TEST REPORT 14 24 00900

BATH SPONGES
ZANSOT S.A.

USE TEST
PANEL OF 10 SUBJECTS

JUNE 2014

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OBJECTIVE

The study objective is to proof the effect that the product 'Bath Sponges' has on the skin after a 7 day used period in a controlled panel test.

TEST PRODUCT DESCRIPTION

PRODUCT MANUFACTURED BY	:	ZANSOT S.A.
RECEIPT DATE	:	26/05/2014
STUDY PERIOD	:	26/05/2014 - 06/06/2014
LAB ID	:	14 24 00900
TEST PRODUCT	:	BATH SPONGES
BRAND	:	-
PRODUCT TYPE	:	BATH SPONGE
METHOD	:	IN USE TEST, 10 SUBJECTS
STUDY SPONSOR	:	ZANSOT S.A.

STUDY SUMMARY

Two different types of bath sponges (orange and blue/pink) were used in the study described below (Annex I-Products photo).
10 healthy volunteers (male and female) were included in the study. The product was used for 7 days on one forearm (right) while the other (left) was used as reference. Before and after product use, moisture on both forearms was measured. Skin hydration is linked to skin tolerance of a product. In case the skin hydration remains unchanged after the use of a product, then the product can be considered as 'dermatologically tested'.
Prior to any measurement, the volunteers stayed sited in a room at a controled environment for twenty minutes (20min acclimatisation at 21^0C). The moisture was measured using Delfin's Moisture Meter SC on the inner forearm of each volunteer.

The product was used by the volunteers on a daily basis for 7 days. At the end of the use the volunteers were asked to answer a questionnaire.

The study was conducted under the supervision of a dermatologist.

The study was performed by QACS Ltd.

Assessment after the end of the treatment:

- ✓ Instrumental measurement
- ✓ Auto evaluation (use test by consumers/questionnaire)

NORMATIVE, CONFIDENTALITY 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.

A safety assessment to the formula was performed prior to the use test of the product.

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 safety evaluation has been conducted on the product tested, 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 and 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 : 18-70 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

Non inclusion criteria

- ✓ volunteers who does 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.

General directions for the participants

48hours before the measurement:

- ✓ Avoid the use of hydrating milks, lotions, creams and other cosmetics only to the area to be tested
- ✓ bathing restricted to once daily

At the days of the measurements:

- ✓ Avoid alcohol and caffeine
- ✓ volunteers can read magazines/books
- ✓ the area of measurement should not be covered with clothing or jewelry - volunteers to be dressed suitably
- ✓ volunteers stay relaxed and with no intense physical activity

METHODOLOGY

The methodological approach used to evaluate whether or not the product tested has any affect on the skin's moisture was the sensorial approach by consumers themselves and by measuring the skin's moisture following the application of a product on human subjects (see Colipa Guidelines Efficacy 2008).

The forearm skin was selected to reduce method artifacts from environmental conditions.

Measurements are made under the control of a suitably qualified professional and use precise criteria: e.g. measurement of hydration (Colipa Guidelines Efficacy 2008). The study took place in QACS Ltd., under the supervision of a dermatologist.

The test was conducted on a sufficient number (see Statistical Guidance) of people.

The tests are performed with instruments that can precisely measure given parameters, according to a defined principle.

The hydration of the skin was measured using Delfin's MoistureMeter SC.
The skin is electrically a layered structure. The electrical properties of these layers are related to their water content. The probe head, the skin surface and the deeper skin layers form a structure, similar to an electrical capacitor. The measured capacitance is proportional to the water content of the surface layer of the skin. The higher the measured value, the higher the moisture content.
The MoistureMeterSC measurement values are arbitrary units and a combination of the dielectric constant and the changing thickness of the stratum corneum's dry layer. This technique makes skin hydration measurements extremely sensitive and reproducible.
The values obtained were then statistically assessed using the t-test.

The sensorial test is based on the appreciation of product 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 (use test by consumers/questionnaire)

A use test of that type evaluates the consumers' perception of product efficacy and cosmetic properties based on parameters that they can observe or feel alongside with clinical observation.

The volunteers were given a questionnaire (see Annex) and they were asked to evaluate the products in three parameters at a scale of 1-5 (where 1 being repulsive and 5 being excellent). The results are depicted on the Tables below.

QUESTIONNAIRE QUANTIFICATION

The volunteers were asked to evaluate the products at a scale of 1-5 where:

1 Repulsive

2 Not satisfactory

3 Acceptable

4 Good

5 Excellent

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

Q1- Evaluate the overall use experience and how pleasant the product is in-use

Q2- Rate how the skin feel directly after application (dry or irritated is negative, moisturised or soft is positive)

Q3- Would you buy this product?

The volunteer satisfaction rate was then calculated using the algorithm:

$$\{[\Sigma \text{ (number of volunteers x assessment)}]/\text{maximum rate}\}\%$$

Example; If 3 volunteers assessed one parameter with 3 and 7 volunteers with 4 then the satisfaction rate will be

{[(3x3)+(4x7)]/50}%=37/50 %= 74% rate of satisfaction

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

VOLUNTEER DATA

Table I depicts the number and the sex of the volunteers, while Tables II, III and Graph 1 depict the moisture measurements for each volunteer.

Table I. Volunteers Description

Volunteer No	Initials	Sex	Sponge Type
1	E.N.	MALE	ORANGE
2	G.G.	MALE	ORANGE
3	V.K.	MALE	ORANGE
4	E.A.	FEMALE	BLUE/PINK
5	E.P.	FEMALE	BLUE/PINK
6	V.T.	FEMALE	BLUE/PINK
7	Y.G.	MALE	BLUE/PINK
8	C.S.	MALE	ORANGE
9	S.S.	FEMALE	ORANGE
10	A.S.	FEMALE	BLUE/PINK

RESULTS ON MOISTURE MEASUREMENTS

Table II. Moisture measurements, blank, no product use

Volunteer No	1	2	3	4	5	6	7	8	9	10	STDEV
Before	20,40	44,13	31,97	50,97	24,77	42,47	29,47	54,17	33,13	40,57	11,08
After	19,83	23,20	34,10	59,00	39,97	62,03	11,43	69,97	29,57	25,43	19,83

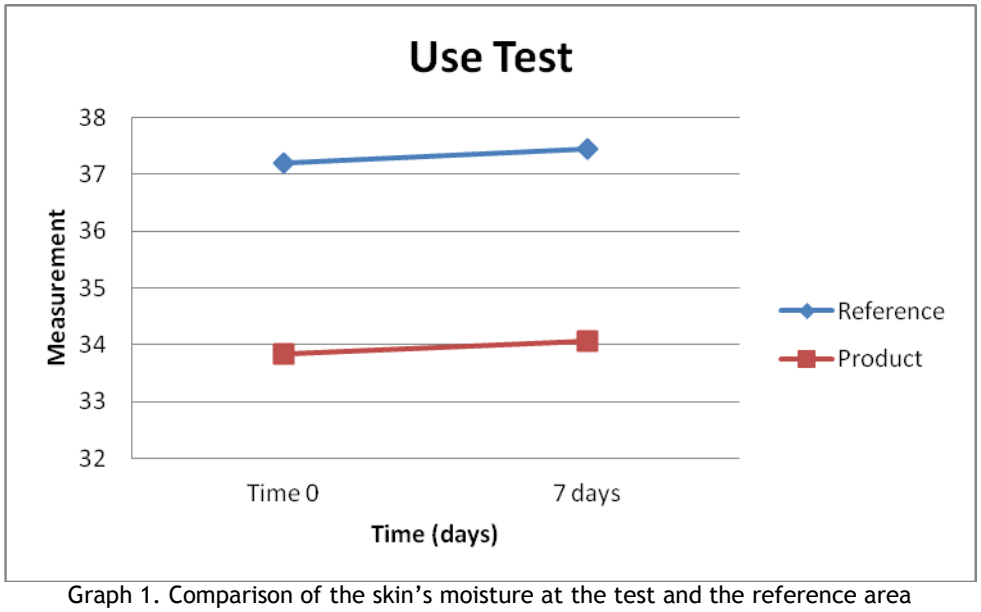
Table III. Moisture measurements, where product was used

Volunteer No	1	2	3	4	5	6	7	8	9	10	STDEV
Before Use	24,90	29,10	35,03	47,10	30,27	36,33	30,93	40,80	24,33	39,57	7,29
After Use	18,07	34,20	24,93	47,50	36,73	54,47	14,47	50,57	23,90	35,73	13,77

Table IV. Average values for product and reference

Time	Reference	Product
Before Use	37,20333	33,83667
After Use	37,45333	34,05667

Graph1. Comparison of the skin's moisture before and after the use of the product for the reference and the test area.



Graph 1. Comparison of the skin's moisture at the test and the reference area

STATISTICS

To evaluate whether or not the product has any statistically relevant effect on the skin's moisture, t-tests were performed.

A t-test assesses whether the means of two sets of data are statistically different from each other.

The H_0 (null hypothesis) is that the means are equal (results are the same) while, the H_1 is that the means are not equal (results are not the same).

The risk level (alpha level) for this study is set at 0.05.

The risk level is then compared to the P value that is calculated for each condition.

If the calculated P value is greater than the critical value, then the null hypothesis is accepted and there is not a statistically significant difference for the two measurements.

The means that were compared for each hand were:
Measurement at time 0 was compared to measurement after the product's application.

In case there was a difference to the skin's moisture as time went by to the test hand (right forearm) and not to the reference hand (left forearm) then the product would appear to have an effect on the skin's moisture. In case there was difference to both hands then the results could not be easily assessed.

Comparison of the area where the product was applied and the reference

The Tables below depict the t-test statistical data between skin moisture measurements at the reference hand and the test hand.

Table V. Comparison of measurements at time 0h for the reference and the product

	Reference Before	Product Before
Mean	33,83667	37,20333
Variance	53,18777	122,7878
Observations	10	10
Pearson Correlation	0,755781	
Hypothesized Mean Difference	0	
df	9	
t Stat	-1,45119	
P(T<=t) one-tail	0,090337	
t Critical one-tail	1,833113	
P(T<=t) two-tail	0,180673	
t Critical two-tail	2,262157	

- ✓ Before the application of the product at the test and reference hand the $P_{exp}(0.18)>0.05$ and the null hypothesis is accepted, the results are not significantly different

Table VI. Comparison of measurements at time 0 and after the use of the product for the reference

	Reference Before	Reference After
Mean	37,20333	37,45333
Variance	122,7878	393,384
Observations	10	10
Pearson Correlation	0,684548	
Hypothesized Mean Difference	0	
df	9	
t Stat	-0,05388	
P(T<=t) one-tail	0,479103	
t Critical one-tail	1,833113	
P(T<=t) two-tail	0,958206	
t Critical two-tail	2,262157	

- ✓ At the reference hand during the study the $P_{exp}(0.95)>0.05$ and the null hypothesis is accepted, the results are not significantly different

Table VII. Comparison of measurements before and after product's application at the test area

	Product Before	Product After
Mean	33,83667	34,05667
Variance	53,18777	189,5232
Observations	10	10
Pearson Correlation	0,696072	
Hypothesized Mean Difference	0	
df	9	
t Stat	-0,06857	
P(T<=t) one-tail	0,473416	
t Critical one-tail	1,833113	
P(T<=t) two-tail	0,946831	
t Critical two-tail	2,262157	

- ✓ At the test hand during the study the $P_{exp}(0.94)>0.05$ and the null hypothesis is accepted, the results are not significantly different

Based on the above:

- ✓ the moisture of the reference hand and the hand were the product was used prior to product's use was not significantly different
- ✓ the moisture of the reference hand during the study remained unchanged
- ✓ the moisture of the test area remained statistically unchanged after the use of the product
- ✓ the area where the product was used was not dehydrated

RESULTS ON QUESTIONAIRES

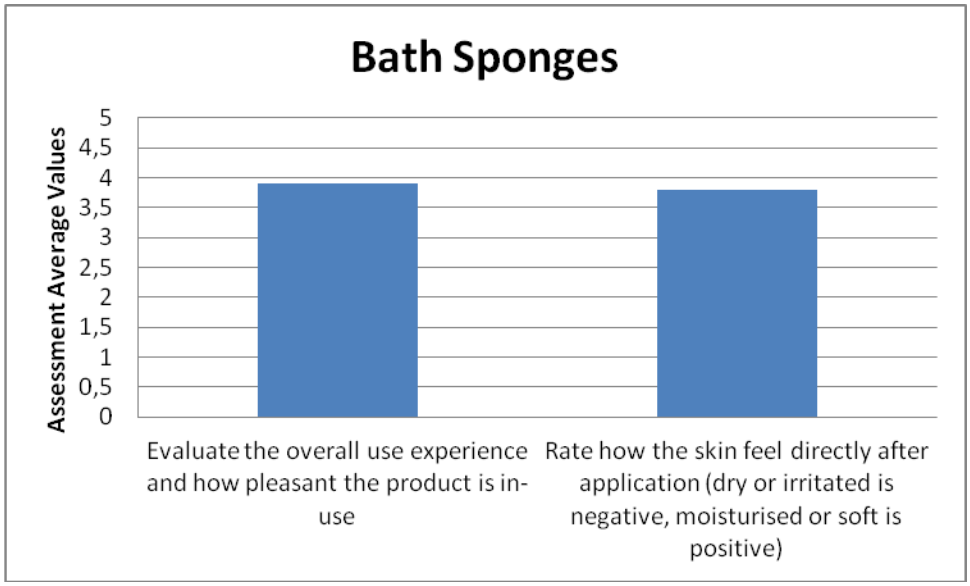
Table VIII. Volunteer assessment on the products

	Volunteer No.									
	1	2	3	4	5	6	7	8	9	10
Evaluate the overall use experience and how pleasant the product is in-use	5	2	4	5	5	4	5	3	2	4
Rate how the skin feel directly after application (dry or irritated is negative, moisturised or soft is positive)	4	4	4	5	4	4	5	2	2	4
Would you buy this product? (Y/N)	Y	N	Y	Y	Y	Y	Y	N	N	Y

Table IX. Average volunteer assessment on the products

	Average	STDEV
Evaluate the overall use experience and how pleasant the product is in-use	3,9	1,197219
Rate how the skin feels directly after application (dry or irritated is negative, moisturised or soft is positive)	3,8	1,032796

The Graph below depicts the average assessments of the volunteers for each parameter.



Overall Use Experience

Parameter 1. How satisfied are you with the product you have used?

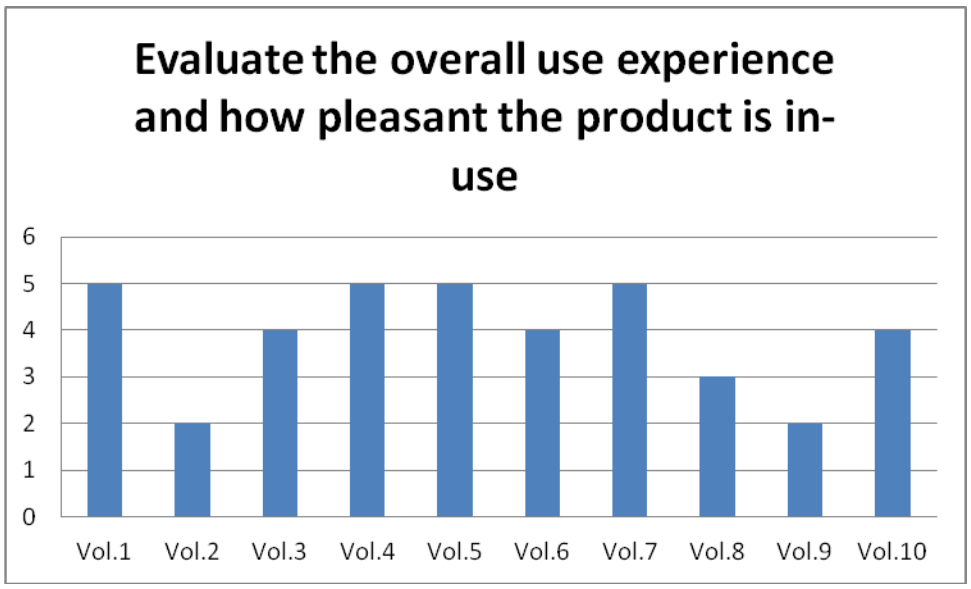


Table X. Answers on Parameter 1.

1	2	3	4	5	Total
0	2	1	3	4	10

- 70% of the volunteers answered that they found the overall use experience: Good

The results are depicted in the chart below:

Total Rate
78%

Skin Directly After Use

Parameter 2. How did your skin feel directly after use?

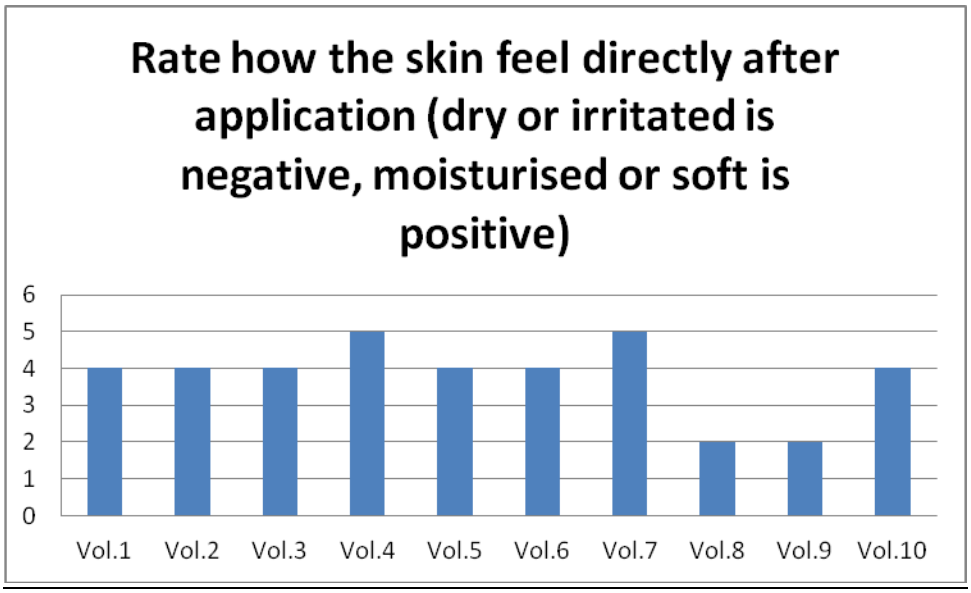
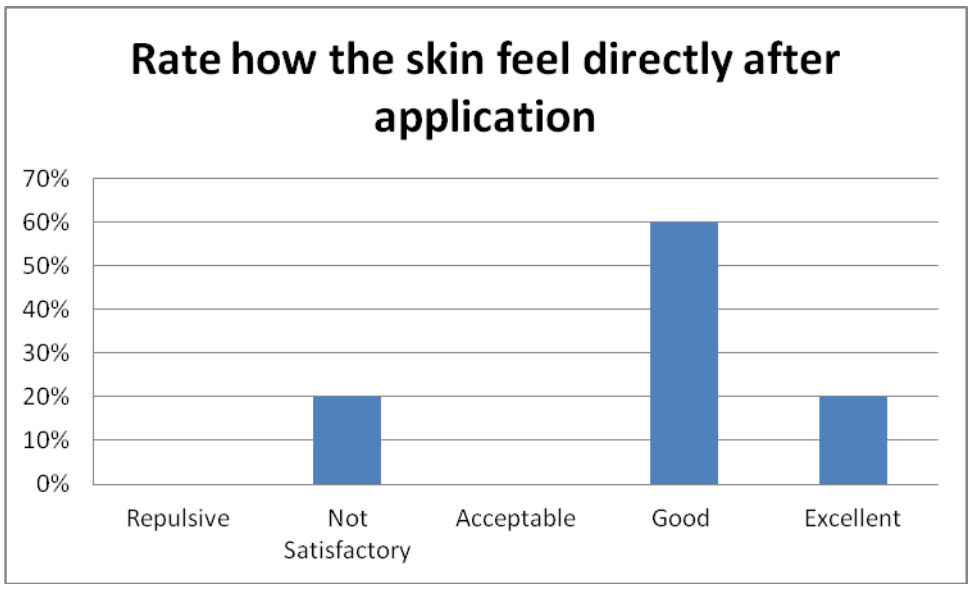


Table XI. Answers on Parameter 2.

1	2	3	4	5	Total
0	2	0	6	2	10

- 80% of the users answered that the hydration of their skin directly after the use of the product was more than good



Total Rate 76%

Would You Buy This Product?

Parameter 3. Would you buy this product?

Table XI. Answers on Parameter 3 (orange sponge).

Vol1	Vol2	Vol3	Vol8	Vol9
Yes	No	Yes	No	No

Table XII. Answers on Parameter 3 (blue/pink).

Vol4	Vol5	Vol6	Vol7	Vol10
Yes	Yes	Yes	Yes	Yes

DISCUSSION

General comments that the volunteers made on the product:

- Volunteers 2, 8 and 9 said that they found the texture of the orange sponge to be too firm
- Volunteer 7 said that he found the texture of the blue/pink sponge on his skin to be good

Note: Not all the users provided feedback.

CONCLUSIONS

The objective of the study was to investigate the effect that the product **'Bath Sponges'** has on the skin when used.
The product was used by 10 volunteers for a week on a daily basis on one forearm and the other forearm was used as reference. The skin's moisture was measured prior and after the use of the product. Skin hydration is linked to skin tolerance of a product. In case the skin hydration remains unchanged after the use of a product, then the product can be considered as 'dermatologically tested'.

Measurements
The study was conducted under the supervision of a dermatologist.

- At the end of the test, the test product was found to present excellent skin tolerability
- During the study the moisture on the reference area remained unchanged. The moisture of the test area remained statistically unchanged after the use of the product. The area where the product was applied was not dehydrated.

Questionnaire
The volunteers were asked to use the product for 7 days and then answer 3 questions:

Q1- Evaluate the overall use experience and how pleasant the product is in-use **Ans. 3.9/5**

Q2- Rate how the skin feel directly after application **Ans. 3.8/5**

Q3- Would you buy this product? **Ans. 40% Yes (Orange), 100% Yes (Blue/Pink)**

After the use of the product **'Bath Sponges'**, the skin moisture at the test area, where the product was used, remained statistically unchanged and it was not dehydrated as it would have been expected. This claim **'dermatologically tested'** may be written on the label.

Full name and Signature of the Investigator
Printed name : Dr. Christos Prevezas
Date : 05/06/2014

ΧΡΗΣΤΟΣ Δ. ΠΡΕΒΕΖΑΣ
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Annex I-Samples photo

Annex II-QUSTIONNAIRE

ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ

Ονοματεπώνυμο	
Ηλικία	
Φύλο	
Προϊόν	Sponges

Παρακαλούμε χαρακτηρίστε, βαθμολογώντας από το 1 μέχρι το 5, το παραπάνω προϊόν σύμφωνα με τα παρακάτω κριτήρια αξιολόγησης:

1	ΑΠΩΘΗΤΙΚΟ
2	ΜΗ ΙΚΑΝΟΠΟΙΗΤΙΚΟ
3	ΑΠΟΔΕΚΤΟ
4	ΚΑΛΟ
5	ΆΡΙΣΤΟ

Πως κρίνετε το προϊόν προς:	
1. Την γενική χρήση του και ικανοποίησή που σας προσέφερε;	
2. Την αίσθηση που άφησε στο δέρμα σας αμέσως μετά την χρήση του;	

Παρακαλούμε χαρακτηρίστε, απαντώντας με ΝΑΙ ή ΟΧΙ, το παραπάνω προϊόν σύμφωνα με τα παρακάτω κριτήρια αξιολόγησης:

3. Θα αγοράζατε αυτό το προϊόν;	

Έχετε κάποιο άλλο σχόλιο ή υποδείξεις σχετικά με το προϊόν

……

……

……

Ονοματεπώνυμο και Υπογραφή του Εθελοντή

../../2014

*** <u>Το ερωτηματολόγιο παρακαλούμε να επιστραφεί μετά το τέλος της έρευνας.</u>**