

TEST REPORT 15 24 02117

PAIN-LESS DEPILASYON YAN ETKILERINI AZALTAN SOLUSYON /
PAIN- LESS DEPILATION SIDE EFFECTS REDUCING SOLUT ION
(FORMUL YK -001)

USE TEST
PANEL OF 10 SUBJECTS

NOVEMBER 2015

OBJECTIVE

The study's objective is to prove the effect that the product 'PAIN-LESS DEPILASYON YAN ETKILERINI AZALTAN SOLUSYON / PAIN- LESS DEPILATION SIDE EFFECTS REDUCING SOLUTION (FORMUL YK -001)' has on the level of pain and irritations during and after the waxing process respectively, in a controlled panel test.

TEST PRODUCT DESCRIPTION

PRODUCT MANUFACTURED BY	: TREDA HIZLI
RECEIPT DATE	: 20/11/2015
STUDY PERIOD	: 23/11/2015 - 27/11/2015
LAB ID	: 15 24 02117
TEST PRODUCT	: PAIN-LESS DEPILASYON YAN ETKILERINI AZALTAN SOLUSYON / PAIN- LESS DEPILATION SIDE EFFECTS REDUCING SOLUTION (FORMUL YK -001)
BRAND	: -
PRODUCT TYPE	: OIL
METHOD	: IN USE TEST, 10 SUBJECTS
STUDY SPONSOR	: QACS Ltd

STUDY SUMMARY

The product 'PAIN-LESS DEPILASYON YAN ETKILERINI AZALTAN SOLUSYON /PAIN- LESS DEPILATION SIDE EFFECTS REDUCING SOLUTION (FORMUL YK -001)', is a light yellow oil with characteristic odor that is kept in a plastic container (see Annex 2).

10 healthy female volunteers with leg hair, were included in the study. The product was used on one leg (right) while the other (left) was used as reference. After waxing both legs, the level of pain sensed on each leg was rated and compared by the volunteers. A comparative clinical evaluation regarding the level of irritation, was also performed by the dermatologist.

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, plain 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
- iii) a patch test was conducted before the initiation of the use test.

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
- ✓ users of wax

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.

METHODOLOGY

The methodological approach used to evaluate whether or not the product tested has any effect on the reduction of pain and irritation during & after the waxing process, 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 right leg (test site). The other leg was used as reference. The product was massaged for 1-2 minutes. 10-12 minutes after application and right before the waxing process, the area was dried and cleaned properly using damp paper towel.

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) and they were asked to evaluate the test as well as the reference site, in three parameters, at a scale of 0-10 (where 0 meaning "no indication" and 10 meaning "strong indication").

The clinical evaluation included comparison of the level of irritation after the waxing process, for the test and the reference site, and was supported by photos, plain 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	1520	F	22
2	1518	F	22
3	1469	F	35
4	1521	F	22
5	1380	F	61
6	1433	F	49
7	1424	F	48
8	1522	F	46
9	1414	F	27
10	1402	F	29

QUESTIONNAIRE QUANTIFICATION

The volunteers were asked to evaluate the test and reference site according to a scale from 0 to 10 where:

0 is “No indication” and

10 is “Strong indication”.

The parameters that were evaluated by the users were the following:

How do you judge the product regarding:

Q1. Pain

Q2. Swelling sensation

Q3. Irritation

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. Pain	6	3	0	4	1	5	0	1	1	5
	Q2. Swelling sensation	0	0	0	3	0	3	0	0	0	3
	Q3. Irritation	2	0	0	0	0	3	0	4	1	3

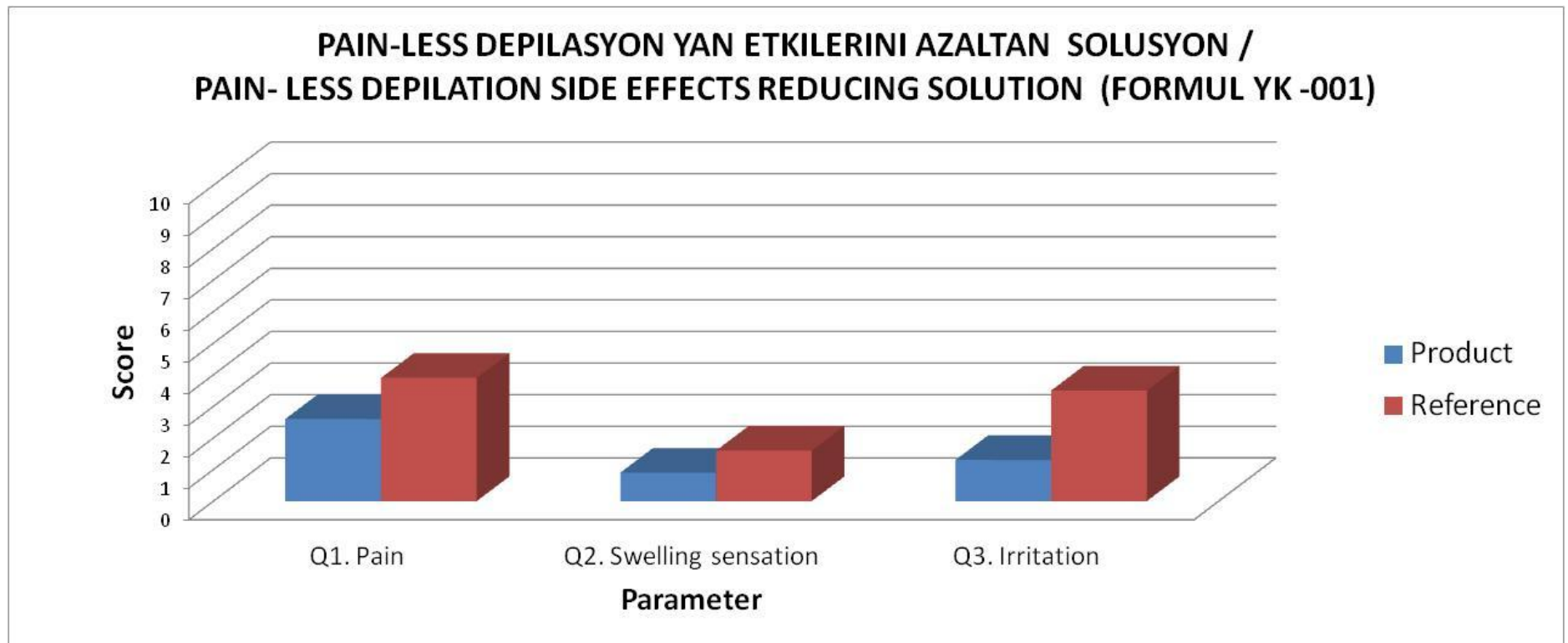
Table III. Volunteer assessment on the reference

REFERENCE	Volunteer No	1	2	3	4	5	6	7	8	9	10
	Q1. Pain	3	8	0	7	3	9	0	2	1	6
	Q2. Swelling sensation	0	2	0	3	0	5	5	0	0	1
	Q3. Irritation	1	3	0	3	0	8	5	6	2	7

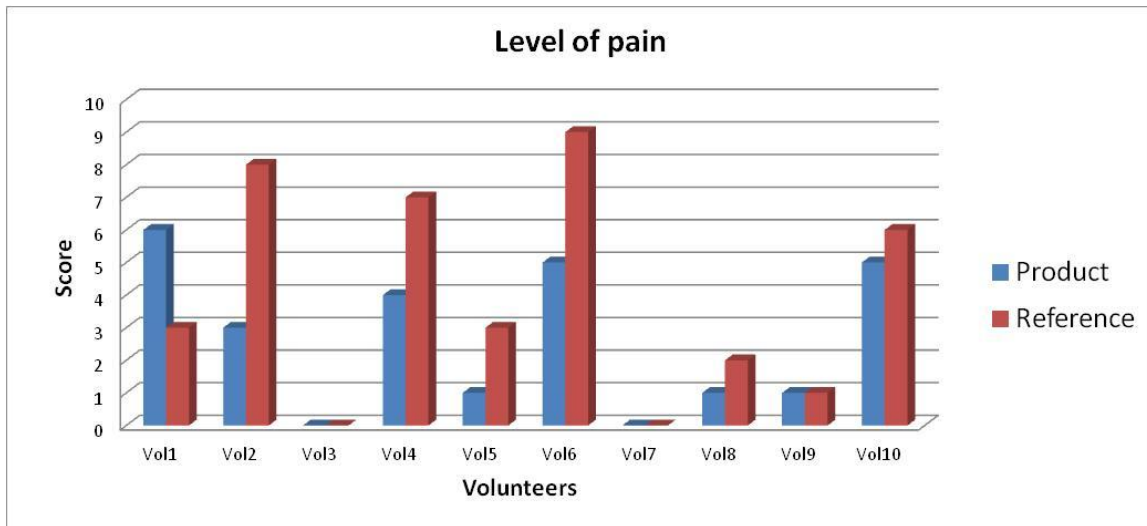
Table IV. Average assessment on the product and the reference

	Average (Product)	Average (Reference)
Q1. Pain	2,6	3,9
Q2. Swelling sensation	0,9	1,6
Q3. Irritation	1,3	3,5

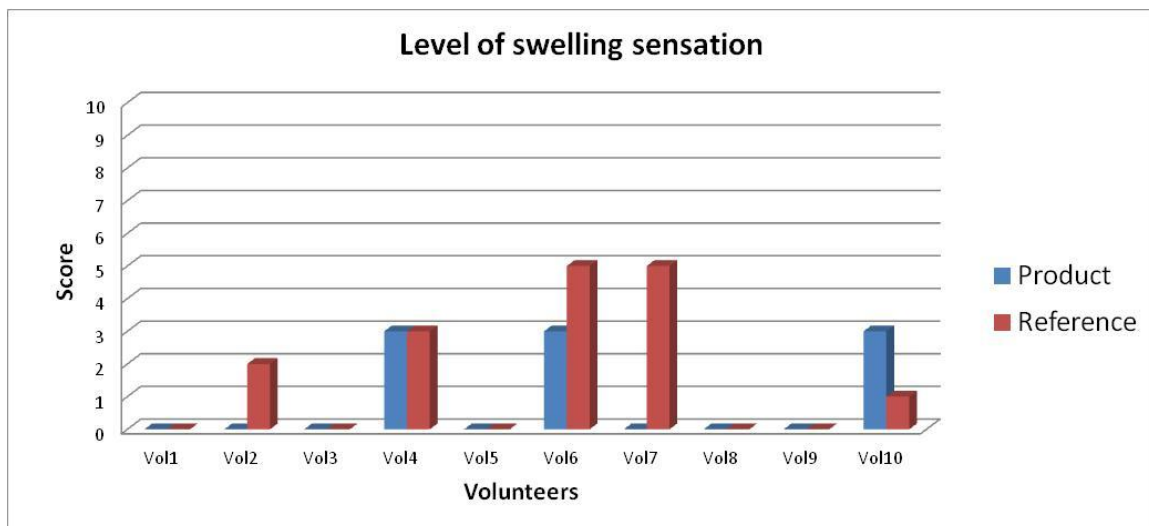
The Graph below depicts the average assessments of the volunteers for each parameter for the test and reference site (Q1 - Q3).



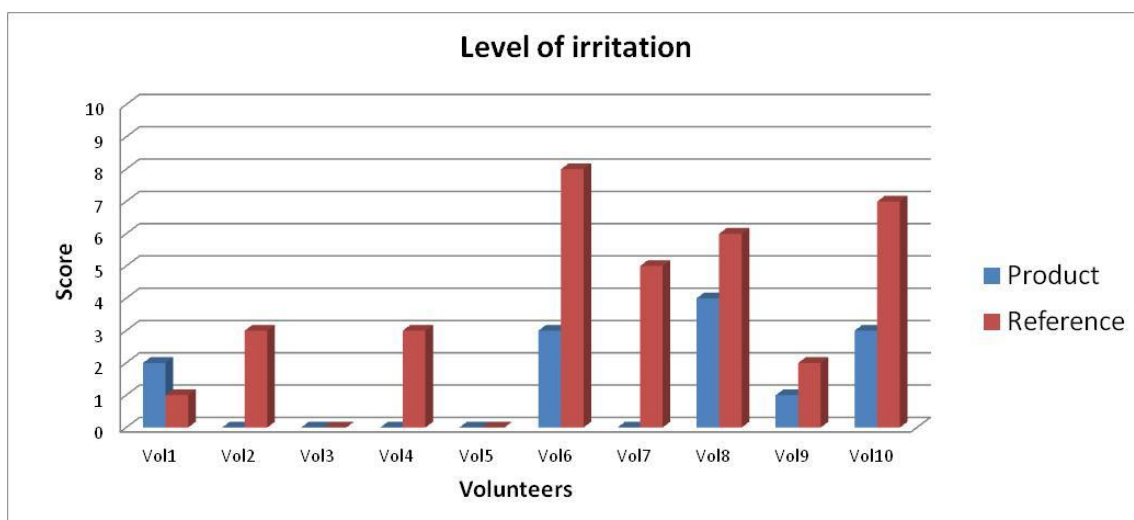
Q1. Pain



Q2. Swelling sensation



Q3. Irritation



Overview of scored parameters

The volunteers were asked to score 3 parameters after the application of the product. The overall results concerning the level of pain, swelling sensation and irritation on the test and the reference site, can be seen in the following table.

Parameter	Test site	Reference site
1. Level of pain	26%	39%
2. Level of swelling sensation	9%	16%
3. Level of irritation	13%	35%

Discussion

General comments that the volunteers made:

- Volunteer No.1 noted that during the waxing process the level of pain was slightly higher on the test site. Nevertheless, she indicated that the overall result was more satisfying on the test site than the reference.
- Volunteer No.2 noted a stinging sensation on the reference site after the waxing process.
- Volunteer No.3 noted that she felt a very slight itching sensation on the test site, right after the application of the oil.
- Volunteer No.7 noted a slight stinging sensation on the reference site after the waxing process.
- Volunteer No.9 noted a smoother result on the test site in comparison to the reference site, after the waxing process.
- Volunteer No.10 noted a freshness sensation for as long as the product remained in contact with her skin.

No side-effects were reported by the volunteers.

CLINICAL EVALUATION

Dermatologist's comments

All volunteers completed the use test with no particular adverse incidents.

The product was well tolerated. It was applied and removed with ease according to manufacturer's instructions.

Almost all volunteers (except Volunteer No.1) reported that the stinging and burning sensation was less pronounced to the side where the product was applied in comparison to the contralateral one.

Volunteer No.1 was the only one who noted that the side of the product was slightly more irritated although this was not clinically supported.

Volunteer No.3 reported mild stinging sensation a few minutes post-waxing on both sides. This was not clinically supported. This volunteer reported history of dermatographism and sensitive skin.

The irritation on the product as well as the reference area, was captured by the dermatoscope.

The irritation observed was graded and was related to perifollicular erythema (quantitative and qualitative), scaling, perifollicular oedema and erosions.

Overall, the product has been able to effectively prevent post-waxing irritation compared to the non-product area.

Irritancy grading

A dermoscopic image was taken in the center of each macroscopic area one minute after the waxing process.

The dermatologist assessed dermoscopically the following parameters:

Perifollicular erythema (quantitative)

0: absent

1: 1-20% of hair follicles

2: 21-40%

3: 41-60%

4: 61-80%

5: 81-100%

Perifollicular erythema (qualitative)

0: absent

1: perifollicular, slight

2: perifollicular, moderate

3: perifollicular, strong

4: diffuse, slight

5: diffuse, moderate

6: diffuse, strong

Scaling

0 : absent

1 : localized (perifollicular)

2 : generalized (mild)

3 : generalized (moderate)

4 : generalized (severe)

Perifollicular oedema

0 : absence

1 : presence

Erosions

0 : absence

1 : presence

Representative comparative examples


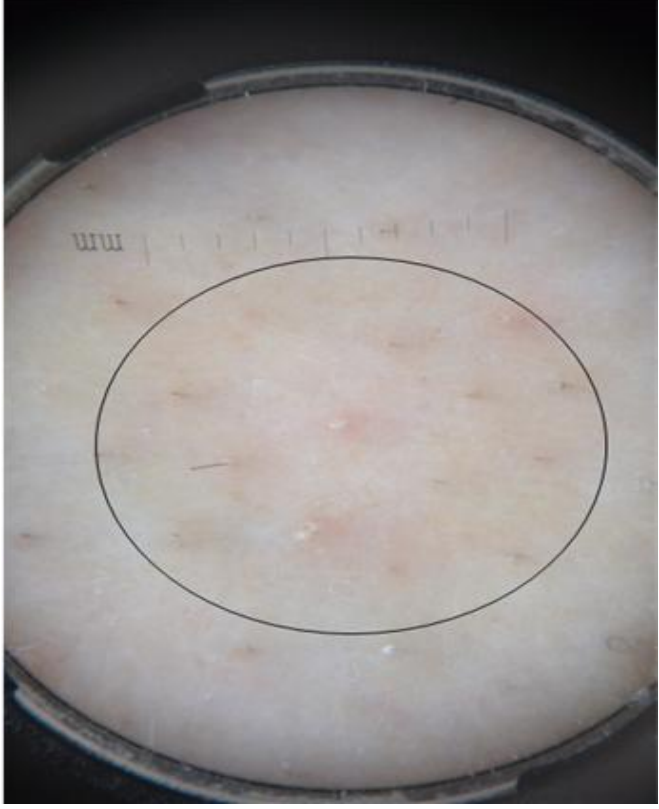
Example 1 (Vol. 8)



Picture 1a. Before waxing



Picture 1b. After waxing (The symbol “o” indicates where the dermoscopic image has been captured).

	
<p><u>PRODUCT</u> Perifollicular erythema (quantitative): 1 Perifollicular erythema (qualitative): 1 Scaling : 0 Perifollicular oedema : 0 Erosions: 0 Total score : 2</p>	<p><u>REFERENCE</u> Perifollicular erythema (quantitative): 2 Perifollicular erythema (qualitative): 2 Scaling: 1 Perifollicular oedema: 0 Erosions: 0 Total score : 5</p>

Picture 1c. Dermoscopic images - quantitative results

Dermatologist's comments on Example 1 :

Test site : Slight perifollicular erythema (arrows)

Reference site : Irritation is more pronounced and is occupying more hair follicles (circle). The skin develops whitish scales (arrows) due to a peeling effect of wax to superficial epidermal layers

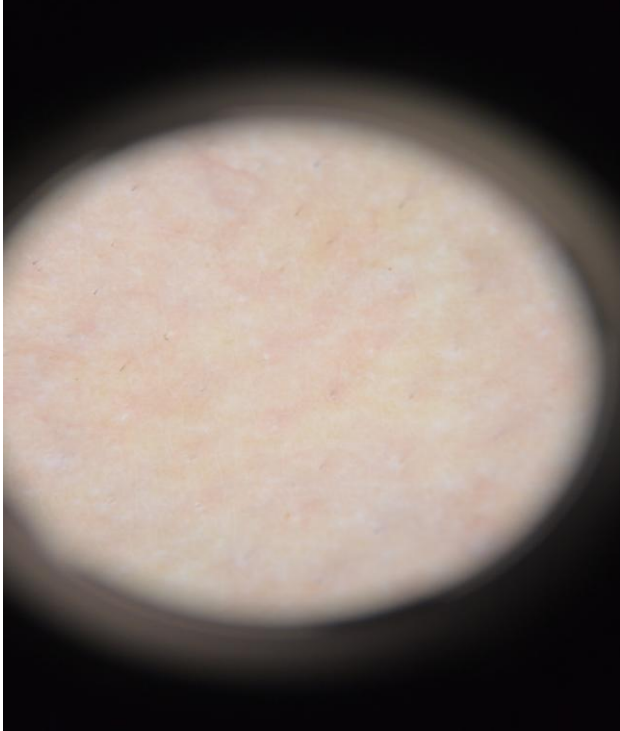
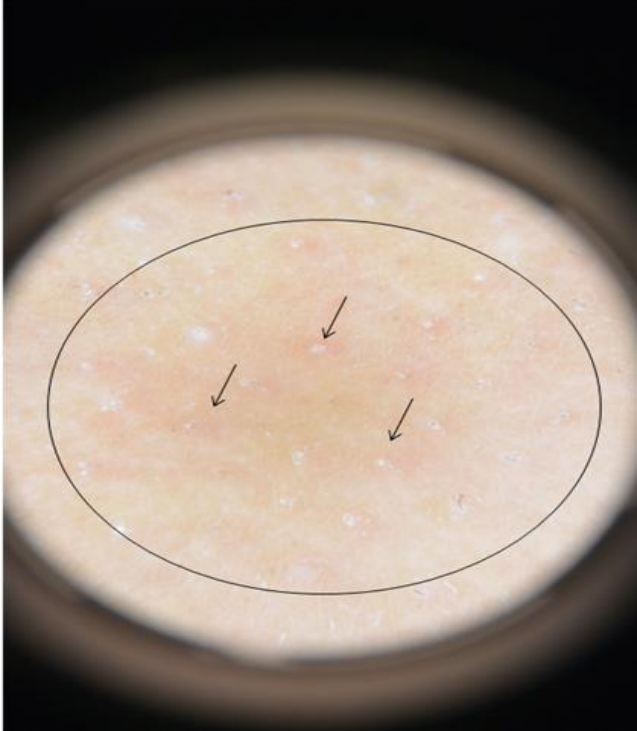
Example 2 (Vol. 9)



Picture 2a. Before waxing



Picture 2b. After waxing (The symbol “o” indicates where the dermoscopic image has been captured).

	
<p><u>PRODUCT</u></p> <p>Perifollicular erythema (quantitative): 1 Perifollicular erythema (qualitative): 1 Scaling: 0 Perifollicular oedema: 0 Erosions: 0 Total score : 2</p>	<p><u>REFERENCE</u></p> <p>Perifollicular erythema (quantitative): 2 Perifollicular erythema (qualitative): 2 Scaling: 1 Perifollicular oedema: 0 Erosions: 0 Total score : 5</p>

Picture 2c. Dermoscopic images - Quantitative results

Dermatologist's comments on Example 2 :

Test site : Very slight irritation.

Reference site : Post-waxing area is more irritated with perifollicular redness (arrows) and desquamation/xerosis (circle).

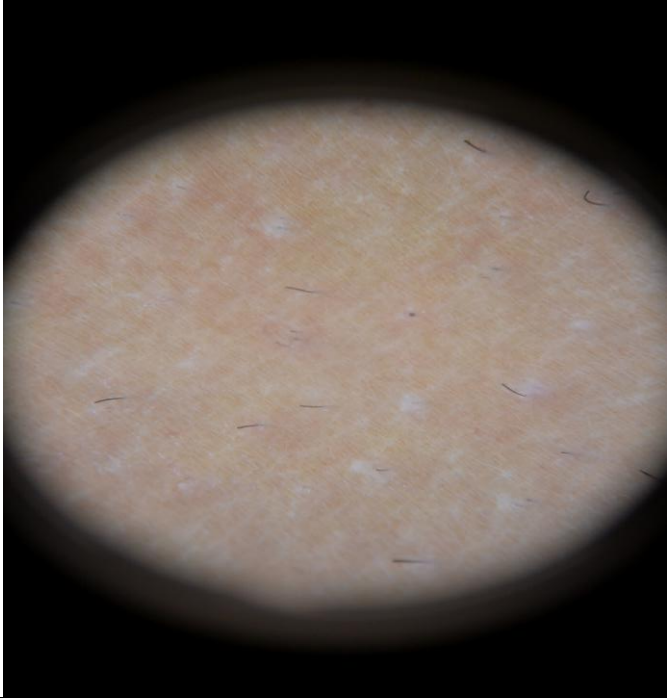
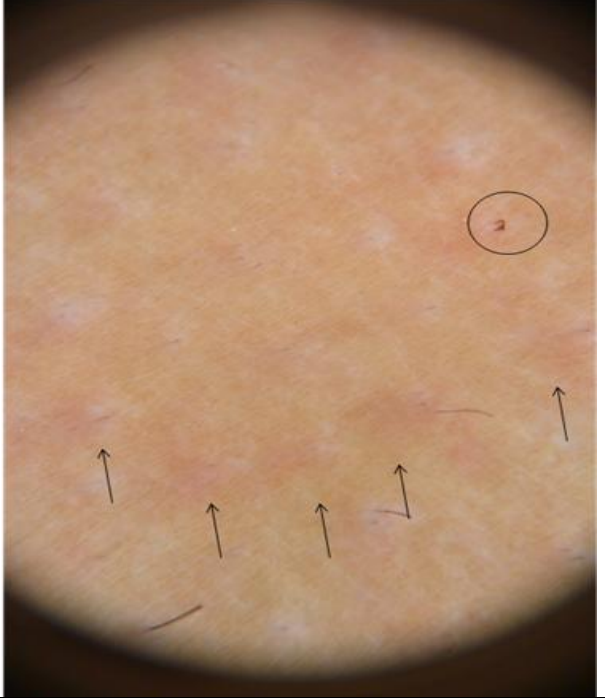
Example 3 (Vol.10)



Picture 3a. Before waxing



Picture 3b. After waxing (The symbol “o” indicates where the dermoscopic image has been captured).

	
<p><u>PRODUCT</u></p> <p>Perifollicular erythema (quantitative): 1 Perifollicular erythema (qualitative): 1 Scaling: 0 Perifollicular oedema: 0 Erosions: 0 Total score : 2</p>	<p><u>REFERENCE</u></p> <p>Perifollicular erythema (quantitative): 1 Perifollicular erythema (qualitative): 2 Scaling: 0 Perifollicular oedema: 0 Erosions: 1 Total score : 4</p>

Picture 3c. Dermoscopic images - Quantitative results

Dermatologist's comments on Example 3 :

Test site : Mild irritation.

Reference site : The perifollicular irritation is more prominent. Additionally, the circle depicts a follicular hemorrhage due to skin trauma.

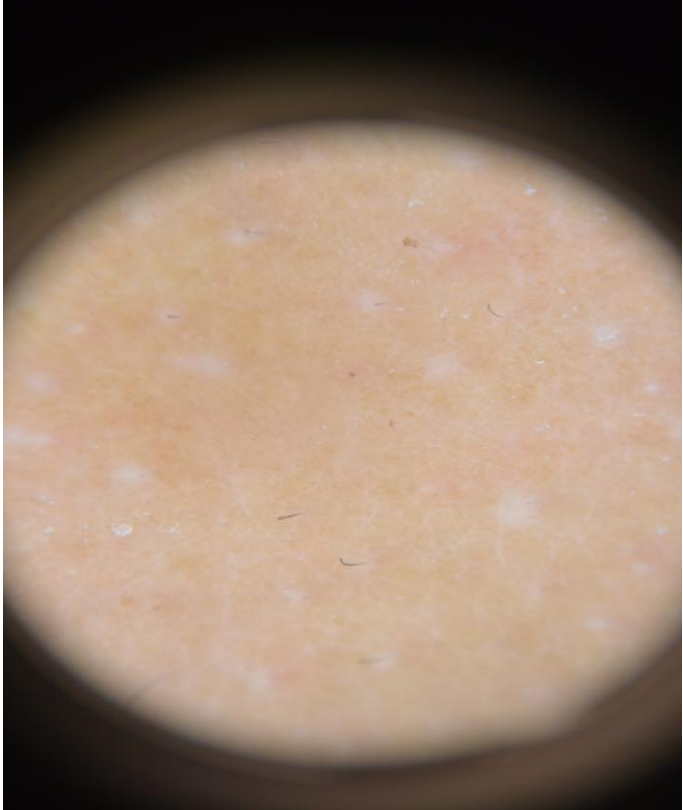
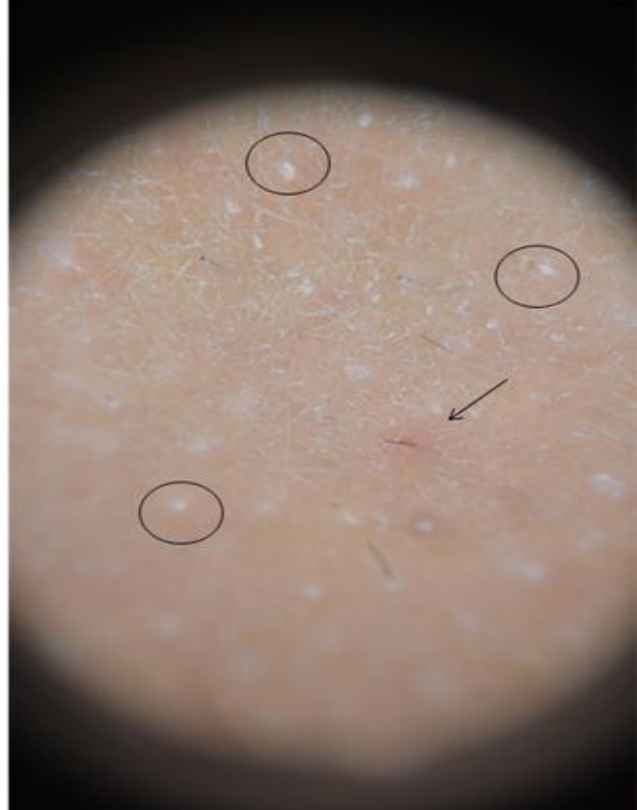
Example 4 (Vol. 2)



Picture 4a. Before waxing



Picture 4b. After waxing (The symbol “o” indicates where the dermoscopic image has been captured).

	
<p><u>PRODUCT</u> Perifollicular erythema (quantitative): 1 Perifollicular erythema (qualitative): 1 Scaling : 0 Perifollicular oedema : 0 Erosions: 0 Total score : 2</p>	<p><u>REFERENCE</u> Perifollicular erythema (quantitative): 2 Perifollicular erythema (qualitative): 2 Scaling: 1 Perifollicular oedema: 0 Erosions: 0 Total score : 5</p>

Picture 4c. Dermoscopic images - Quantitative results

Dermatologist's comments on Example 4 :

Test site : Very slight irritation that is noted only on grand magnification.

Reference site : The skin looks more xerotic, with areas of perifollicular erythema (arrow) and flaking (circles).

CONCLUSIONS

The objective of the study was to investigate the effect that the product 'PAIN-LESS DEPILASYON YAN ETKILERINI AZALTAN SOLUSYON / PAIN- LESS DEPILATION SIDE EFFECTS REDUCING SOLUTION (FORMUL YK -001)' has on the level of pain and irritations during and after the waxing process respectively, in a controlled panel test.

10 healthy female volunteers with leg hair, were included in the study. The product was used on one leg (right) while the other (left) was used as reference. After waxing both legs, the level of pain sensed on each leg was rated and compared by the volunteers. A comparative clinical evaluation regarding the level of irritation, was also performed by the dermatologist.

The study was conducted under the supervision of a dermatologist.

Auto-evaluation - Questionnaire

The product 'PAIN-LESS DEPILASYON YAN ETKILERINI AZALTAN SOLUSYON / PAIN- LESS DEPILATION SIDE EFFECTS REDUCING SOLUTION (FORMUL YK -001)' in comparison to the reference, scored:

Parameter	Test site (product)	Reference site (no product)
1. Level of pain	26%	39%
2. Level of swelling sensation	9%	16%
3. Level of irritation	13%	35%

Clinical evaluation - Photos

The product was well tolerated and was applied as well as removed with ease.

Overall, the product has been able to effectively prevent post-waxing irritation compared to the reference.

After its use, the product 'PAIN-LESS DEPILASYON YAN ETKILERINI AZALTAN SOLUSYON / PAIN- LESS DEPILATION SIDE EFFECTS REDUCING SOLUTION (FORMUL YK -001)' was proved to reduce the level of pain and irritations during and after the waxing process respectively.

Full name and Signature of the Investigator

Printed name : Dr. Christos Prevezas

Date : 27/11/2015

Dr Christos PREVEZAS
Dermatologist - Venereologist



Study Manager:

Printed name : Yiannis Kapetanstratakis

Date : 27/11/2015

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.

The test report shall not be reproduced except in full, without written approval of the laboratory.

ANNEX 1 - QUESTIONNAIRE

ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ

Όνοματεπώνυμο	
Ηλικία	
Φύλο	Θήλυ
Προϊόντα	Pain-Less Depilasyon Yan Etkilerini Azaltan Solüsyon (FORMUL YK -001)
Περιοχή τοποθέτησης της αποτριχωτικής ταινίας: 	

Παρακαλούμε συγκρίνετε, βαθμολογώντας από 0 μέχρι 10 σύμφωνα με την παρακάτω κλίμακα :

- 0 -καμία ένδειξη
- 10 -ισχυρή ένδειξη

Παράμετρος	Περιοχή με προϊόν	Περιοχή χωρίς προϊόν
Πόνος		
Αίσθηση πρηξίματος		
Ερεθισμός		

Έχετε κάποιο άλλο σχόλιο ή υποδείξεις σχετικά με το προϊόν;

.....
.....

../../2015

Όνομα και υπογραφή εθελοντή.....

ANNEX 2 - PHOTO

