sup>®</sup>	Flu	D 10	D 10
	Fervex <sup>®</sup>		D 16	D 17
	Panadol <sup>®</sup>	Headache	D 14	D 14

#### 4.5. OCULAR ACCEPTABILITY

The individual results of ocular acceptability are presented, below:

Ocular acceptability			
Subject#	D21		
	Signs reported by the subjects		Clinical signs observed by the Ophthalmologist
	Functional signs	Physical signs	
1	None	None	None
2	None	None	None
3	None	None	None
4	None	None	None
5	None	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

#### 4.6. SUBJECTIVE EVALUATION QUESTIONNAIRE

To be easier to read, the percentages are rounded off. The sum of these percentages may be different from 100%.

- In this study (n=22), one subject represents 4.5%.

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

##### APPRECIATION GLOBALE ET CARACTERISTIQUES / GLOBAL APPRECIATION AND PROPERTIES

		D'accord / I agree	Plutôt d'accord / I somewhat agree	Plutôt pas d'accord / I somewhat disagree	Pas d'accord / I disagree
1	<b>Dans l'ensemble, le produit est agréable /</b> <i>Globally, the product is pleasant</i>	86%	5%	0%	9%
2	<b>La texture du produit est agréable /</b> <i>The texture of the product is pleasant</i>	82%	5%	9%	5%
3	<b>La texture du produit n'est pas collante au toucher /</b> <i>The texture of the product is not sticky when touching</i>	77%	5%	9%	9%
4	<b>L'aspect du produit est agréable /</b> <i>The aspect of the product is pleasant</i>	91%	9%	0%	0%
5	<b>L'odeur du produit est agréable /</b> <i>The scent of the product is pleasant</i>	86%	9%	5%	0%
6	<b>L'application du produit est facile /</b> <i>The product is easy to apply</i>	100%	0%	0%	0%

## EFFICACITE / EFFICACY

		D'accord / I agree	Plutôt d'accord / I somewhat agree	Plutôt pas d'accord / I somewhat disagree	Pas d'accord / I disagree
7	<b>Le produit est doux pour la peau /</b> <i>The product is gentle for the skin</i>	82%	9%	9%	0%
8	<b>Le produit laisse la peau confortable /</b> <i>The product leaves the skin comfortable</i>	86%	0%	5%	9%
9	<b>Le produit nettoie la peau en douceur sans l'irriter /</b> <i>The product cleans the skin gently without irritating it</i>	95%	0%	5%	0%
10	<b>Le produit élimine les impuretés et les traces de maquillage /</b> <i>The product removes impurities and traces of make-up</i>	95%	0%	5%	0%
	<b>Le produit démaquille la peau avec efficacité /</b> <i>The product removes makeup with efficacy:</i>				
11	<b>Maquillage léger /</b> <i>Light makeup</i>	95%	0%	0%	5%
12	<b>Maquillage waterproof /</b> <i>Makeup waterproof (population concernée/concerned population)</i>	100%	0%	0%	0%
13	<b>Maquillage des yeux /</b> <i>Makeup of eyes</i>	95%	0%	0%	5%
14	<b>Maquillage du visage /</b> <i>Makeup of face</i>	95%	0%	0%	5%
15	<b>Maquillage de la bouche /</b> <i>Makeup of mouth</i>	95%	0%	0%	5%
16	<b>Le produit tonifie et adoucit la peau /</b> <i>The product tones and softens the skin</i>	91%	0%	5%	5%
17	<b>Le produit apaise la peau /</b> <i>The product soothes the skin</i>	91%	0%	5%	5%
18	<b>Le produit apporte un véritable coup d'éclat à la peau /</b> <i>The product brings a real boost to the skin</i>	91%	0%	5%	5%
19	<b>La peau est douce /</b> <i>The skin is soft</i>	91%	0%	5%	5%
20	<b>Le produit ne laisse pas la peau grasse /</b> <i>The product does not leave oily skin</i>	82%	0%	5%	14%
21	<b>La peau n'est pas desséchée après utilisation /</b> <i>The skin is not dehydrated after usage</i>	86%	0%	9%	5%
22	<b>Le produit apporte une sensation de « pureté » /</b> <i>The product gives a sensation of « purification »</i>	91%	0%	5%	5%
23	<b>Le produit est adapté au nettoyage de la peau sujette aux environnements pollués /</b> <i>The product is adapted for the cleansing of skin subjected to polluted environments</i>	91%	0%	5%	5%



## UTILISATION ULTERIEURE / FUTURE USE

24 Souhaiteriez-vous poursuivre l'utilisation de ce produit ? / Would you like to continue to use the product?

Oui / yes	Non / no
91%	9%

25 A l'issue de cette étude achèteriez-vous ce produit (indépendamment de son prix) ? / At the end of this study, would you buy the product (regardless of its price)?

Oui / yes	Non / no
91%	9%

CONTROLE QUALITE EN COURS