

TEST REPORT 15 24 01854

PEN CIRE WAX FORMUL NO SY 001

USE TEST  
PANEL OF 10 SUBJECTS

JANUARY 2016

## OBJECTIVE

The study's objective is to investigate the effect that the product 'PEN CIRE WAX FORMUL NO SY 001)' has, regarding hair removal, when used in a controlled panel test.

## TEST PRODUCT DESCRIPTION

PRODUCT MANUFACTURED BY	: TREDA HIZLI
RECEIPT DATE	: 23/10/2015
STUDY PERIOD	: 26/10/2015 - 21/01/2016
LAB ID	: 15 24 01854
TEST PRODUCT	: PEN CIRE WAX FORMUL NO SY 001
BRAND	: -
PRODUCT TYPE	: WAX
METHOD	: IN USE TEST, 10 SUBJECTS
STUDY SPONSOR	: QACS Ltd

## STUDY SUMMARY

The product 'PEN CIRE WAX FORMUL NO SY 001', is a yellow wax that is kept in a pen-style plastic container (see Annex 2).

10 healthy female volunteers with facial hair (hair length of 1-10mm), were included in the study. The product was used on the face (upper lip). After waxing, a clinical evaluation regarding the level of efficacy, was performed by the dermatologist, with the aid of photos, macroscopic and dermoscopic. The volunteers were asked to answer a questionnaire regarding the product, 4 weeks after waxing.

The study was conducted under the supervision of a dermatologist.

The study was performed by QACS Ltd.

### Assessment after the end of the treatment:

- ✓ Clinical evaluation (including photos, macroscopic and dermoscopic)
- ✓ Auto evaluation (questionnaire)

## **NORMATIVE, CONFIDENTIALITY AND ARCHIVING**

### **Normative**

The study was conducted by suitably trained and experienced personnel in accordance with the Efficacy Evaluation Guidelines published by COLIPA - May 2008.

Precautions were taken to avoid the possibility that participants in the study might experience undesirable effects. The test products were complying with requirements of the Regulation 1223/2009.

The manufacturer of the test product is responsible for its compliance with requirements of current Cosmetics Regulation (EC/1223/2009).

Ethical requirements which have been taken into consideration in the planning of the study include:

- i) participants are informed volunteers selected after application of inclusion/non inclusion criteria
- ii) participants are aware of the purpose and nature of the study and of any foreseeable risks involved in participation in the study and have given written informed consent before the study starts.

### **Confidentiality**

Requirements of Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal are taken into consideration. The anonymity of the volunteers is respected, no personal records have been kept. Each volunteer can be identified by the persons in charge of the study, thanks to his personal volunteer's code.

### **Archiving**

The laboratory book which contains all the information (raw data and results) regarding the study and the study reports are kept in the laboratory archives for 2 years.

## PANEL STUDIED, INCLUSION / NON INCLUSION CRITERIA

### Number of volunteers

A number of 10 volunteers has been recruited to satisfy the objectives of the test.

### Panel characteristics

Volunteers were selected on the basis of inclusion and non-inclusion criteria. The volunteers satisfied all the inclusion criteria, were not in conflict with any of the non-inclusion criteria and had a medical examination (health certificate) and a dermatological examination. The volunteers were clearly informed, verbally and in writing, regarding the nature of the study, the timetable, constraints and possible risks. They gave their written informed consent before participation in the study.

### Inclusion criteria

- ✓ Informed volunteers who agree to follow the conditions specified
- ✓ where appropriate of relevant age : 18-65 years old
- ✓ where appropriate of relevant gender : male and female
- ✓ where appropriate of relevant origin and health
- ✓ free from any dermatological problems on the area studied
- ✓ able to understand the Greek language and the study requirements
- ✓ no use of any depilatory products for 1 month

### Non inclusion criteria

- ✓ volunteers who do not meet the inclusion criteria
- ✓ pregnancy or nursing condition
- ✓ irritated skin on test site(s)
- ✓ blemishes, marks (e.g. tattoos, scars, sunburn) on the test site(s)
- ✓ presenting contact allergy to one of the ingredients of the tested product
- ✓ volunteers who refused to give their free and informed consent.

### Instructions given to the volunteers

- After the waxing process, let the hair grow naturally for 4 weeks

## METHODOLOGY

The methodological approach used to evaluate whether or not the product tested has any effect on hair removal, was the sensorial approach by consumers themselves, and clinical evaluation by the dermatologist (see Colipa Guidelines Efficacy 2008).

The study took place in QACS Ltd., under the supervision of a dermatologist.

The volunteers applied the product on the upper lip under the supervision of trained personnel. The product was removed with a rapid motion against the direction of hair growth, using cloth strips. Before and after the waxing process, macroscopic and dermoscopic photos of the test site were taken. The volunteers were instructed to let the hair of the test site grow naturally, for the following 4 weeks.

The sensorial test is based on the appreciation of product's performance made through the senses of either panellists and/or of experts. They give information mainly on observed or perceived parameters.

The sensorial test that was used for this study was auto evaluation (questionnaire).

The volunteers were given a questionnaire (see Annex 1), 4 weeks after the waxing process. They were asked to evaluate the product, in five parameters, at a scale of 1-5 (where 1 being "repulsive" and 5 being "excellent").

The clinical evaluation included efficacy grading of the product by the dermatologist and was supported by photos, macroscopic and dermoscopic.

## VOLUNTEER DATA

Table I depicts the number, code, sex and age of the volunteers.

Table I. Volunteers Description

Volunteer No	Volunteer Code	Sex	Age
1	1421	F	27
2	1395	F	28
3	1509	F	30
4	1390	F	29
5	1480	F	28
6	1478	F	29
7	1291	F	28
8	1347	F	36
9	1424	F	49
10	1529	F	26

## QUESTIONNAIRE QUANTIFICATION

The volunteers were asked to evaluate the product according to a scale from 1 to 5 where:

- 1 is Repulsive
- 2 is Not Satisfying
- 3 is Acceptable
- 4 is Good
- 5 is Excellent.

The questions the users were asked to answer regarding the product, were the following:

- Q1- Evaluate the impact on the skin (redness, burning, peeling, itching etc.).*
- Q2- Is the product easy to use?*
- Q3- Does the product remove many hairs after one use?*
- Q4- Does the product remove the hairs from their roots?*
- Q5- Did you feel the smoothness and softness on your skin up to 4 weeks?*

They were also asked to answer the following YES-NO questions:

- Q6- Would you buy this product?*
- Q7- Would you recommend this product?*

The users were also asked to add comments, if any, after the use of the product.

**RESULTS ON QUESTIONNAIRES**

Table II. Volunteer assessment on the product

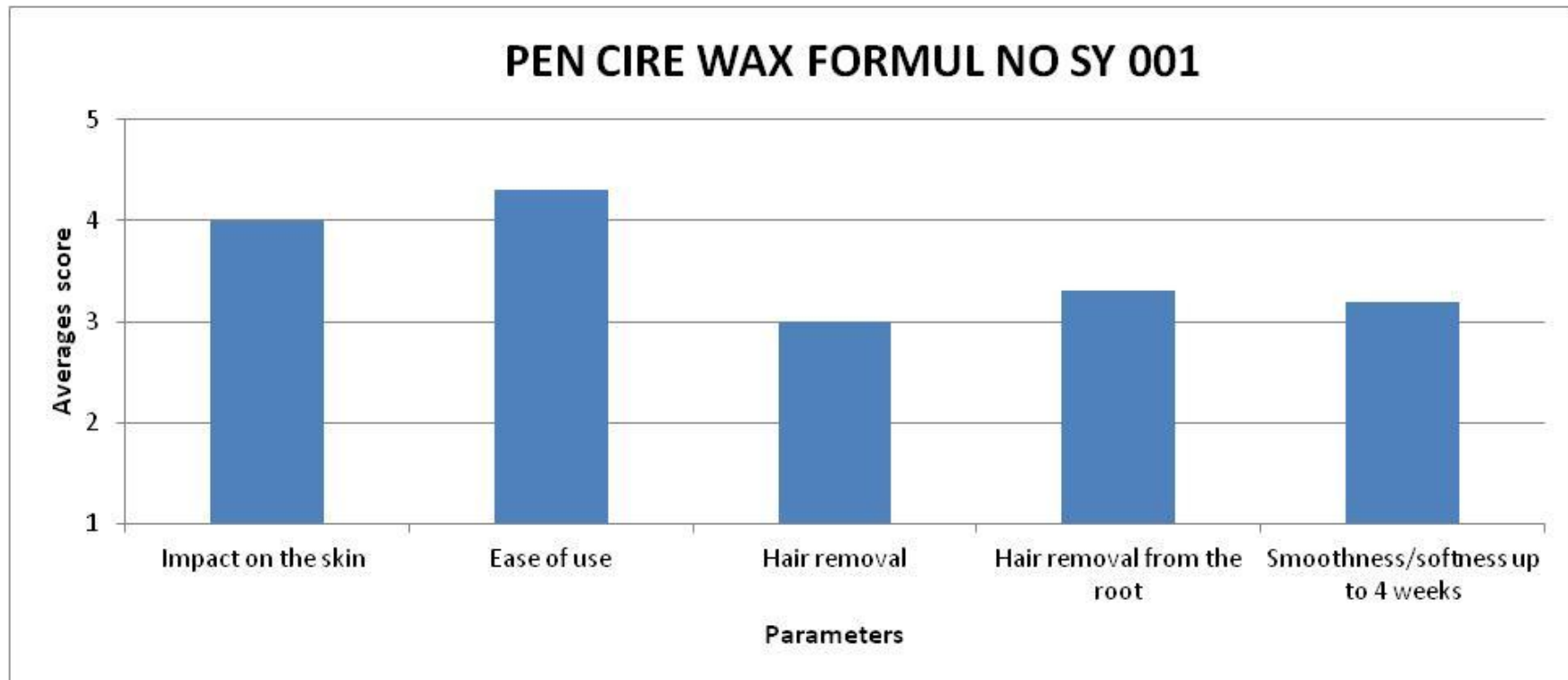
PRODUCT	Volunteer No	1	2	3	4	5	6	7	8	9	10
	Q1. Impact on the skin (redness, burning, peeling, itching etc.)	5	4	5	3	4	3	4	5	3	4
	Q2. Ease of use	4	5	5	4	5	2	5	5	3	5
	Q3. Hair removal	2	4	3	3	4	1	4	3	3	3
	Q4. Hair removal from the root	2	3	3	4	3	1	4	5	3	5
	Q5. Smoothness/softness up to 4 weeks	3	3	5	2	3	1	3	4	3	5

Table III. Average assessment on the product

	Average score	Classification
Q1. Impact on the skin (redness, burning, peeling, itching etc.)	4	Good
Q2. Ease of use	4,3	More than good
Q3. Hair removal	3	Acceptable
Q4. Hair removal from the root	3,3	More than acceptable
Q5. Smoothness/softness up to 4 weeks	3,2	More than acceptable



The Graph below depicts the average assessments of the volunteers for each parameter for the product (Q1 - Q5).



**Q1. Impact on the skin (redness, burning, peeling, itching etc.)**

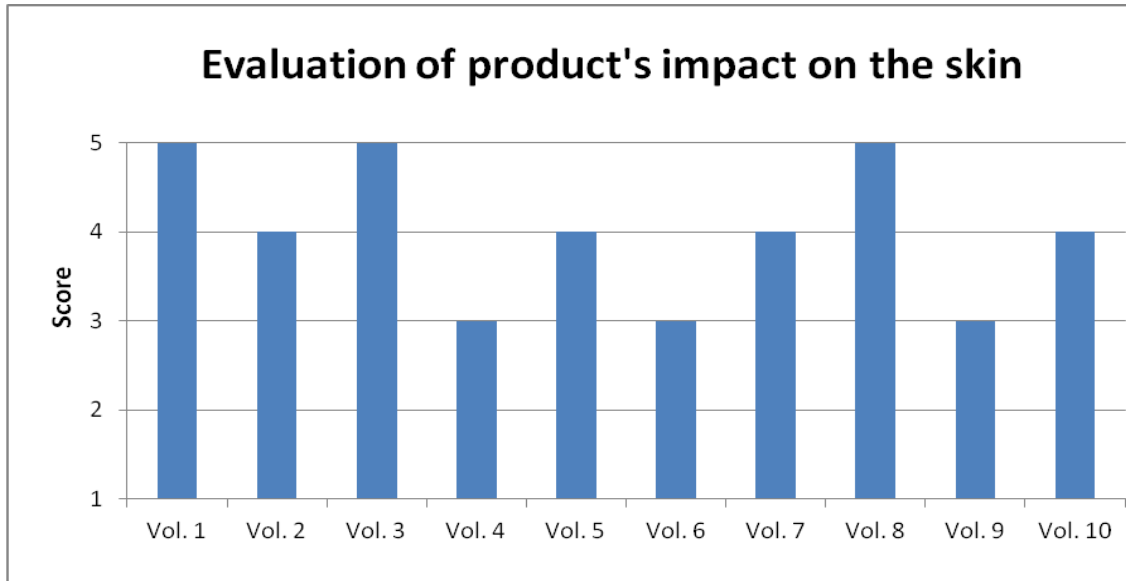
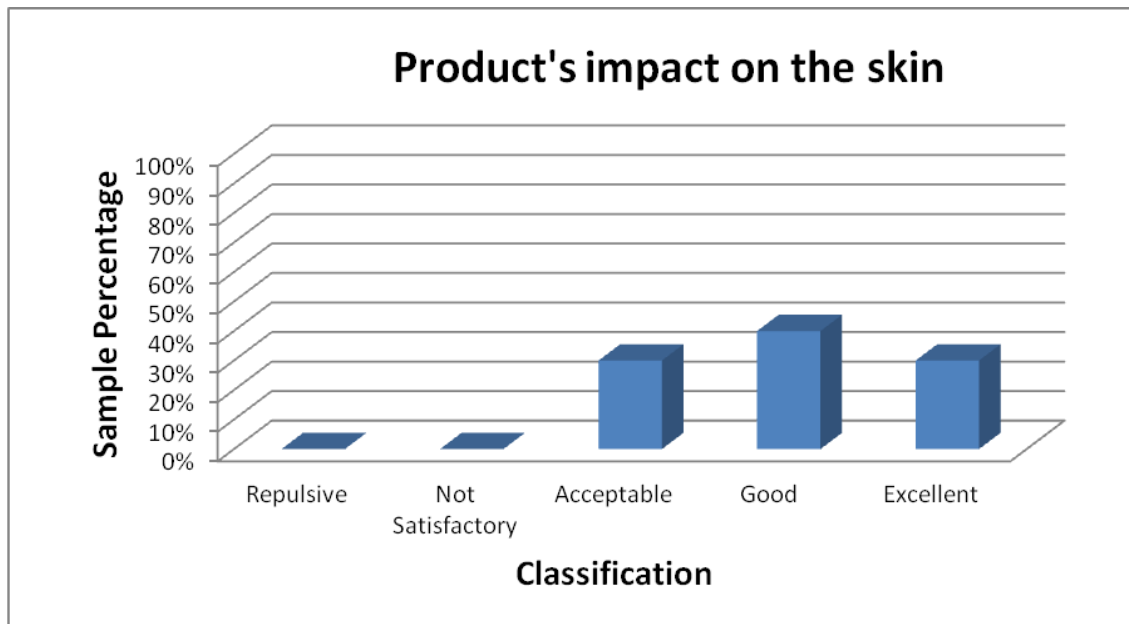


Table IV. Answers on Parameter 1.

1 (Repulsive)	2 (Not satisfactory)	3 (Acceptable)	4 (Good)	5 (Excellent)	Total
0	0	3	4	3	10

- 70% of the users assessed the impact of the product on the skin as more than good



**Q2. Ease of use**

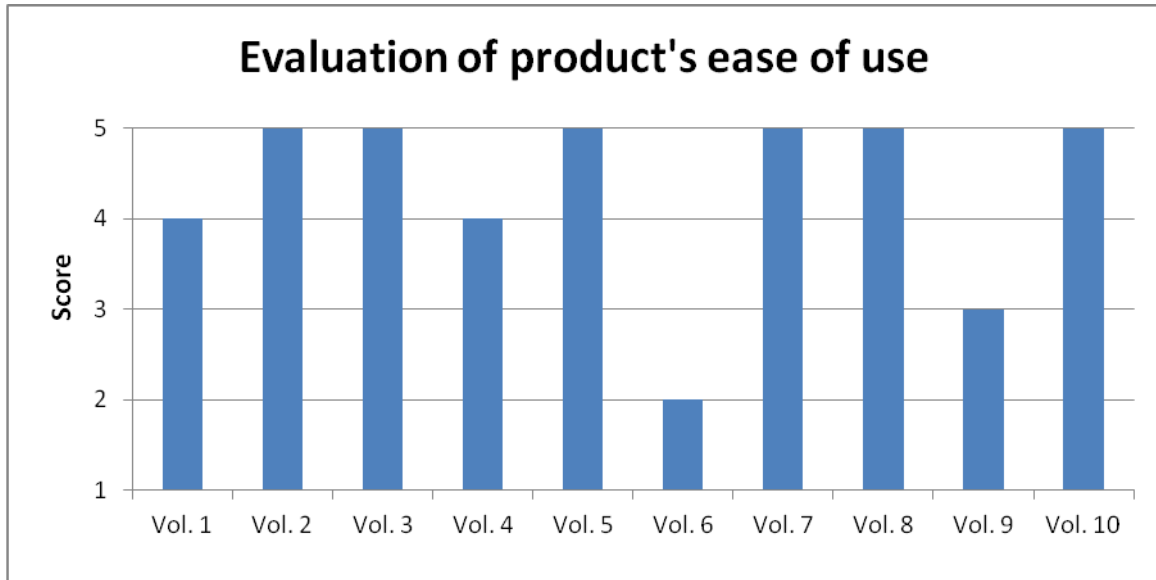
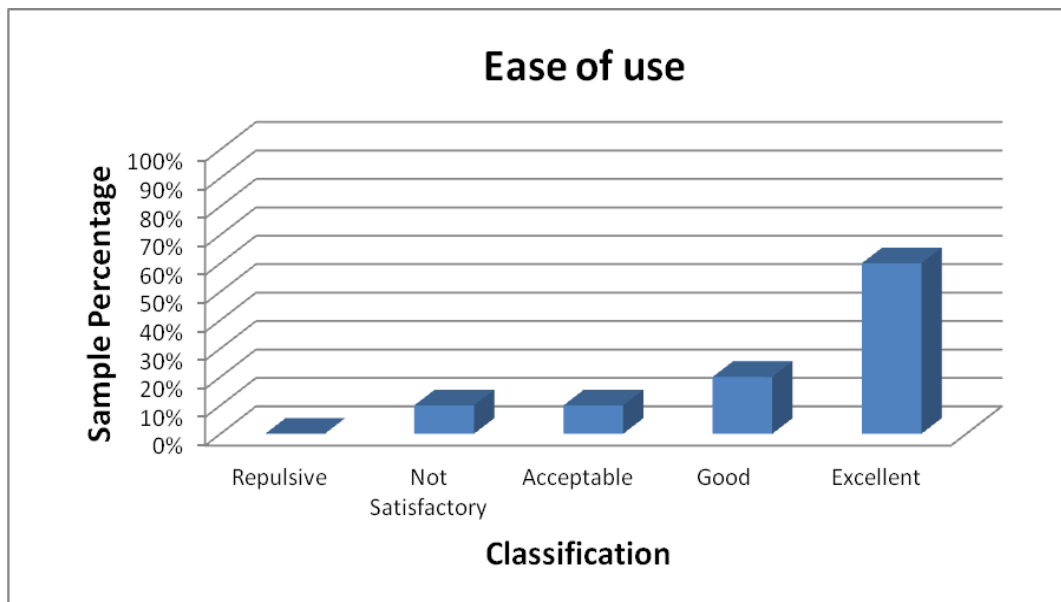


Table V. Answers on Parameter 2.

1 (Repulsive)	2 (Not satisfactory)	3 (Acceptable)	4 (Good)	5 (Excellent)	Total
0	1	1	2	6	10

- 80% of the users assessed the ease of product's use as more than good



**Q3. Hair removal**

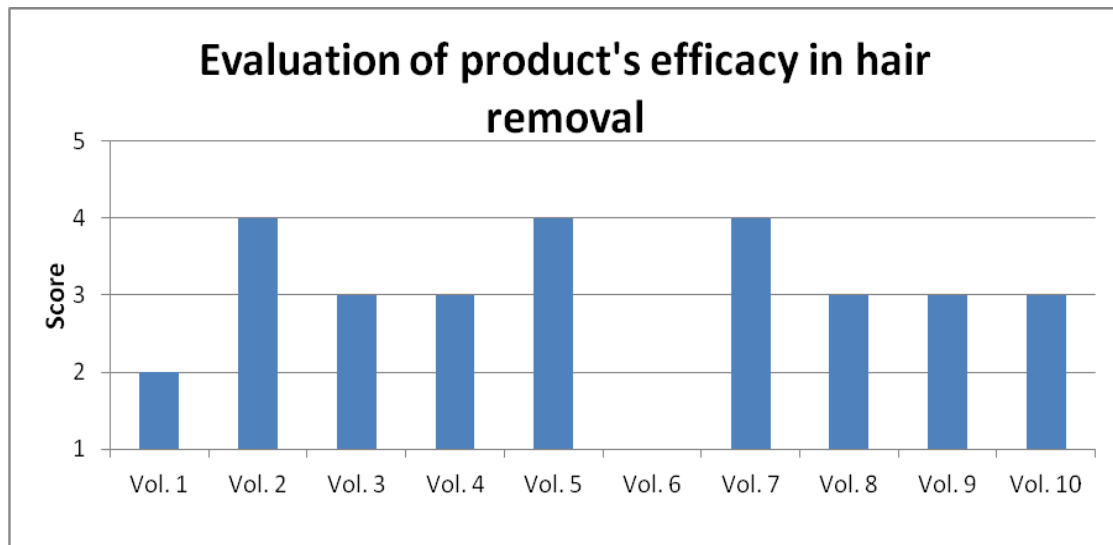
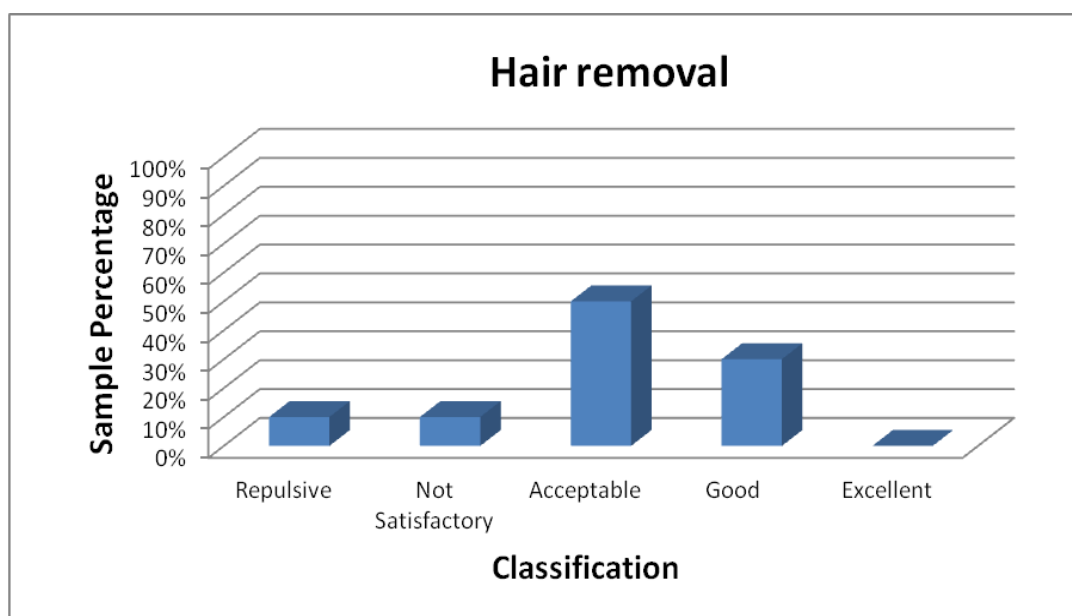


Table VI. Answers on Parameter 3.

1 (Repulsive)	2 (Not satisfactory)	3 (Acceptable)	4 (Good)	5 (Excellent)	Total
1	1	5	3	0	10

- 30% of the users assessed the product's efficacy in hair removal as more than good



**Q4. Hair removal from the root**

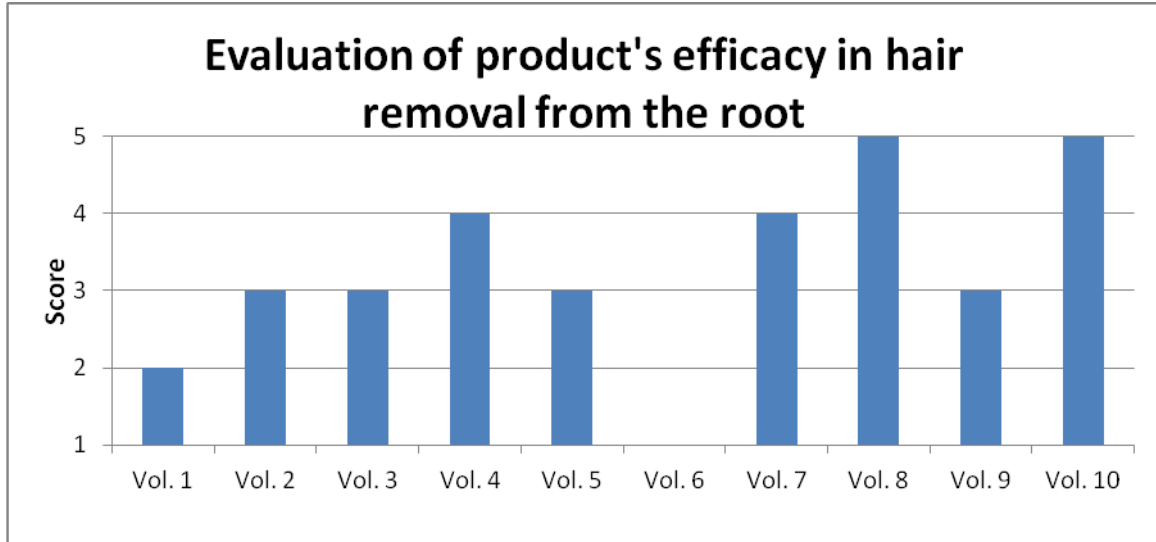
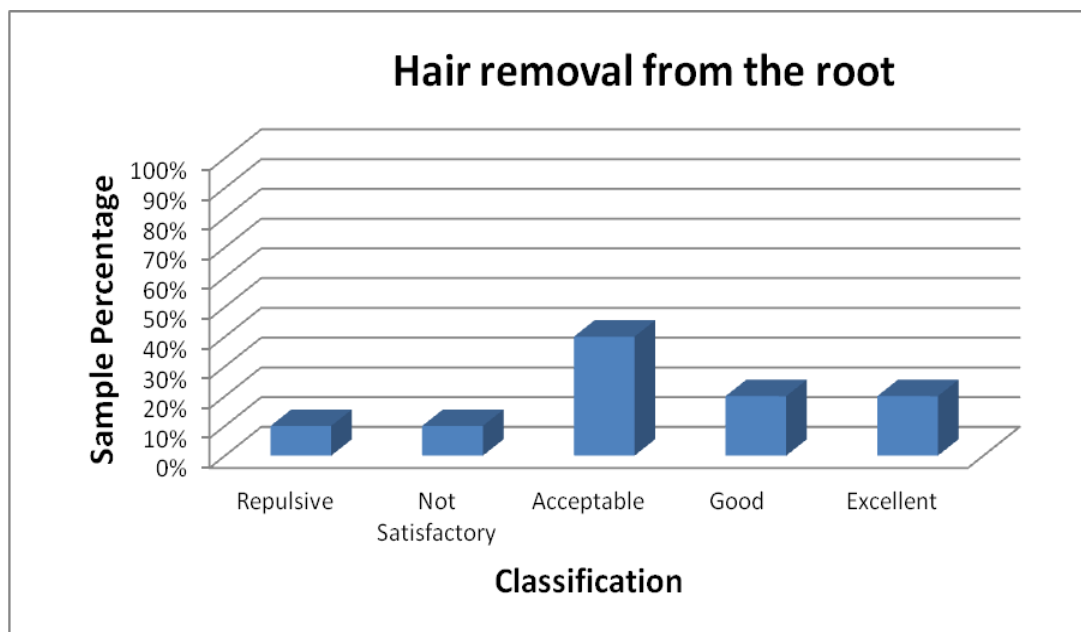


Table VII. Answers on Parameter 4.

1 (Repulsive)	2 (Not satisfactory)	3 (Acceptable)	4 (Good)	5 (Excellent)	Total
1	1	4	2	2	10

- 40% of the users assessed the product's efficacy in hair removal from the root as more than good



**Q5. Smoothness/ softness sensation up to 4 weeks**

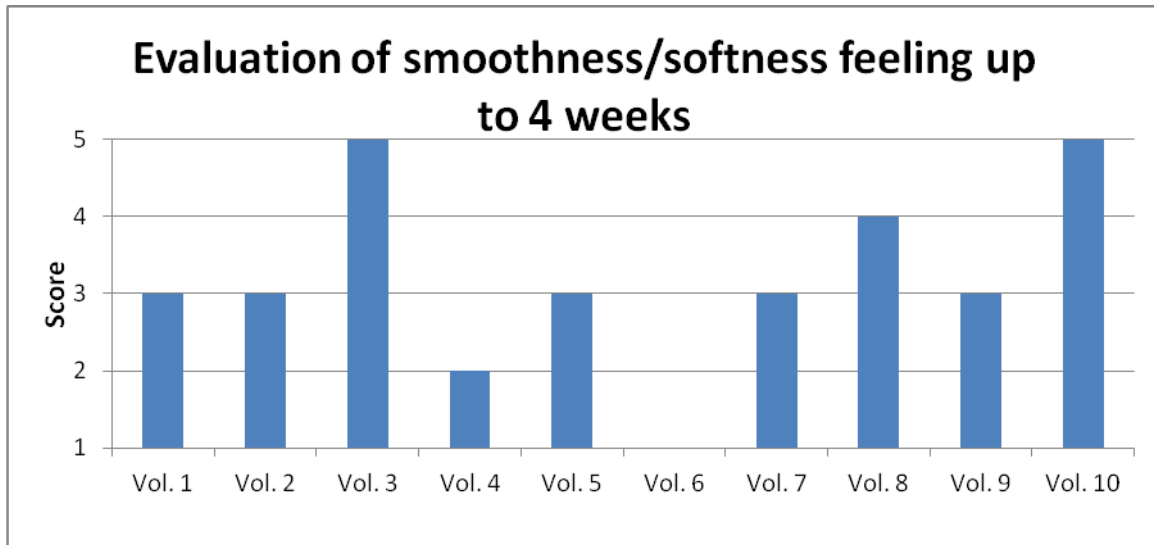
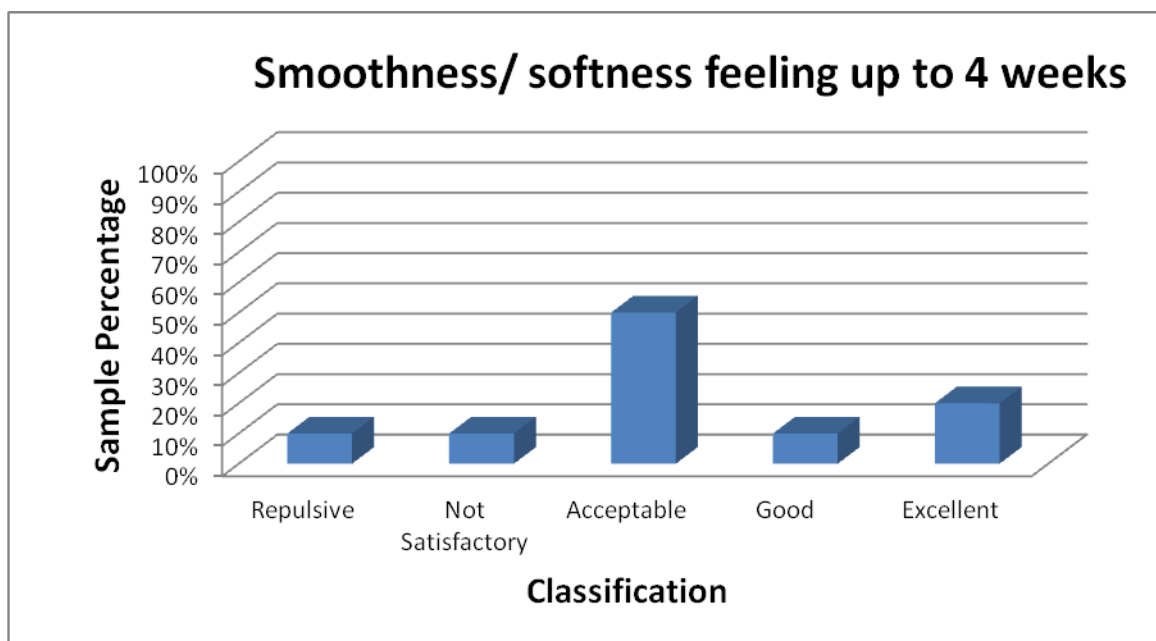


Table VIII. Answers on Parameter 5.

1 (Repulsive)	2 (Not satisfactory)	3 (Acceptable)	4 (Good)	5 (Excellent)	Total
1	1	5	1	2	10

- 30% of the users assessed the smoothness/ softness feeling on skin up to 4 weeks after the epilating process as more than good



**Q6. Purchase intention**

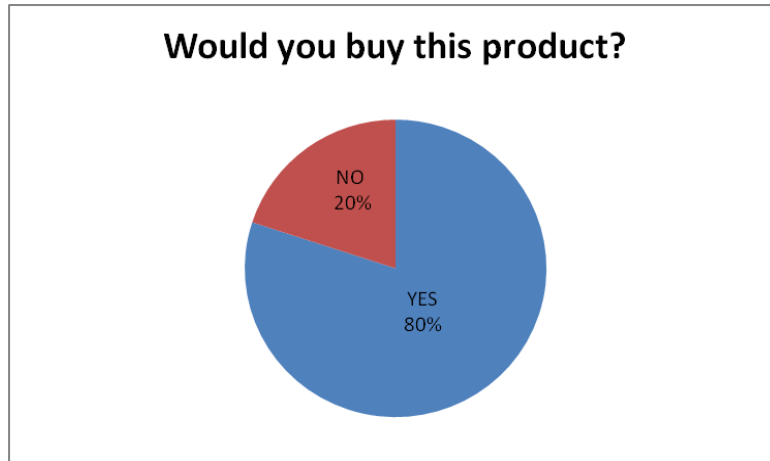


Table IX. Answers on Parameter 6.

Volunteer No.									
1	2	3	4	5	6	7	8	9	10
NO	YES	YES	YES	YES	NO	YES	YES	YES	YES

**Q7. Recommendation intention**

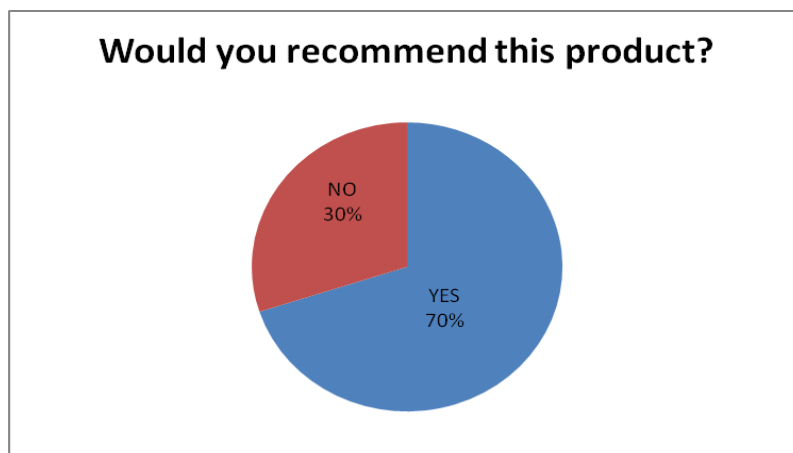


Table X. Answers on Parameter 7.

Volunteer No.									
1	2	3	4	5	6	7	8	9	10
NO	YES	YES	YES	YES	NO	YES	YES	YES	NO

### Overview of scored parameters

The volunteers were asked to score 5 parameters after the application of the product. The overall results can be seen in the following table.

Parameter	Score
Impact on the skin	80/100
Ease of use	86/100
Efficacy in hair removal	60/100
Efficacy in hair removal from the root	66/100
Smoothness/ softness feeling, up to 4 weeks	64/100

### Discussion

None of the volunteers added comments or indications regarding the product.  
No side-effects were reported by the volunteers.



## CLINICAL EVALUATION

### Efficacy (Dermoscopic)

A dermoscopic image is taken in the center of each macroscopic area before and one minute after the procedure. The center is marked with a dot.

The physician assesses dermoscopically the percentage of hair follicles that contain less than 1mm of hair shaft and grades the efficacy result as follows:

0 : none (failure to remove any hair)

1 : 1 - 25%

2 : 26 - 50%

3 : 51 - 75%

4 : 76 - 100%

The efficacy grading of the product for each volunteer, can be seen on the table below:

Volunteer No	Efficacy grading
1	2
2	4
3	2
4	4
5	4
6	2
7	4
8	4
9	4
10	4

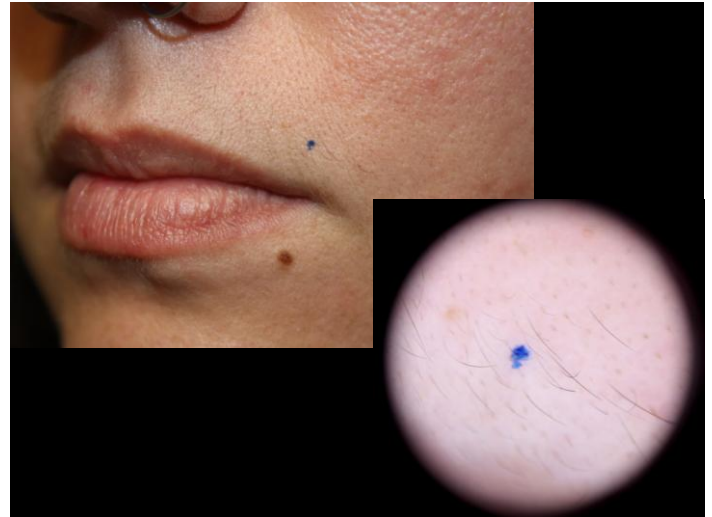
### Dermatologist's comments

The device for face waxing is handy as the use of excess product is avoided.

Mild irritation is anticipated when treating this sensible area (upper lip). 7/10 of the volunteers had a level 4 of efficacy. The rest of the volunteers had a lower efficacy level due to low pain threshold or irritation during the procedure (volunteers 1, 3 and 6).

## Representative comparative examples

### Example 1 (Vol. 2)



Pictures 1a - 1b. Before waxing



Picture 1c - 1d. Immediately after waxing

### Dermatologist's comments on Example 1:

Immediately after waxing:

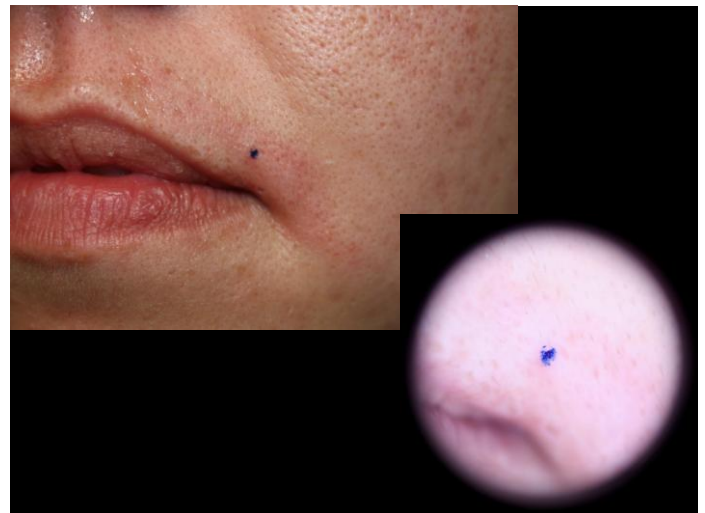
Blue arrows indicate the parts of the hair shaft that has been retained inside the follicle after the waxing procedure.

The result is optimal, classified as level 4 of efficacy (more than 76% of hair has been removed).

Example 2 (Vol. 8)



Pictures 1a - 1b. Before waxing



Picture 1c - 1d. Immediately after waxing

Dermatologist's comments on Example 2:

Immediately after waxing:

Efficacy level 4

## CONCLUSIONS

The objective of the study was to investigate the efficacy of hair removal of the product 'PEN CIRE WAX FORMUL NO SY 001', in a controlled panel test.

10 healthy female volunteers with facial hair, were included in the study. The product was used on the face (upper lip). After waxing, a clinical evaluation regarding the level of efficacy, was performed by the dermatologist, with the aid of photos, macroscopic and dermoscopic. The volunteers were asked to answer a questionnaire regarding the product, 4 weeks after waxing.

The study was conducted under the supervision of a dermatologist.

### Auto-evaluation - Questionnaire

The product 'PEN CIRE WAX FORMUL NO SY 001' scored:

- 80% on the impact on the skin (absence of redness, burning, peeling, itching etc.)
- 86% on the ease of use
- 60% on hair removal efficacy
- 66% on the efficacy of hair removal from the root
- 64% on smoothness/softness sensation, up to 4 weeks
- 80% on purchase intention
- 70% on recommendation intention

### Clinical evaluation - Photos

The product 'PEN CIRE WAX FORMUL NO SY 001' was well tolerated. Additionally, itnd was applied and removed with ease.

Overall, the product has been able to effectively remove facial hair.

Full name and Signature of the Investigator  
Printed name : Dr. Christos Prevezas  
Date : 21/01/2016

Dr Christos PREVEZAS  
Dermatologist - Venereologist



Study Manager:  
Printed name : Yiannis Kapetanstratakis  
Date : 21/01/2016

**QACS Laboratories**  
Antigonis str 144 51 Metamorfossi Greece  
tel no EL 999709411 email info@qacs.gr  
tel +30-210 2934745 FAX +30-210 2934606  
www.qacs.gr



Results refer to the sample as received and analyzed on the period specified.

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**ANNEX 1 - QUESTIONNAIRE**

**ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ**

Όνοματεπώνυμο	
Ηλικία	
Φύλο	
Προϊόν	PEN CIRE WAX FORMUL NO SY 001 15 24 01854

Σύμφωνα με τα ακόλουθα κριτήρια αξιολόγησης,

- 1- ΑΠΩΘΗΤΙΚΟ
- 2- ΜΗ ΙΚΑΝΟΠΟΙΗΤΙΚΟ
- 3- ΑΠΟΔΕΚΤΟ
- 4- ΚΑΛΟ
- 5- ΑΡΙΣΤΟ,

παρακαλούμε χαρακτηρίστε, βαθμολογώντας από το 1 μέχρι το 5, το παραπάνω προϊόν:

<b>Πώς κρίνετε το παραπάνω προϊόν ως προς:</b>	
1. Την επίδρασή του στο δέρμα (ερεθισμός, αίσθηση καψίματος, απολέπιση, φαγούρα);	
2. Την ευκολία χρήσης;	
3. Την ποσότητα των τριχών που αφαιρεί μετά από μία χρήση;	
4. Την αφαίρεση των τριχών από τη ρίζα;	
5. Την αποτελεσματικότητα μετά από χρήση τεσσάρων εβδομάδων;	

Παρακαλούμε απαντήστε με ΝΑΙ ή ΟΧΙ στα ακόλουθα ερωτήματα:

Θα αγοράζατε αυτό το προϊόν;	
Θα συστήνατε αυτό το προϊόν;	

**Έχετε κάποιο άλλο σχόλιο ή υποδείξεις σχετικά με το προϊόν;**

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Υπογραφή του εθελοντή

../../2016

ANNEX 2 - PHOTO

