STUDY REFERENCE: 02/DER-3_247_19-001

Study Report - Version nº 1

ACCEPTABILITY, SUBJECTIVE EFFICACY AND TOLERANCE USE TEST OF A PRODUCT UNDER PEDIATRIC AND DERMATOLOGICAL CONTROL

CUSTOMER: CV MEDICA S.L.
ELEMENT TESTED: DISPOBAÑO ESPONJAS JABONOSAS
REFERENCE: 0000100

Madrid, March 26th 2019

REPORT INDEX

1. SYNOPSIS

SPONSOR	**CV MEDICA S.L.** C/ PONENT 1, PI LA PLANA 43424, SARRAL – TARRAGONA (SPAIN)
Tested product	DISPOBAÑO ESPONJAS JABONOSAS
Date of order	February 5th 2019
Testing Facility	ZURKO RESEARCH S.L. Almansa, nº 110, local 18. 28040, Madrid (España). Tel: (+34) 91.521.15.88
Supervisors of Study	Ana García Blanco, Biologist. Mª Cristina Chiatti Gassino, Pediatrician. Eliana San Juan Lasser, Dermatologist.
Study code	02/DER-3_247_19-001
Subjects	Number of Subjects enrolled: 10 Age: 3 months– 3 years old Gender: both Skin type: all skin type (sensitive and resistant skin) Number of Subjects Completed: 10
Test area	Body
Application	Duration: 14 days Frequency: daily
Test period	February 2nd 2019– March 16th 2019
Test parameters	Organoleptic characteristics and subjective efficacy of the product after 14 days of use. Cutaneous tolerance evaluation by pediatrician and dermatologist.
Design of study	Day 0 (Beginning) and D14 (Ending).
Evaluation	Evaluation of acceptability, subjective evaluation and tolerance evaluation of the product during use.

Results:

According to the dermatological tolerance evaluation carried out by the pediatrician and the dermatologist, 100% of volunteers didn't show any unwanted symptoms during the study.

Regarding the subjective tolerance evaluation by the responsible of the volunteers, 100% of volunteers didn't show any unwanted symptoms during the study.

100% of the responsible of the volunteers were satisfied in a higher or lesser grade with the result of the product.

100% of the responsible of the volunteers indicated that the product meets their expectations and would be willing to buy it against their usual product if the price is right.

2. IDENTIFICATION OF THE STUDY

Name of the study: Acceptability, subjective efficacy and tolerance use test of a product under pediatric and dermatological control.

Director of the laboratory: Irene Zaldívar Notario.

Director of the study: María Barbero Calderón.

Sponsor: CV MEDICA S.L.

Sponsor address: C/ PONENT 1, PI LA PLANA 43424, SARRAL – TARRAGONA (SPAIN).

Tested element: DISPOBAÑO ESPONJAS JABONOSAS, reference: 0000100, batch: 1901050.

3. OBJECTIVE AND PRINCIPLE OF THE STUDY

The objective of this study is to evaluate the acceptability, subjective efficacy and tolerance for the product **DISPOBAÑO ESPONJAS JABONOSAS**, reference **0000100**, in 10 volunteers for a period of 14 days, using the product according to the conditions stipulated for the customer.

The evaluated product is soapy sponges for children between 3 months old and 3 years old.

Therefore, this study has as objective to evaluate the acceptability, subjective efficacy and tolerance of the volunteer participants in the study, and to perform the pediatric and dermatological following-up of the possible adverse symptoms that could appear with the use of the product.

The acceptability of the product was measured additionally, by means of the subjective evaluation of the efficiency, evaluation of the product (organoleptic properties), and way of application. Other characteristics of the product also were valued by means of subjective evaluation.

4. TYPE OF STUDY

This test was performed under pediatric and dermatological control by the center.

The study was carried out following general conditions in Zurko Research, established for the execution of study projects on humans (Structure and Content of Clinical Study Reports from ICH Harmonised Tripartite Guideline; Guideline for good clinical practice E6 (R2) of June 14th 2017, EMA/CHMP/ICH/135/1995 of May 1st 1996, European Parliament and Council Guideline 2001/20/CE – May 1st 2001)

Previously, Zurko Research assessed the suitability of the product for the type of study and the methodology to be employed.

5. RESEARCH CENTER

5.1. Research Center

ZURKO RESEARCH S.L.

Calle Almansa 110, local 18

28040 Madrid (Spain)

Tel: (+34) 91.521.15.88

5.2. Research team

Director of the study: María Barbero Calderón, Pharmacist.

Researcher: Ana García Blanco, Biologist.

Technician: Naiara Linaza Reyna/ Beatriz Pradillo Alvez.

Pediatrician: Mª Cristina Chiatti Gassino. Medical license number: 280838462.

Dermatologist: Eliana San Juan Lasser. Medical license number: 283805700.

6. STUDY SCHEDULE

Beginning: March 2nd 2019

End: March 16th 2019

7. VOLUNTEERS

7.1. Ethical aspects

Each responsible of the volunteers participating in the study was previously informed about the type and the procedures of the study and signed an informed consent before the beginning of the study. The original informed consents were archived in Zurko Research.

7.2. Number of volunteers

10 volunteers were included in the study. The number of volunteers required at the end of the study was 10, considering that the number of volunteers used in this type of study is sufficient to verify compatibility of a cosmetic product.

None volunteer left the study and no volunteer was excluded by the researcher.

The acceptability, subjective efficacy and tolerance of the tested product were therefore verified in 10 volunteers.

The participants volunteers in the study complied with the following criteria of inclusion and exclusion, checked through the recruitment questionnaire.

Information about the volunteers' participants in the study is included in **Annex I.**

7.3. Specific inclusion and exclusion criteria

Inclusion criteria

The specific inclusion criteria, defined in the protocol, were as follow:

- Age: 3 months – 3 years old.
- Gender: both.
- Skin type: all skin type (sensitive and resistant skin).
- Good health.
- Availability during the duration of the test.
- Understanding the information provided on the purpose and development of the study by signing the informed consent.

Exclusion criteria

The specific exclusion criteria, defined in the protocol, were as follow:

- Presence of cutaneous marks in the experimental area that could interfere in the evaluation of cutaneous reactions (pigmentation, scars, excessive freckles, angioma…),
- Presence of injuries, pathologies or infection in the experimental area,
- Eczematous reaction that has not completely disappeared, scars or pigmentation derived from previous studies in the experimental area,
- Intense exposure to the sun or UV light during the study, or having sunbathing or UV light during the month prior to the study in the experimental area,

- Volunteers who are carrying out a treatment that contains vitamin A or its by-products, during the 3 months before the study,
- Volunteers who are carrying out a treatment that contains topical corticosteroids in the experimental area during the 8 days before to the start of the study,
- Volunteers who are subjected to some type of treatment with psoriasis medications, vitiligo, in the month before the start of the study,
- Volunteers who have been vaccinated within 3 weeks before the study,
- Application of other cosmetics products in the experimental area,
- Presence of allergies or reactions to cosmetic products of the same category that the one in the study,
- Refusal to sign the informed consent (form).

The responsible of the volunteers were warned about the possible adverse or disgusting reactions of the product and its reversibility. In case of any adverse reaction or doubt of it, the volunteers were advised to suspend immediately the application of the product, and to contact the center that would inform the specialists responsible for the clinical evaluation.

The total availability of the volunteers was also confirmed so as not to compromise the clinical and subjective evaluation at the end of the study.

8. METHODOLOGY

8.1. Criteria for product application

Product type: rinse-off soapy sponges.

Experimental area: body.

Duration of the study: 14 days.

Frequency of use: daily.

Recommended quantity: one sponge each bath.

Mode of use: moist the sponge, don't sink in water, press repeatedly until foam appears. Do the habitual bath and rinse-off with water. Discard after use.

The responsible of the volunteers were advised to not apply any other product of the same type during the study as so any other product that they do not usually use during the study.

8.2. Experimental procedure

The first day, previous to the beginning of the study, the responsible of the volunteers received the instructions of the study. They were instructed in oral and writing form, to apply the product at home. The technician verified that the volunteers met the inclusion and exclusion criteria.

They also read and completed the Informed Consent, the exclusion criteria and the recruitment questionnaire, where they were asked about their consumption habits and preferences.

The pediatrician and the dermatologist examined clinically the volunteers, filling out a questionnaire about the initial conditions of the experimental area.

At the end of the study, the pediatrician and the dermatologist together with the technician examined clinically the volunteers, filling out a questionnaire about the conditions of the experimental area after the use of the product.

The responsible of the volunteers filled out also a subjective questionnaire after the use of the product.

8.3. Pediatric and dermatological evaluation of tolerance

On the first day of attendance at the center, the pediatrician and dermatologist together with the technician verified the inclusion and exclusion criteria defined for the study. The pediatrician and the dermatologist evaluated the experimental area for possible previous alterations that the volunteers might present. No volunteer had to be excluded at the beginning of the study due to non-compliance with some criteria.

At the end of the study, the pediatrician and the dermatologist performed a visual evaluation of the experimental area of the volunteers, filling out a questionnaire about the possible alterations that might appear after the use of the product.

The parameters that were analyzed were the following ones: desquamation, dryness, acne prone skin, redness, spots, edema, vesicles, and others, in a scale of five points: absence, very slight alteration, slight alteration, medium alteration and severe alteration. Therefore, it was indicated if the alterations observed were related with the use of the product, in a scale of six points (not related, unlikely, possible, likely, certain and not assessable).

The interpretation of the results of the cutaneous examination was collected in individual evaluation sheets.

8.4. Subjective evaluation

At the end of the study, when the responsible of the volunteers visited the center, they completed a questionnaire answering questions concerning the organoleptic characteristics and subjective efficacy of the product, as so as the tolerance of the product and its possible future use.

A hedonic scale of five points is used for organoleptic characteristics and global appreciation:

5: I like it very much

4: I like it slightly

3: I neither like it nor dislike it

2: I dislike it slightly

1: I dislike it very much

Volunteers with opinions between 4 and 5 are considered satisfied with the organoleptic characteristics and global appreciation.

For the subjective efficacy, a Likert scale of five points is used to assess the attitude of the volunteers to the different aspects of efficacy and characteristics of the product. The scale is divided into:

5: I strongly agree

4: I agree

3: I neither agree nor disagree

2: I disagree

1: I strongly disagree

Volunteers with opinions between 4 and 5 are considered satisfied with the subjective efficacy.

The questionnaire of subjective evaluation that the volunteers complete at the end, also includes questions relative to tolerance after the continued use of the product. In case the volunteer detected unpleasant symptoms, they will fill a questionnaire of Notification Form of Unwanted Effects with the help of the researcher and specialists.

9. RESULTS OF THE EXPERIMENTAL PROCEDURE

9.1. Tolerance evaluation by specialists.

At the end of the study, the pediatrician and the dermatologist, together with the technician, carried out an evaluation examining the state of the experimental area after the use of the product. 10 volunteers ended the study after 14 days of use of the product.

- **Cutaneous alterations associated with the use of the product**

At the end of the study, none of the volunteers showed any alterations associated with the use of the product (Figure 1, Figure 2).

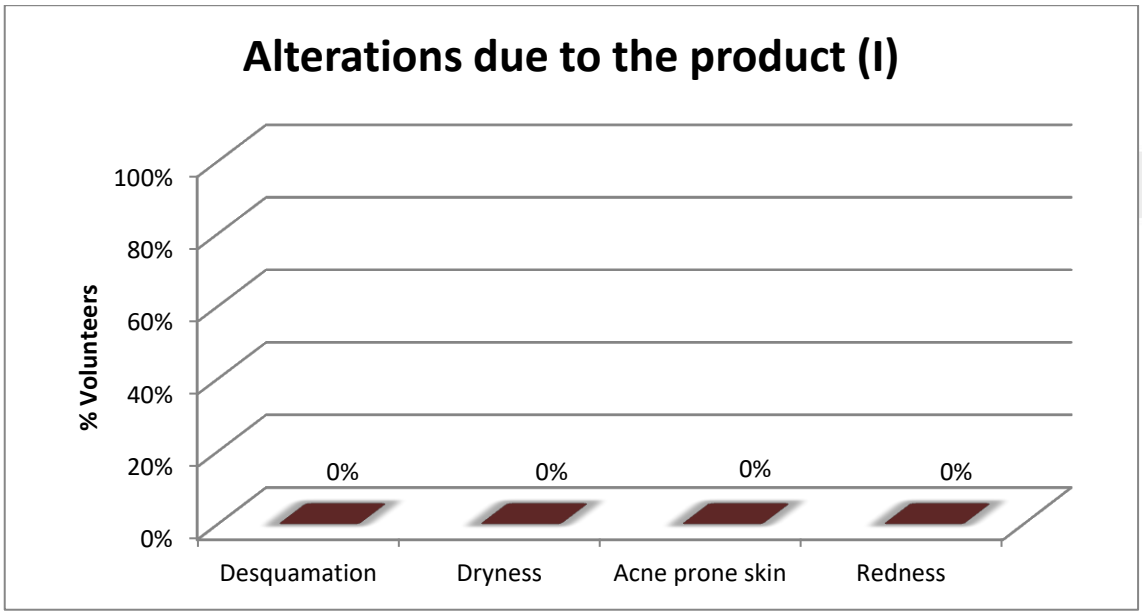


Figure 1. Alterations on the experimental area after the use of the product evaluated by the specialists (n=10).

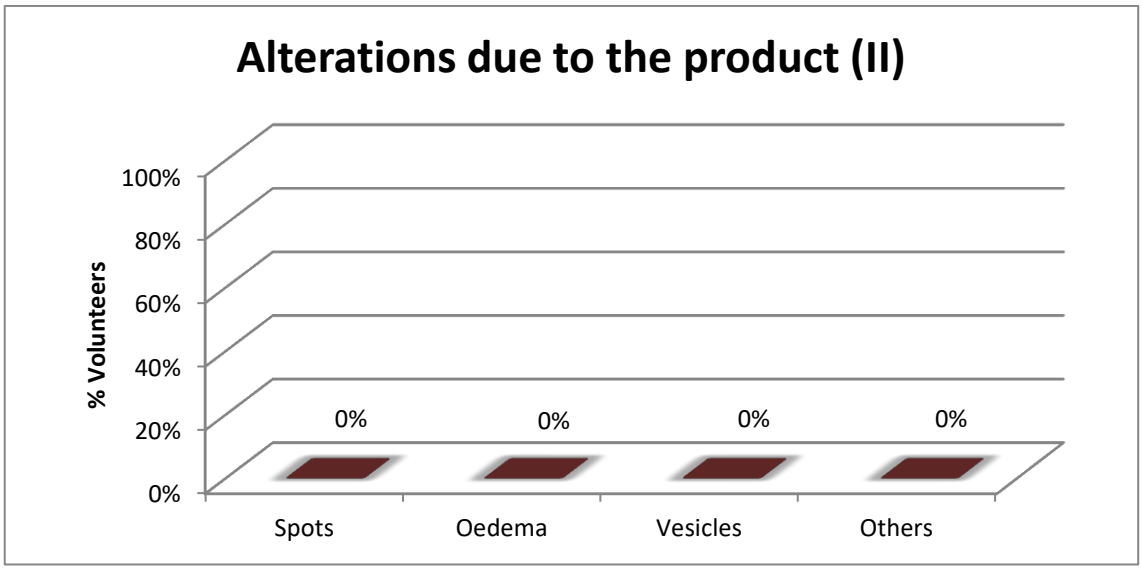


Figure 2. Alterations on the experimental area after the use of the product evaluated by the specialists (n=10).

9.2. Subjective evaluation of the product by the responsible of the volunteers

Subjective evaluation of the organoleptic characteristics and global appreciation of the product after 14 days of use by 10 volunteers.

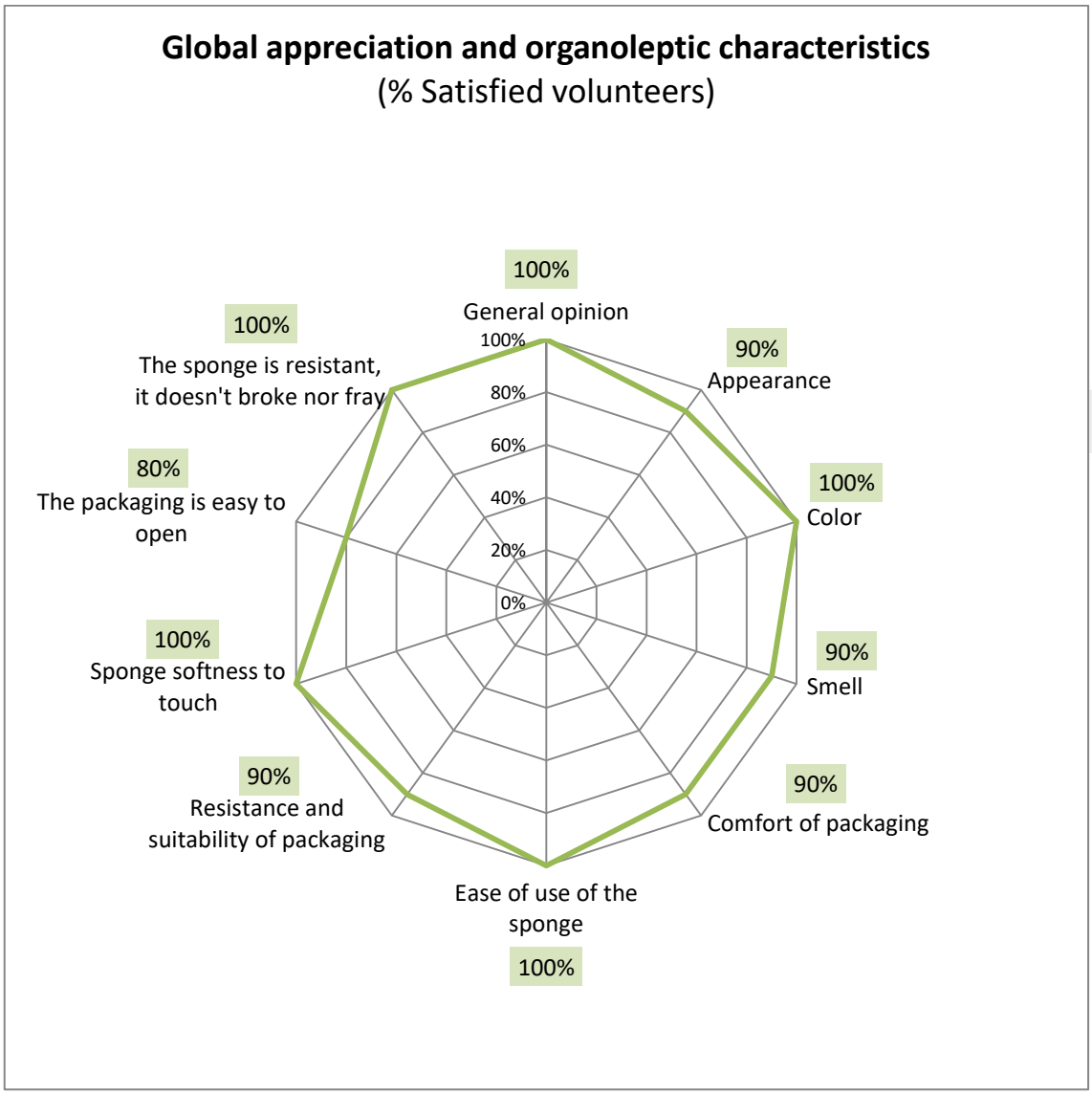


Figure 3. Percentage of satisfied responsible of the volunteers with the general and organoleptic characteristics of the product (n=10).

Evaluation of the efficiency after 14 days of use of the product on 10 volunteers

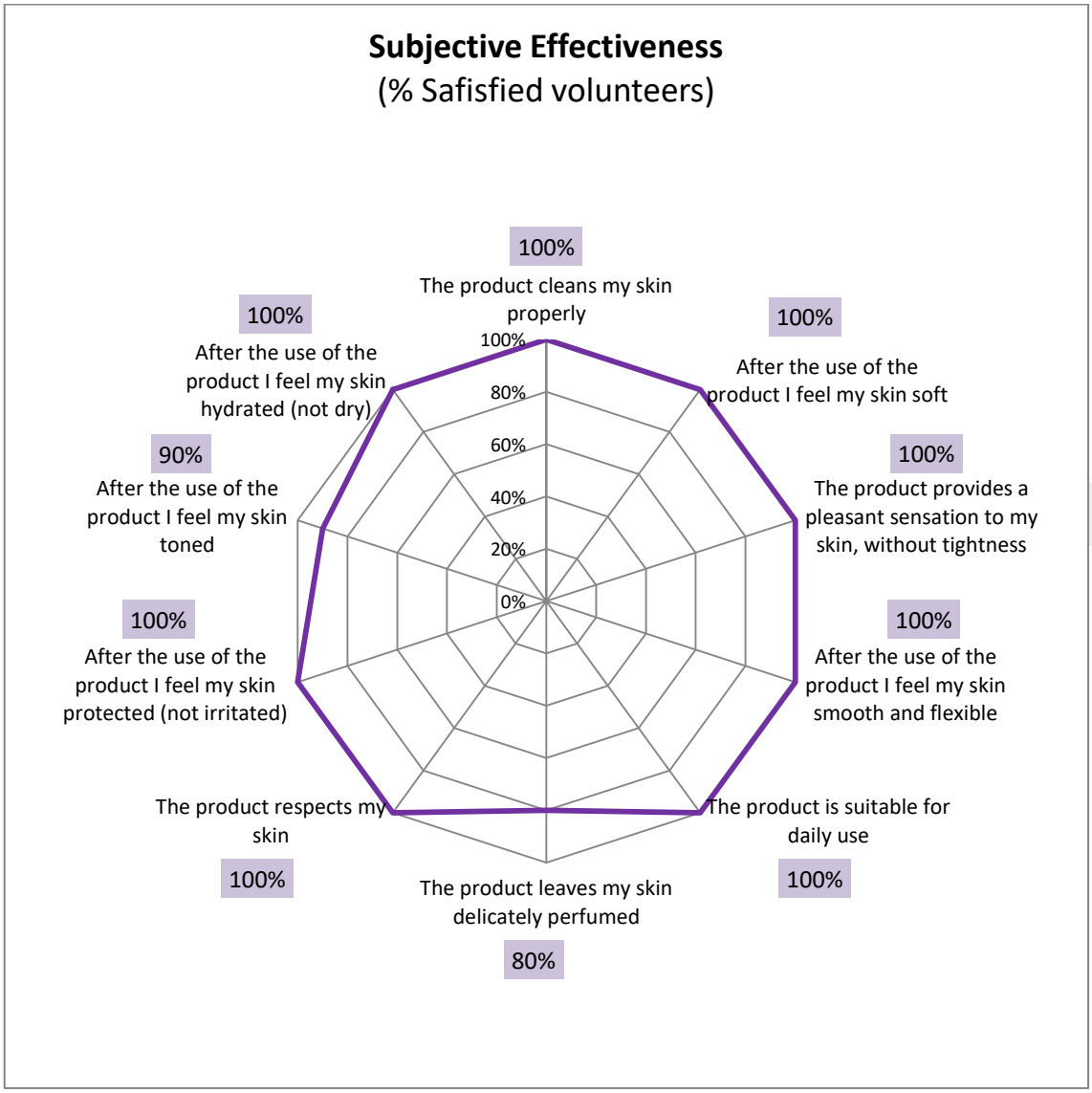


Figure 4. Percentage of satisfied responsible of the volunteers with the efficacy of the product (n=10).

- **Result on the skin**

The responsible of the volunteers were asked about their grade of satisfaction with the result of the product on the skin. 80% of the responsible of the volunteers were very satisfied and 20% satisfied (Figure 5).

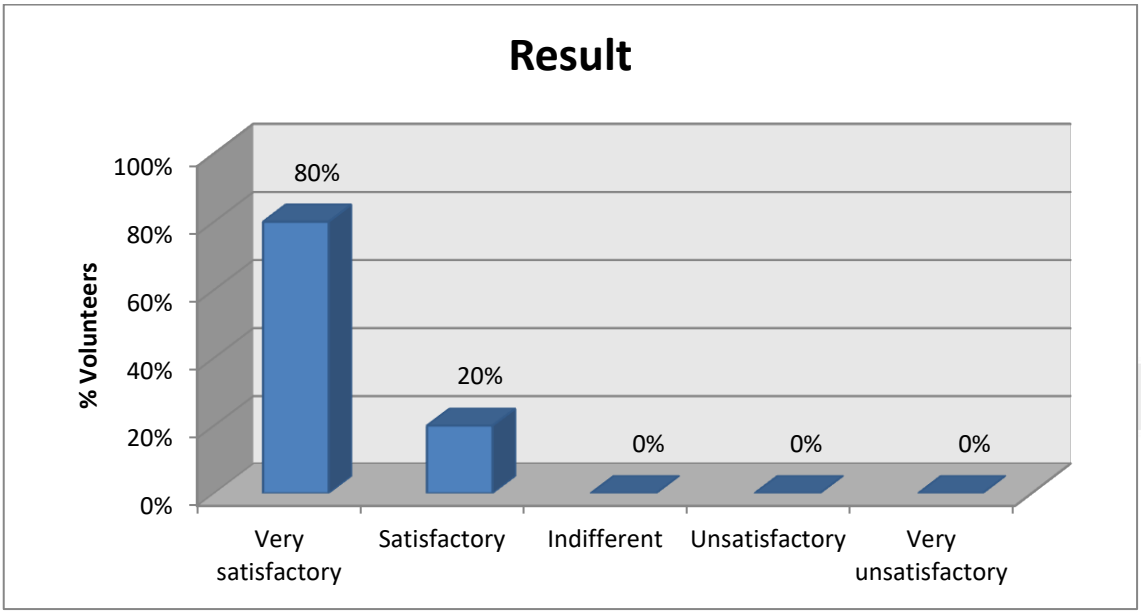


Figure 5. Subjective evaluation about the result of the product by the responsible of the volunteers after the use of the product (n=10).

Subjective evaluation of the tolerance by the responsible of the volunteers after 14 days of use on 10 volunteers.

- **Undesirable symptoms after the use of the product**

100% of the responsible of the volunteers had not undesirable symptoms after using the product (Figure 6).

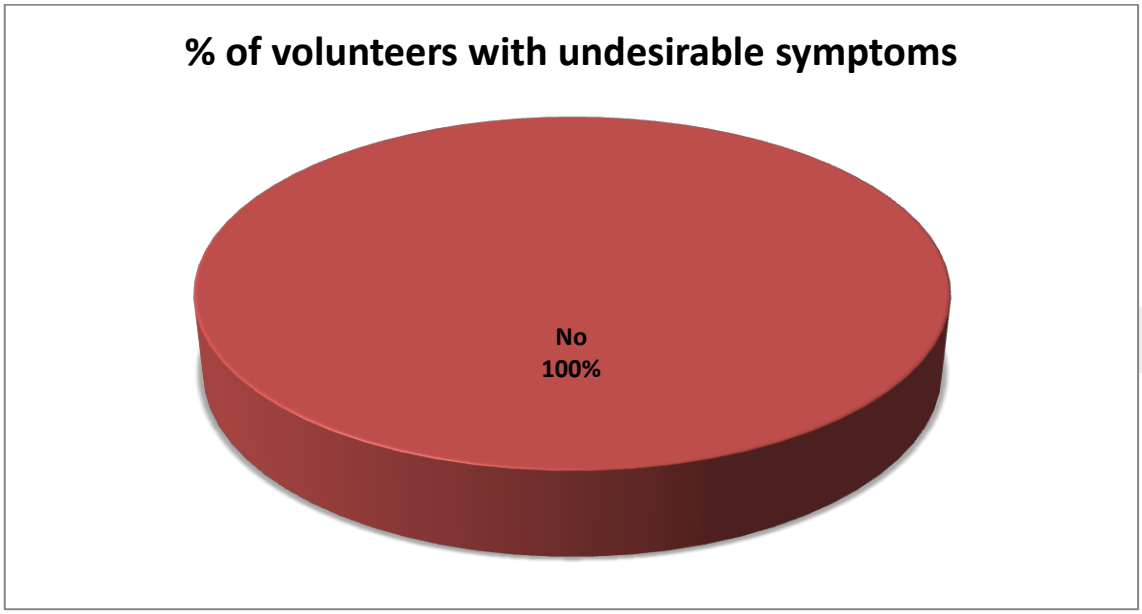


Figure 6. Subjective evaluation of the appearance of undesirable symptoms by the responsible of the volunteers after the use of the product (n=10).

Subjective evaluation about future use of the product after 14 days of use in 10 volunteers

- **Fulfillment with expectations**

The responsible of the volunteers were asked if they considered that the product fulfills with their expectations. 100% of the responsible of the volunteers answered that the product fulfills their expectations (Figure 7).

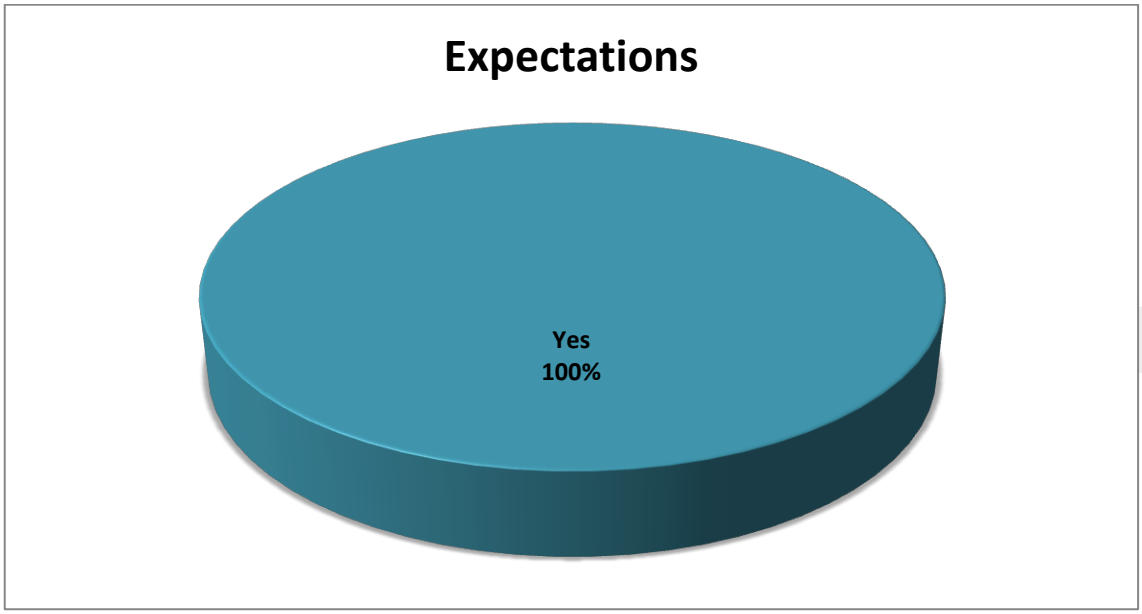


Figure 7. Subjective evaluation on the fulfillment with the expectations by the responsible of the volunteers after the use of the product (n=10).

Among the reasons for compliance with the expectations expressed by the responsible of the volunteers were included:

- "Very practical, with good smell, soft and pleasant",
- "The skin is hydrated, they are easy to use and don't leave residues",
- "The soap is enough for a complete bath",
- "It is easy to carry anywhere",
- "They don't irritate the skin".

- **Purchase intention**

The responsible of the volunteers were asked about if they would buy the tested product against their habitual one in case of the price were right. 80% of the responsible of the volunteers said that they would surely buy it and 20% probably yes (Figure 8).

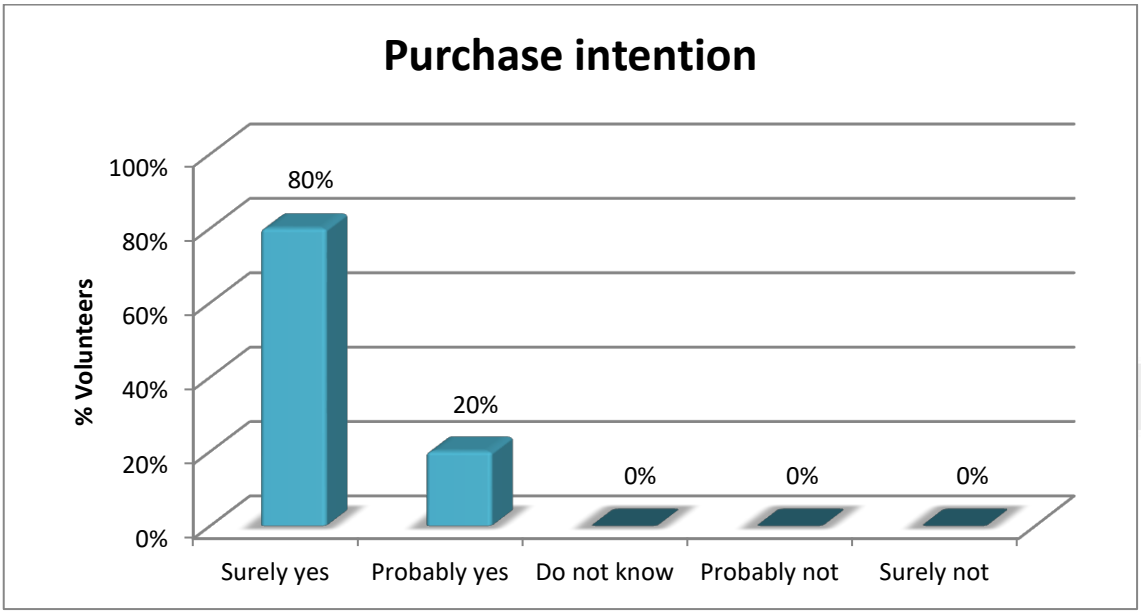


Figure 8. Purchase intention by the responsible of the volunteers after the use of the product (n=10).

10. CONCLUSIONS

This study had as objective evaluates the acceptability, subjective efficacy and tolerance for the product **DISPOBAÑO ESPONJAS JABONOSAS**, reference **0000100**, through a pediatric and dermatological assessment and a subjective evaluation on 10 volunteers during 14 days of use following the instructions provided by the sponsor.

According to the dermatological tolerance evaluation carried out by the pediatrician and the dermatologist, 100% of volunteers didn't show any unwanted symptoms during the study.

Regarding the subjective tolerance evaluation by the responsible of the volunteers, 100% of volunteers didn't show any unwanted symptoms during the study.

100% of the responsible of the volunteers were satisfied in a higher or lesser grade with the result of the product.

100% of the responsible of the volunteers indicated that the product meets their expectations and would be willing to buy it against their usual product if the price is right.

It can be claim: **"Tested Under Pediatric Control",**

"Tested Under Dermatological Control".

11. DOCUMENT CONSERVATION AND SAMPLES

The following documents relating to the study will be stored in the facilities of Zurko Research following the provisions of ISO 9001:2005:

- Study protocol and its modifications (signed)
- Primary data
- Final Report
- Documents provided by the sponsor

The documentation will be stored for 5 years. At 5 years the possibility of an extension due to the commercialization of the test product will be consulted with the promoter.

A sample of the evaluated product (sufficient quantity for the execution of the study) will be stored in Zurko Research's library for 1 year from the date of receipt.

12. BIBLIOGRAPHICAL REFERENCES

1. The SCCS´S Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation 9th Revision
2. www.cosmeticsinfo.org
3. Nueva Clasificación de tipos piel y sus implicaciones en Dermatología Cosmética. Revisión Dermatología Venezolana. Vol. 43, Nº 4, 2005. Leslie Baumann, Sadegh Amini, Eduardo Weiss.
4. JONES, L. V., PEYRAM D.R. and THURSTONE L. L. Development of a scale for measuring soldiers´ food preferences. *Food Research*, 20, 1955, pp. 512-520.

SIGNATURES

Researcher: Ana García Blanco, Biologist. I, the undersigned, Ana Garcia Blanco, declare that this study has been carried out under my responsibility and in the essence of the Clinical Good Practices (Guideline for good clinical practice E6 (R2) of June 14th 2017, EMA/CHMP/ICH/135/1995 of May 1st 1996, European Parliament and Council Guideline 2001/20/CE – May 1st 2001).

-The results here presented reflect accurately and completely the raw data of the study.

Signature:

Pediatrician: Mª Cristina Chiatti Gassino. Medical license number: 280838462.

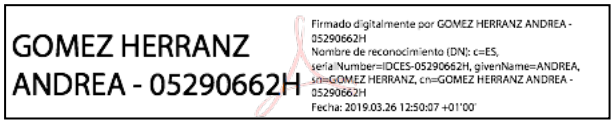
Signature:

Dermatologist: Eliana San Juan Lasser. Medical license number: 283805700.

Signature:

Quality manager: Andrea Gómez Herranz, quality guarantee technician. I, the undersigned, Andrea Gómez Herranz, declare that this study has been checked according to the procedures of the Quality Unit and under my responsibility and in the essence of the Clinical Good Practices (Guideline for good clinical practice E6 (R2) of June 14th 2017, EMA/CHMP/ICH/135/1995 of May 1st 1996, European Parliament and Council Guideline 2001/20/CE – May 1st 2001)

The inspections that have been made, allow to confirm that the final report reflects accurately the primary data of the study.



ANNEX

Annex I: Information about the volunteers

Volunteers		Age (months)	Gender	Skin type	Habitual use	Habitual product	Frequency
Ref.	Acron.						
1	V1	36	M	S	Yes	Deliplus	Daily
2	V2	24	F	S	Yes	Deliplus	Thrice a week
3	V3	12	F	S	Yes	Deliplus	Twice a week
4	V4	36	F	R	No	-	-
5	V5	24	F	R	No	-	-
6	V6	36	F	S	No	-	-
7	V7	24	F	S	Yes	Deliplus	Twice a week
8	V8	24	F	S	No	-	-
9	V9	22	F	R	No	-	-
10	V10	23	F	S	Occasionally	Baby baño	Occasionally

M = Male, F = Female; R = Resistant, S = Sensitive

info@zurkoresearch.com • www.zurkoresearch.com

Annex II: Results of the subjective questionnaire

Aspect	General opinion					Appearance					Color					Smell				
Opinion	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Number of volunteers	10	0	0	0	0	8	1	1	0	0	9	1	0	0	0	9	0	1	0	0
% of volunteers	100%	0%	0%	0%	0%	80%	10%	10%	0%	0%	90%	10%	0%	0%	0%	90%	0%	10%	0%	0%

Aspect	Comfort of packaging					Ease of use of the sponge					Resistance and suitability of packaging					Sponge softness to touch				
Opinion	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Number of volunteers	8	1	1	0	0	10	0	0	0	0	6	3	1	0	0	8	2	0	0	0
% of volunteers	80%	10%	10%	0%	0%	100%	0%	0%	0%	0%	60%	30%	10%	0%	0%	80%	20%	0%	0%	0%

Aspect	The packaging is easy to open					The sponge is resistant, it doesn't broke nor fray				
Opinion	5	4	3	2	1	5	4	3	2	1
Number of volunteers	6	2	0	2	0	9	1	0	0	0
% of volunteers	60%	20%	0%	20%	0%	90%	10%	0%	0%	0%

Aspect	The product cleans my skin properly					After the use of the product I feel my skin soft					The product provides a pleasant sensation to my skin, without tightness				
Opinion	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Number of volunteers	10	0	0	0	0	8	2	0	0	0	9	1	0	0	0
% of volunteers	100%	0%	0%	0%	0%	80%	20%	0%	0%	0%	90%	10%	0%	0%	0%
Aspect	After the use of the product I feel my skin smooth and flexible					The product is suitable for daily use					The product leaves my skin delicately perfumed				
Opinion	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Number of volunteers	8	2	0	0	0	10	0	0	0	0	6	2	2	0	0
% of volunteers	80%	20%	0%	0%	0%	100%	0%	0%	0%	0%	60%	20%	20%	0%	0%
Aspect	The product respects my skin					After the use of the product I feel my skin protected (not irritated)					After the use of the product I feel my skin toned				
Opinion	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Number of volunteers	10	0	0	0	0	10	0	0	0	0	7	2	1	0	0
% of volunteers	100%	0%	0%	0%	0%	100%	0%	0%	0%	0%	70%	20%	10%	0%	0%
Aspect	After the use of the product I feel my skin hydrated (not dry)														
Opinion	5	4	3	2	1										
Number of volunteers	7	3	0	0	0										
% of volunteers	70%	30%	0%	0%	0%										

info@zurkoresearch.com • www.zurkoresearch.com