



STUDY REFERENCE: 02/DER-4_247_18-001

Study Report - Version nº 1

**ACCEPTABILITY, SUBJECTIVE EFFICACY AND TOLERANCE
EVALUATION OF A COSMETIC PRODUCT UNDER DERMATOLOGIC
AND GYNAECOLOGIC CONTROL**



**SPONSOR: C.V. MEDICA, S.L.
TESTED PRODUCT: SOAP SPONGE**

Madrid, July 17th 2018

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1. IDENTIFICATION OF THE STUDY

Name of the study: Acceptability, subjective efficacy and tolerance evaluation of a cosmetic product under dermatologic and gynaecologic control.

Laboratory manager: Irene Zaldívar Notario

Study manager: María Barbero Calderón

Sponsor: C.V. MEDICA, S.L.

Sponsor address: Pol. Ind. La Plana C/ Ponent, 1 43424 Sarral (Tarragona)

Tested product: SOAP SPONGE, batch:180319

2. OBJETIVE AND PRINCIPLE OF THE STUDY

This study had as objective to evaluate the acceptability, subjective efficacy and tolerance for the product **ESPONJA JABONOSA** in 20 volunteers, during 3 weeks of product use, using the product after normal conditions of use provided by the sponsor.

The product tested is an intimate sponge impregnated with soap, tested on women between 18-70 years old.

Therefore, this study was designed to evaluate the acceptability, efficacy and tolerance from participants to a cosmetic product for intimate care, as well as to perform the dermatologic and gynaecologic monitoring (after 3 weeks) of any possible adverse symptoms that could appear with the continued use of the product.

Additionally, product acceptability was assessed by a subjective evaluation of the efficacy, and by a subjective evaluation of organoleptic properties and its mode of application. Other product characteristics were also assessed by subjective evaluation.

3. TYPE OF SYUDY

This test was performed under dermatologic and gynaecologic control in the Experimental Centre.

The study was carried out following general conditions in Zurko Research, established for the execution of study project on humans (Structure and Content of Clinical Study Reports from ICH Harmonized 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 methodology to be employed.

4. RESEARCH CENTER AND RESEARCH TEAM

4.1. Research centre

ZURKO RESEARCH S.L.

110 Almansa street, floor 18.

28040 Madrid (Spain)

Tel: (+34) 91.521.15.88

4.2. Research team

Study manager: María Barbero Calderón, Pharmacist.

Researcher: Ana García Blanco, Biologist.

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

Gynaecologist: Myriam Gracia Segovia. Medical license number: 284115922

5. STUDY'S SCHEDULE

Beginning: May the 03rd, 2018

End: May the 24th, 2018

6. TESTED PRODUCT**6.1. Identification of the tested product**

PRODUCT	SOAP SPONGE
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Batch	<input type="checkbox"/> 180319
<input type="checkbox"/> Zurko Research Reference	<input type="checkbox"/> 02/DER-4_247_18-001
<input type="checkbox"/> Cosmetic form and organoleptic characteristics	<input type="checkbox"/> Sponge impregnated with soap
<input type="checkbox"/> Number and Packaging content	<input type="checkbox"/> 25 packages of 24 units

The tested element was stored at room temperature, following the indications of the Sponsor.

The identity and stability of the tested element are in the product data sheet provided by C.V. MEDICA S.L.

6.2. Information regarding the tested product

The documents related to the tested product are the qualitative formula and the letter of commitment from the client, which demonstrate the coherence of the formula with the current regulation and its safety.

7. VOLUNTEERS

7.1. Ethical aspects

Each volunteer participating in the study has been informed before about the type and procedures of the study, signing an informed consent before the beginning of the study. The original informed consents were archived in Zurko Research.

7.2. Number

23 volunteers were initially included in the study. The number of volunteers required at the end of the study was 20, considering that the number of volunteers used in this type of study is enough to verify acceptability, tolerance and subjective efficacy of a cosmetic product.

One volunteer (V14) abandoned the study for reasons unrelated to it, and no exclusion was determined by the researcher.

Therefore, the compatibility, acceptability and subjective efficacy of the tested product were verified on 22 volunteers at the end of the study.

Volunteer participants in the study complied with the following inclusion criteria and they were outside any exclusion criteria, checked through the recruitment questionnaire (Annex I).

7.3. Specific inclusion criteria

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

- Age: 18 - 70 years old.
- Gender: female.
- All kind of skin.
- Healthy condition.
- Availability during the length of the study.
- Signature of the informed consent.

7.4. Specific exclusion Criteria

- To present pathologies in the experimental area.
- To present pathologies that may interfere with the study.
- To present relevant dermatological pathologies (atopic dermatitis, psoriasis, lupus rosacea, ringworm...).
- Volunteers who have been subjected to an extraction or transplantation of organs; volunteers who have suffered a cranial trauma with lengthy loss of

consciousness in the last five years, or subjects with cranial trauma with current sequels.

- Volunteers who have:
 - o Cardiovascular, digestive, neurological, psychiatric, genital, urinary, haematological or endocrine progressive alteration.
 - o Immunodeficiency.
 - o Previous history of medicinal, cosmetics, healthcare, household, industrial products (especially latex, aluminium or nickel) intolerance.
 - o Previous history of allergies, photosensitivity or phototoxicity.
 - o Progressive cutaneous alteration.
 - o Progressive febrile process.
 - o Metabolic photodermatitis: porphyria, tryptophan metabolism disorders.
- Volunteers who are treated with antibiotics, antihistaminics, corticosteroids, beta blockers, retinoid, azelaic acid, anti-acne treatments or for which treatment is completed during the 15 previous days to the study.
- To apply other similar topical products in the experimental area during the study.
- To apply other cosmetics products not usually used in the experimental area.
- To present allergy to this type of cosmetic products.
- Participation in any other study that would interfere with the current study.
- To refuse to sign of the informed consent.

Volunteers were warned about the possible adverse reactions of the product and its reversibility. In case of some adverse reaction or doubt about it, volunteers were advised to suspend the application of the product immediately and to contact the centre.

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

8. METHODOLOGY

8.1. Criteria for product application

Product type: rinse off sponge impregnated with soap

Experimental area: intimate area.

Frequency of use: minimum once a day. When necessary.

Duration of the study: 3 weeks.

Mode of application: Use one sponge in each wash. Moisten, do not immerse, squeeze until foam and rub through the skin. Clear out.

Volunteers were asked to not use any other product that they do not usually use during the study period.

8.2. Experimental procedure

Volunteers participating in the study signed the informed consent and fill the recruitment where they were asked about their consumption habits and preferences (Annex I).

The first day of the test, volunteers were instructed in oral and written form about the frequency of use and the mode of application of the product. The dermatologist and the gynaecologist clinically evaluated the volunteers, filling a questionnaire of the skin status before the application of the product.

The last day of the study, the dermatologist and the gynaecologist evaluated again the volunteers, filling out a questionnaire of the skin status after product use, as well as possible alterations that might have appeared. They also indicated if the alterations observed were due to the product use.

At the end of the study, volunteers filled a questionnaire about their opinion of the product.

8.3. Dermatologic and gynaecologic tolerance evaluation

In the first test day, the dermatologist and gynaecologist verified the specific inclusion and exclusion criteria of volunteers, before the product application. In case of not fulfilment of any acceptance criteria, those volunteers will be excluded before the beginning of the test.

Then, the dermatologist and gynaecologist performed a visual evaluation of the skin from the experimental area (intimate zone), filling out a questionnaire about any possible alterations/pathologies that might have before using the product.

At the end of the study, the dermatologist and gynaecologist, performed the same visual evaluation of the skin of the experimental area (intimate zone), evaluating skin type and any possible alterations volunteers might have after using the product.

Analysed alterations were the following ones: Irritation/redness, inflammation, dryness, oedema, and others, in a scale of four points (very slight alteration, slight alteration, moderate alteration and severe alteration). Thereafter, it was indicated if the alterations observed were related with the use of the product by using six-point scale (not related, unlikely, possible, likely, certain and not assessable).

The interpretation of the results from the dermatological and gynaecological examination was collected in individual evaluation sheets.

8.4. Subjective evaluation

Volunteers in their visit to the centre at the end of the study (D21) completed a questionnaire, answering questions concerning the acceptability, efficacy, general opinion and organoleptic properties of the product, as well as product tolerance and the possibility of future use.

For organoleptic characteristics:

- General opinion,
- Appearance,
- Color,
- Smell,
- Texture,
- Ease of application,
- Ease of use,
- Attractive packaging,
- Resistance and suitability packaging.

For subjective efficacy:

- Cleaning sensation
- The use of the product helps to maintain good intimate hygiene,
- The product is ideal for the care of delicate and sensitive skin,
- The product has a soft and pleasant texture
- The product is easy and comfortable to use,

- The product is suitable for daily use.

A hedonic scale of seven points is used for the organoleptic characteristics and for the global assessment:

- 7: I like it very much.
- 6: I like it moderately.
- 5: I like it slightly.
- 4: I neither like it nor dislike it.
- 3: I dislike it slightly.
- 2: I dislike it moderately.
- 1: I dislike it very much.

Volunteers with opinions between 5 and 7 are considered satisfied.

A Likert scale of five points is used for the efficacy:

- 5: Strongly agree
- 4: Agree
- 3: Undecided
- 2: Disagree
- 1: Strongly disagree

Volunteers with opinions between 4 and 5 are considered satisfied.

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

Data obtained through the subjective evaluation questionnaires were also analysed and presented in graphics with the percentages of satisfied volunteers.

9. RESULT

9.1. Tolerance evaluation

A clinical evaluation of volunteers was carried out in the experimental area by the dermatologist and gynaecologist, together with the researcher at the end of the study.

Evaluation of alterations associated with the use of product:

None of the volunteers presented any alteration associated with product use (Figure 1).

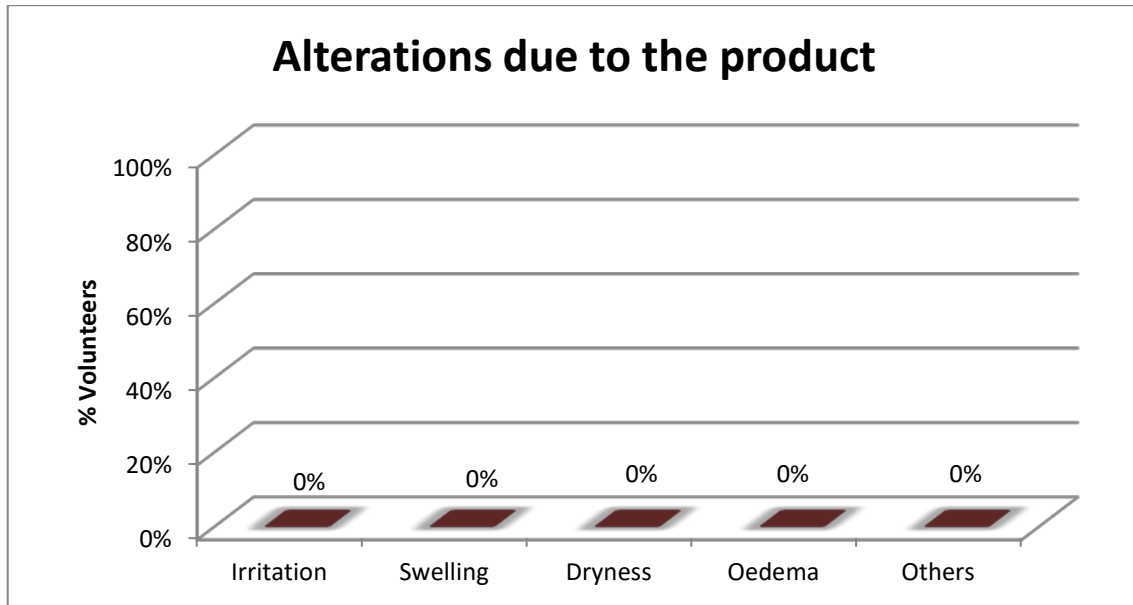


Figure 1. Volunteers with alterations associated with product use as evaluated by the dermatologist and the gynaecologist (n=22).

9.2. Subjective evaluation of the product by the volunteers

Subjective evaluation of organoleptic characteristics and global appraisal of the product after 3 weeks of use:

- **General opinion**

Regarding the general opinion of the product, 64% of the volunteers liked it very much, 27 % liked it moderately, 5% liked it slightly and 5% neither liked it nor disliked it (Figure 2).

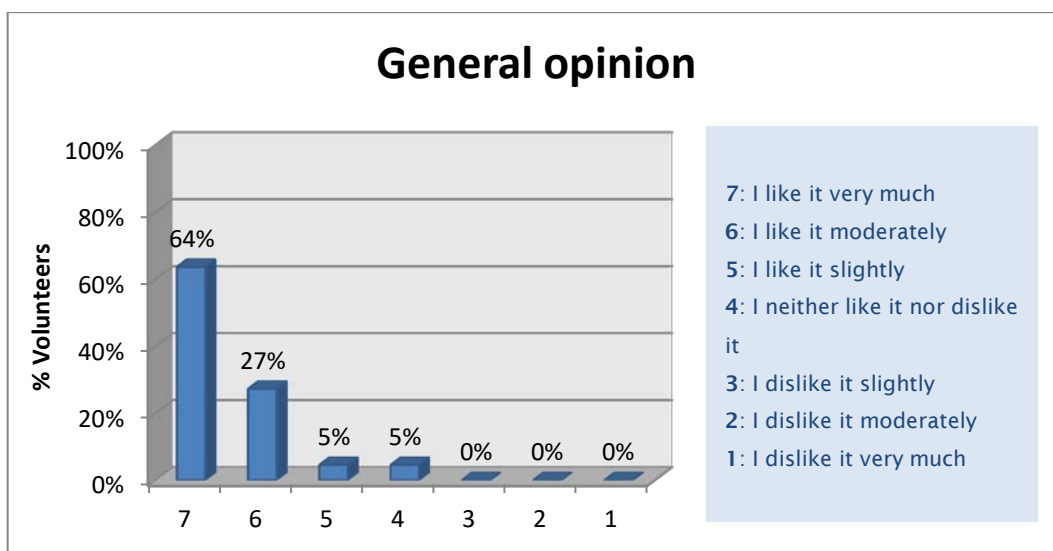


Figure 2. Subjective evaluation of the product by volunteers after 3 weeks. Relative frequency in scale of level of satisfaction (n=22).

- **Appearance**

Regarding product appearance, 55% liked it very much, 27 % liked it moderately, 14% liked it slightly and 5% neither liked it nor disliked it. (Figure 3).

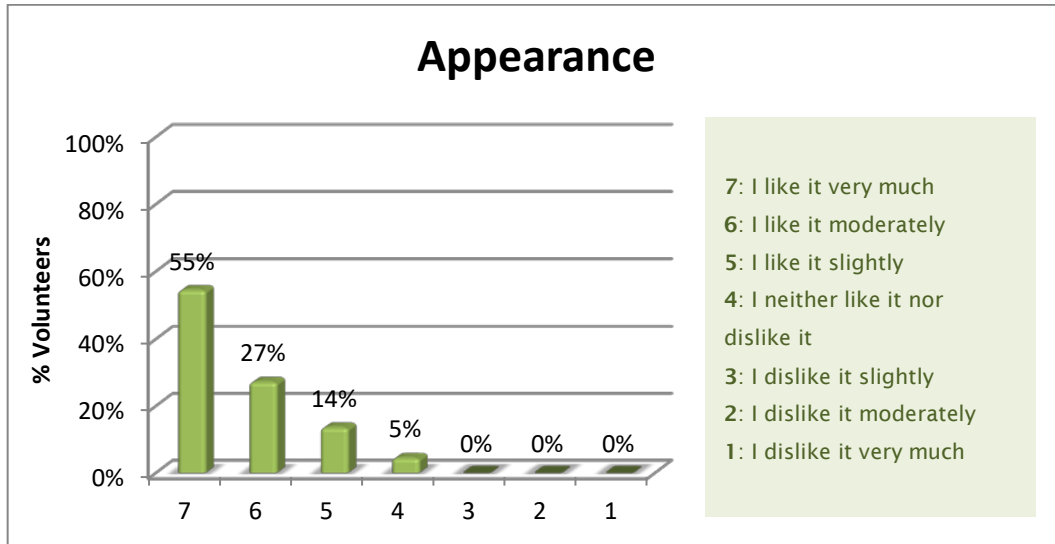


Figure 3. Subjective evaluation of product appearance by volunteers after 3 weeks. Relative frequency in scale of level of satisfaction (n=22).

- **Smell**

Regarding product smell, 82% of the volunteers liked it very much, 5% liked it moderately, 5% liked it slightly and 9% neither like it nor dislike it (Figure 4).

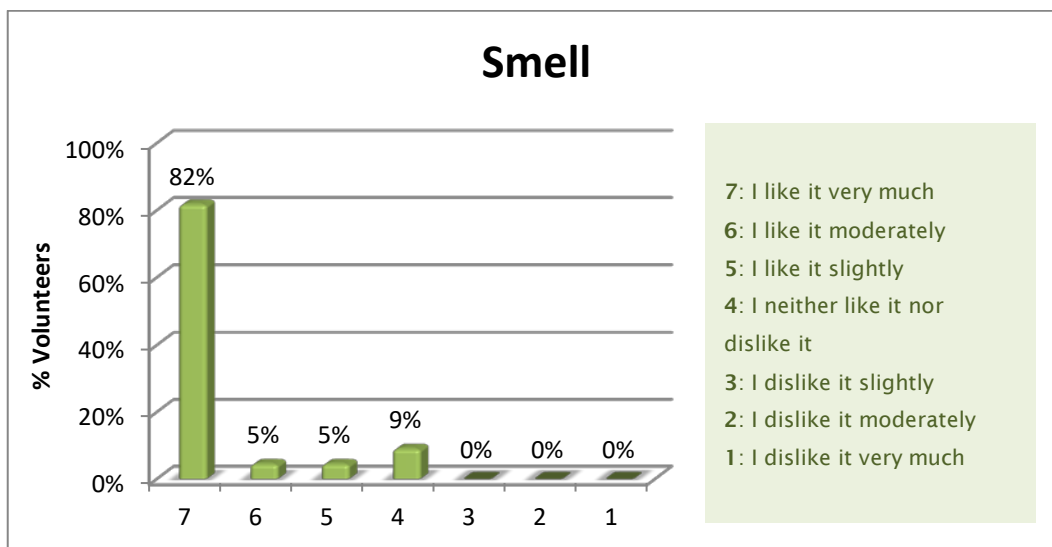


Figure 4. Subjective evaluation of product smell by volunteers after 3 weeks. Relative frequency in scale of level of satisfaction (n=22).

- **Color**

Regarding product coloration, 68% of the volunteers liked it very much, 18% liked it moderately and 14% liked it slightly (Figure 5).

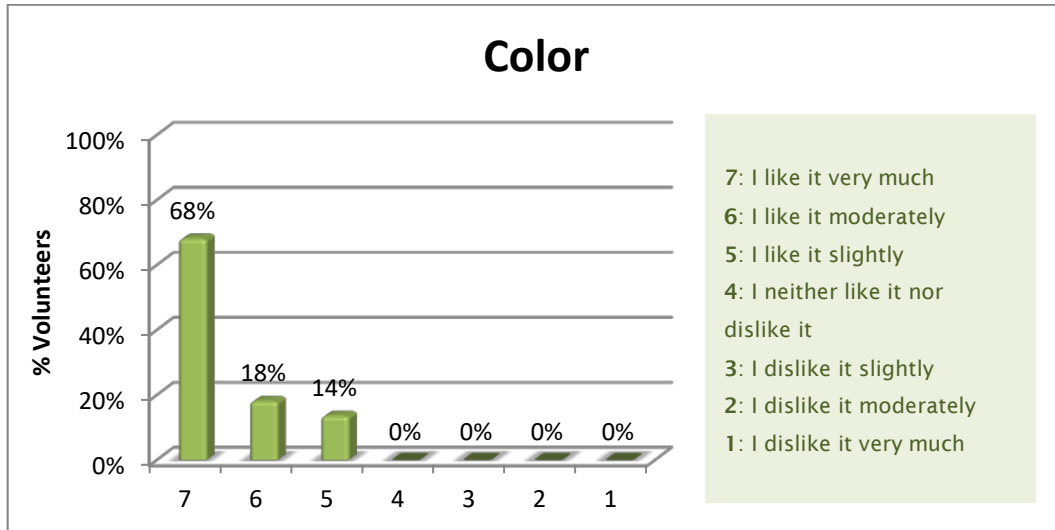


Figure 5. Subjective evaluation of product color by volunteers after 3 weeks. Relative frequency in scale of level of satisfaction (n=22).

- **Texture**

Regarding texture of the product, 64% of the volunteers liked it very much, 32% liked it moderately and 5% liked it slightly (Figure 6).

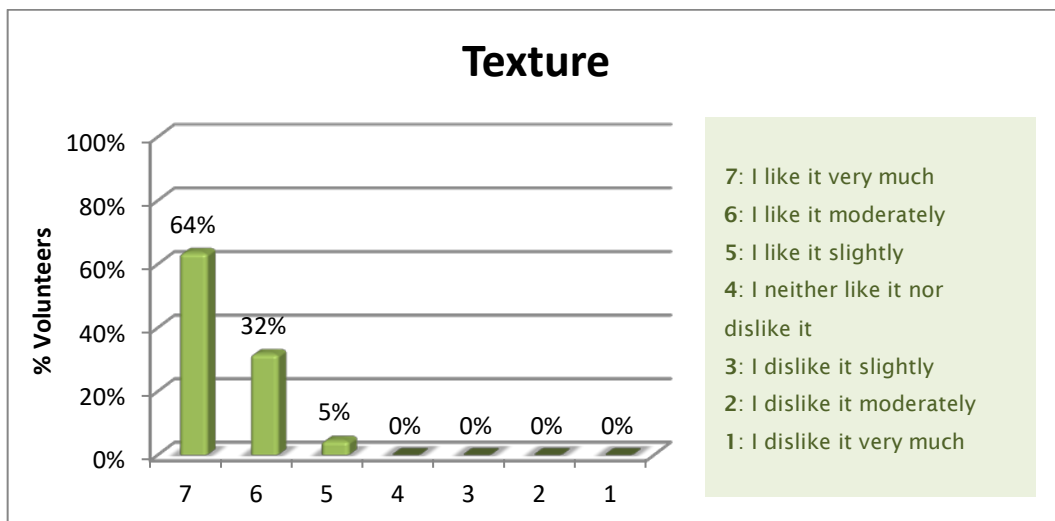


Figure 6. Subjective evaluation of product texture by volunteers after 3 weeks. Relative frequency in scale of level of satisfaction (n=22).

- **Ease of application**

Regarding the extensibility on the skin, 77% of the volunteers liked it very much, 9% liked it moderately and 14% liked it slightly (Figure 7).

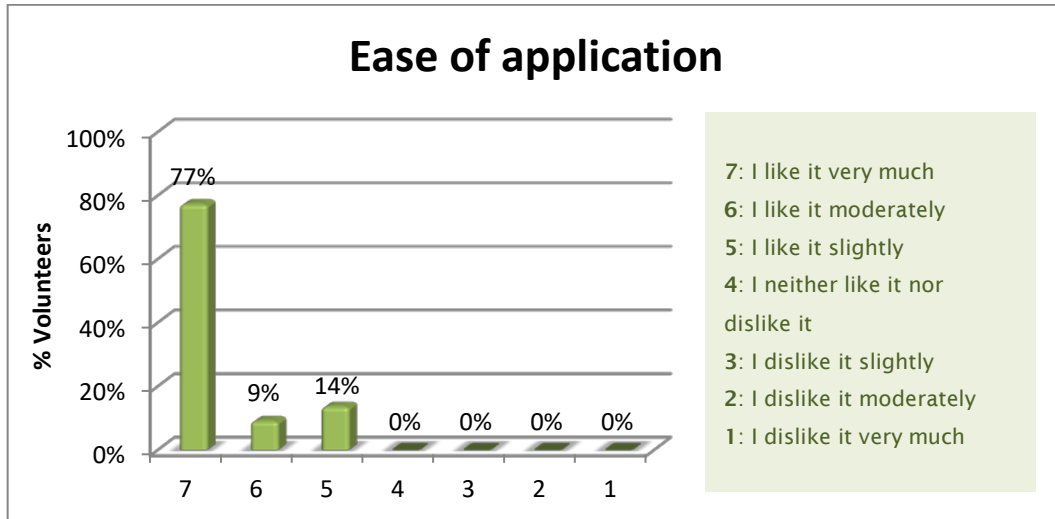


Figure 7. Subjective evaluation of ease of application by volunteers after 3 weeks. Relative frequency in scale of level of satisfaction (n=22).

- **Ease of use**

Regarding easiness of use of the product, 77% of the volunteers liked it very much, 14% liked it moderately and 9% liked it slightly (Figure 8).

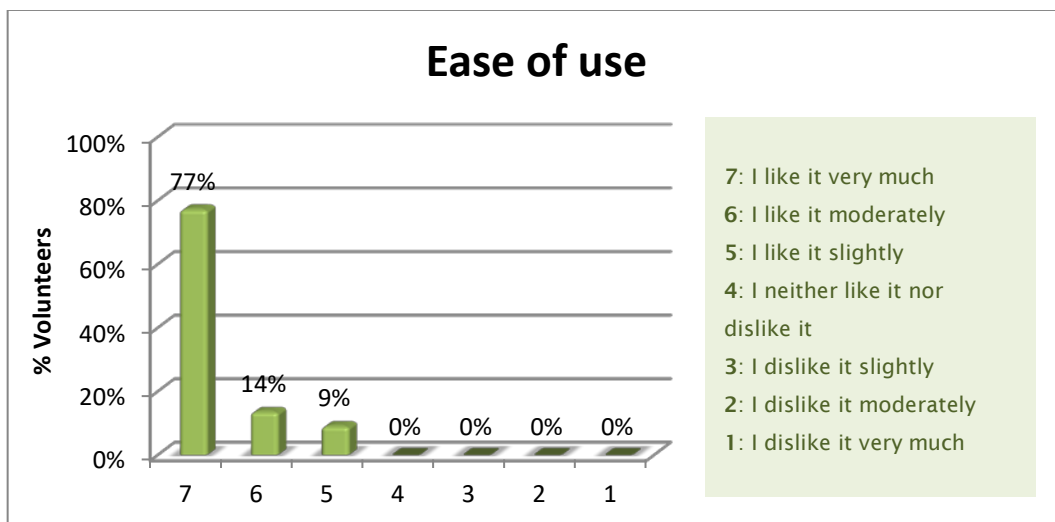


Figure 8. Subjective evaluation of easiness of use of the product by volunteers after 3 weeks. Relative frequency in scale of level of satisfaction (n=22).

- **Attractive packaging**

Regarding the attractiveness of packaging, 50% of the volunteers liked it very much, 27% liked it moderately, 14% liked it slightly and 9% disliked very much (Figure 9).

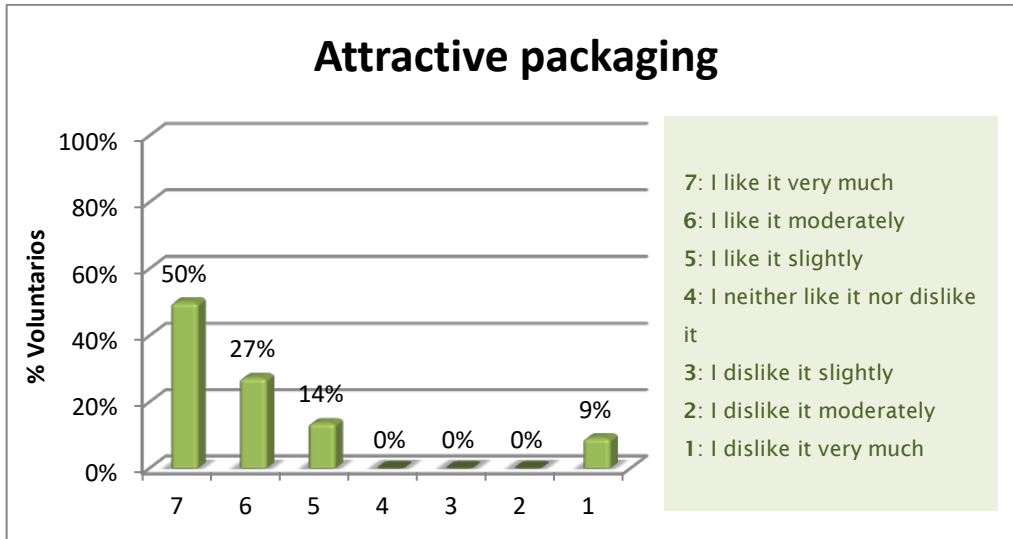


Figure 9. Subjective evaluation of packaging attractiveness by volunteers after 3 weeks. Relative frequency in scale of level of satisfaction (n=22).

- **Resistance and suitability of the packaging**

Regarding resistance and suitability of packaging, 64% of the volunteers liked it very much, 23% liked it moderately, 9% disliked it slightly and 5% disliked it very much (Figure 10).

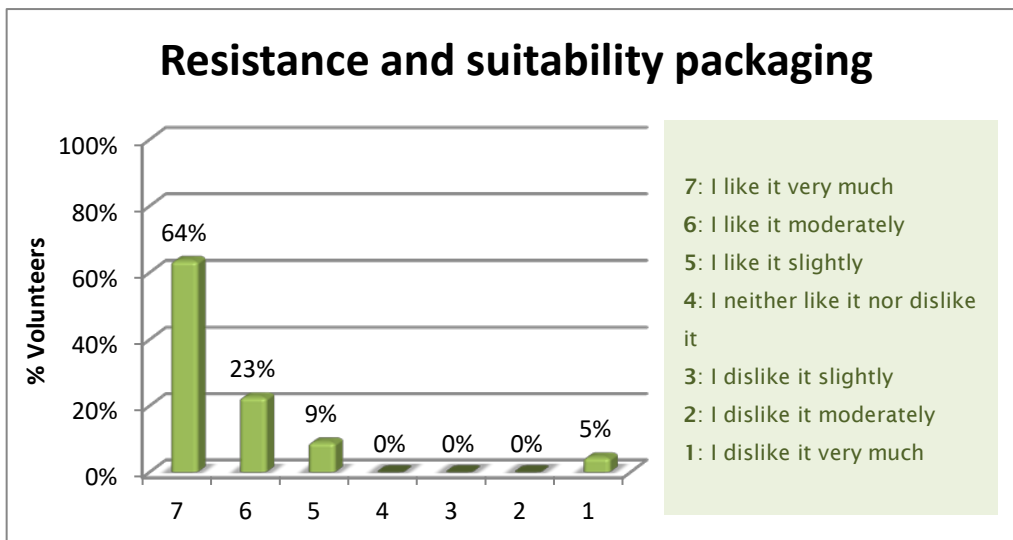


Figure 10. Subjective evaluation of resistance and suitability of packaging by volunteers after 3 weeks. Relative frequency in scale of level of satisfaction (n=22)

- Percentage of satisfied volunteers with general and organoleptic properties of the product

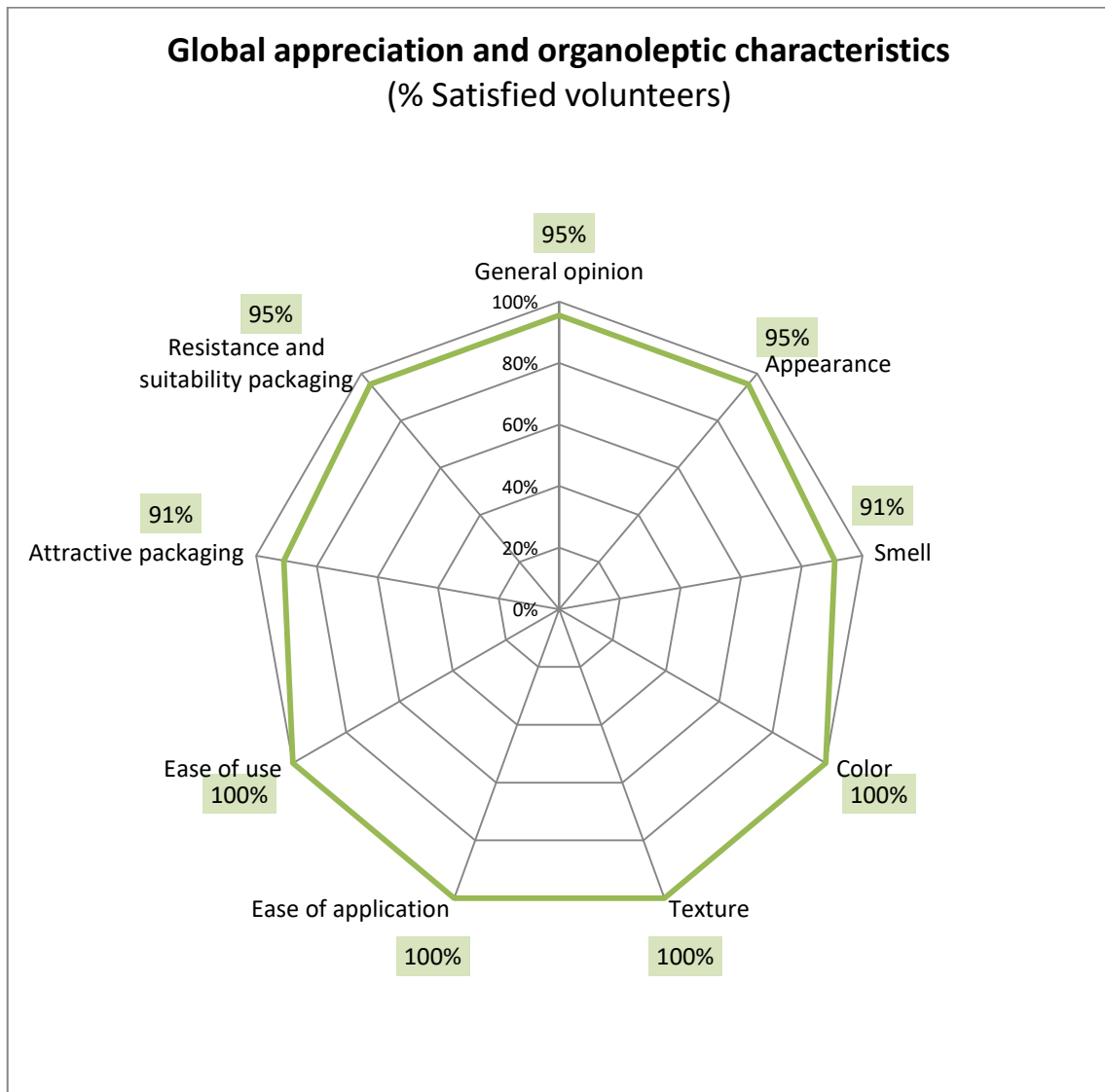


Figure 11. Percentage of volunteers satisfied with the product and its organoleptic properties (n=22).

Subjective evaluation of the efficacy after 4 weeks of use of the product:

- **Cleaning sensation**

Volunteers were asked for whether the product leaves a cleaning sensation, 68% of the volunteers were strongly agree and 32% were agree. (Figure 12).

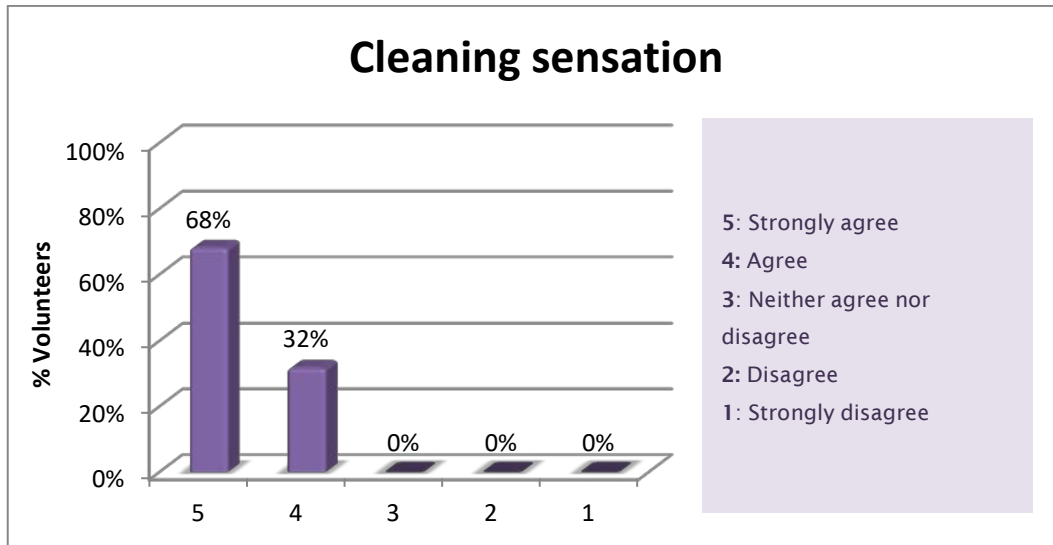


Figure 12. Subjective evaluation about whether the product leaves a cleaning sensation by volunteers after 3 weeks. Relative frequency in scale of level of agreement (n=22).

- **The product maintains a good intimate hygiene**

Volunteers were asked for whether the product maintains a good intimate hygiene, 73% of the volunteers were strongly agree and 27% were agree. (Figure 13).

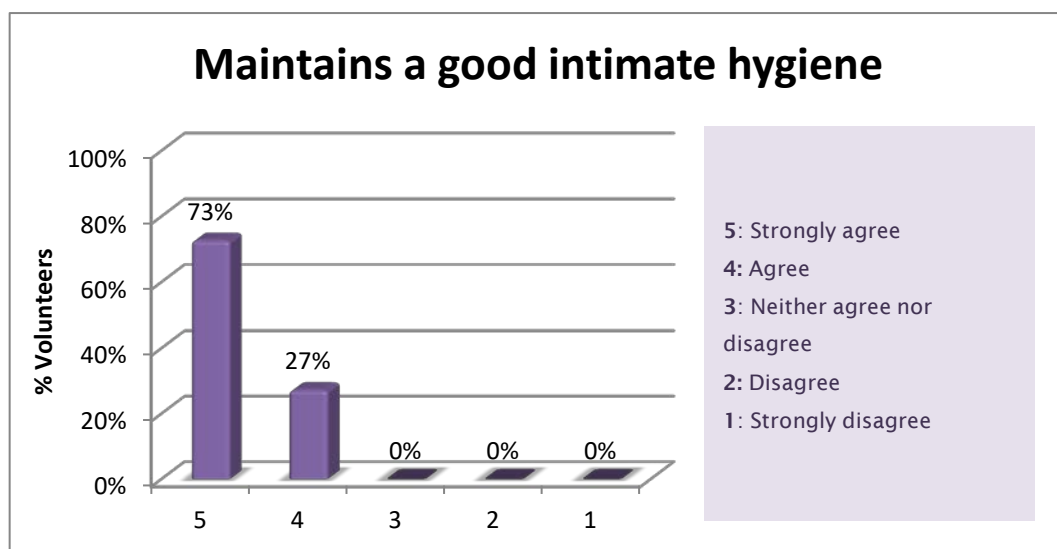


Figure 13. Subjective evaluation about whether the product maintains a good intimate hygiene by volunteers after 3 weeks. Relative frequency in scale of level of agreement (n=22).

- **Ideal for sensitive skin**

Volunteers were asked for whether the product is ideal for sensitive skin, 55% of the volunteers were strongly agree and 45% were agree (Figure 14).

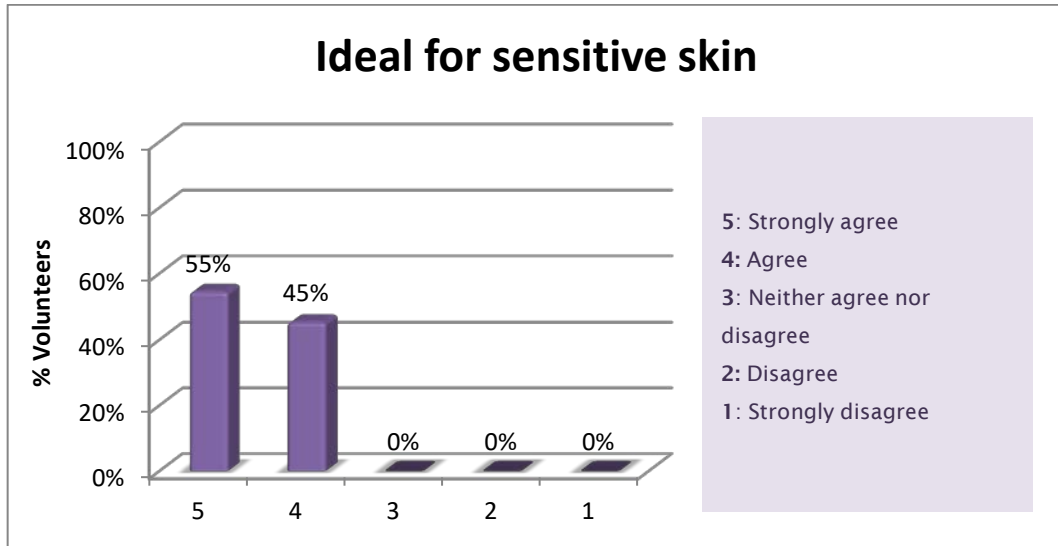


Figure 14. Subjective evaluation about whether the product is ideal for sensitive skin by volunteers after 3 weeks. Relative frequency in scale of level of agreement (n=22).

- **Soft and pleasant texture**

Volunteers were asked for whether the product has a soft and pleasant texture, 55% of the volunteers were strongly agree, 36% were agree and 9% neither agree or disagree (Figure 15).

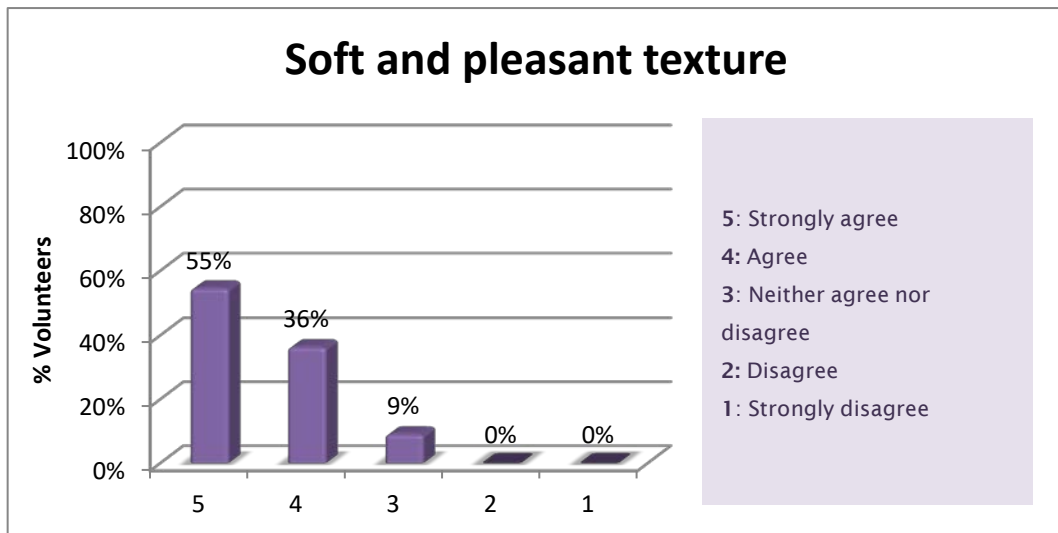


Figure 15. Subjective evaluation about whether the product has a soft and pleasant texture by volunteers after 3 weeks. Relative frequency in scale of level of agreement (n=22).

- **Ease and comfortable to use**

Volunteers were asked for whether the product was easy and comfortable to use, 68% of the volunteers strongly agreed, 27% agreed and 5% neither agreed nor disagreed (Figure 16).

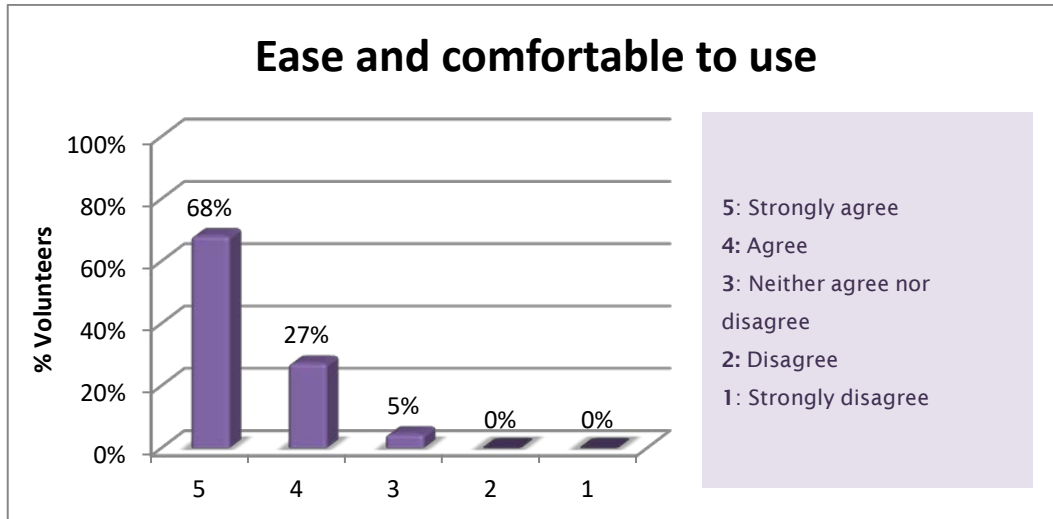


Figure 16. Subjective evaluation about whether the product was easy and comfortable to use by volunteers after 3 weeks. Relative frequency in scale of level of agreement (n=22).

- **Suitable for daily use**

Volunteers were asked for whether the product was suitable for daily use, 68% of the volunteers were strongly agree and 32% were agree (Figure 17).

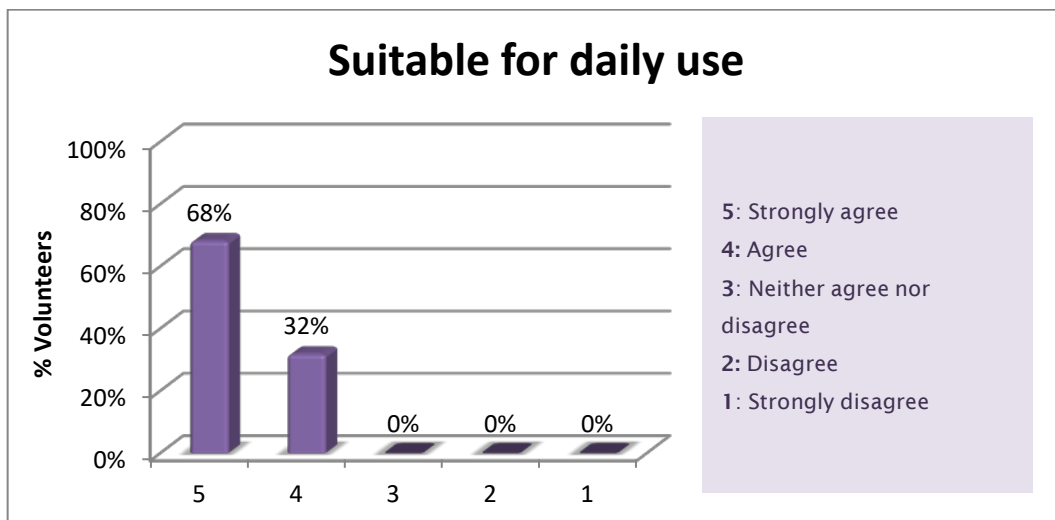


Figure 17. Subjective evaluation about whether the product was suitable for daily use by volunteers after 3 weeks. Relative frequency in scale of level of agreement (n=22).

- Percentage of satisfied volunteers with the efficacy of the product

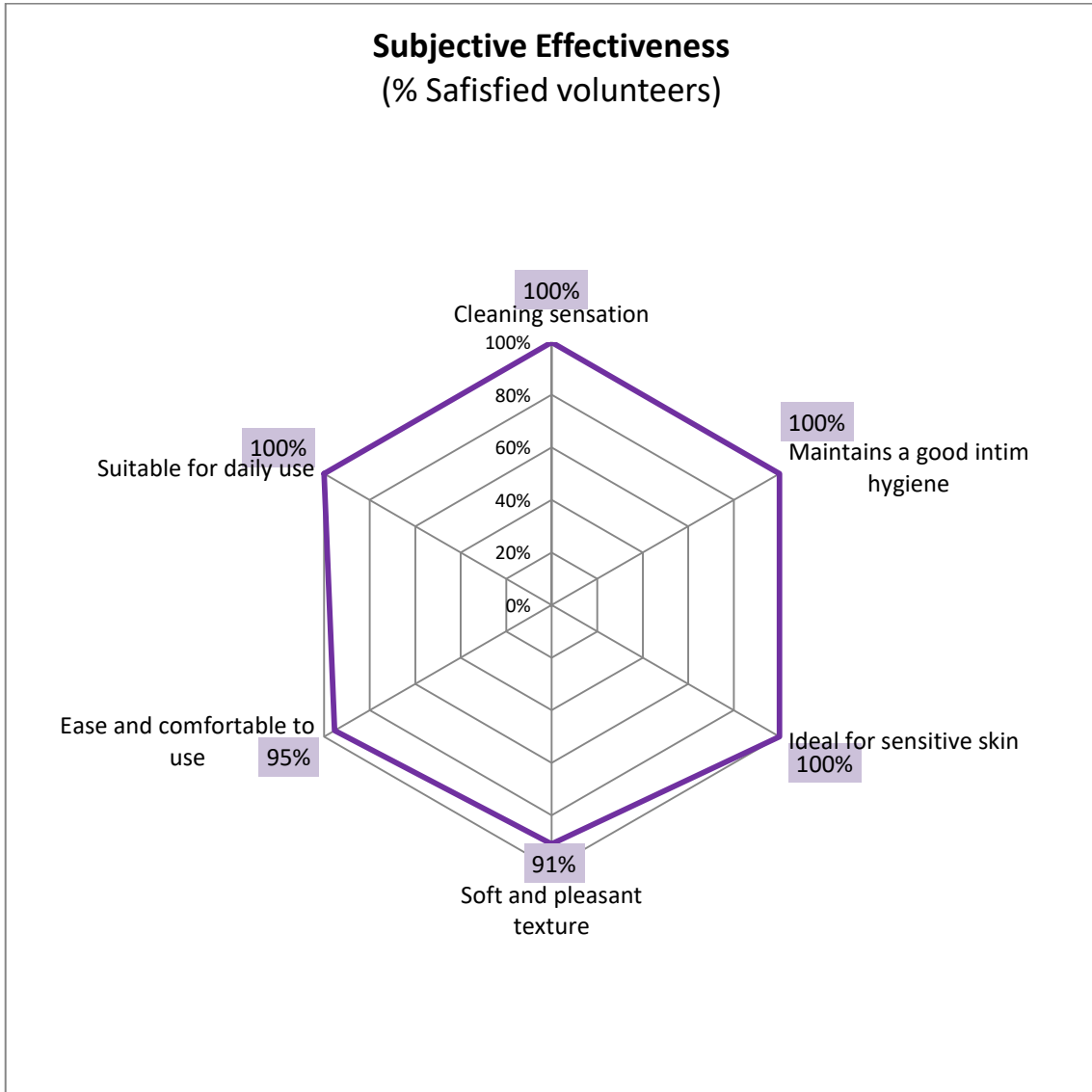


Figure 18. Summary of the subjective efficacy by the volunteers after 3 weeks (n=22).

- **Scoring of results on the skin**

Volunteers were asked to indicate the degree of satisfaction with results of the product. 50% of volunteers were very satisfied with the results on skin and 50% were satisfied (Figure 19).

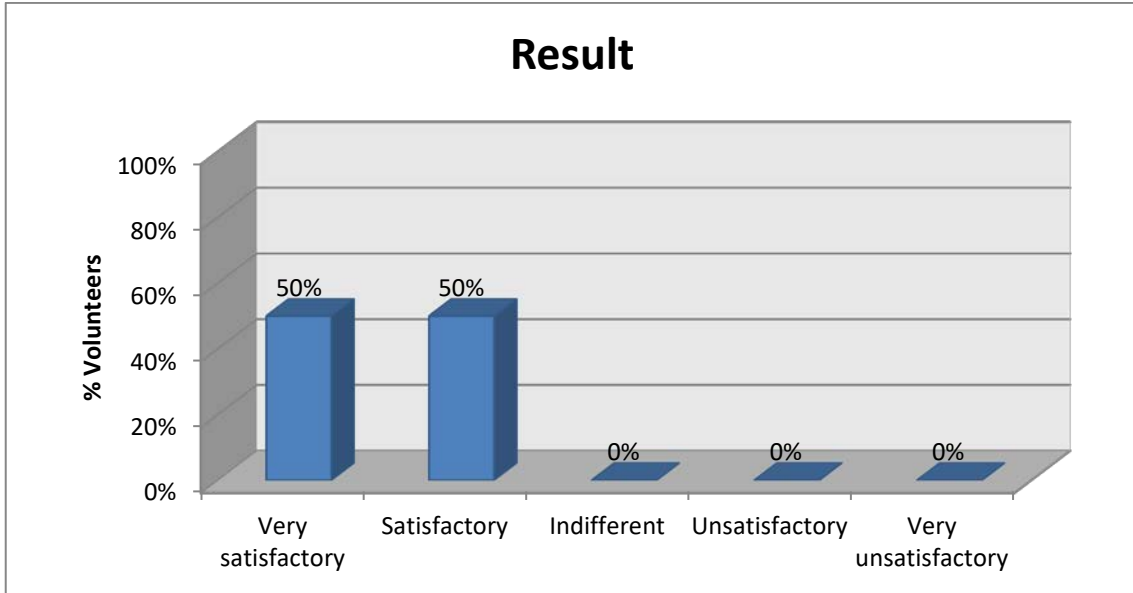


Figure 19. Subjective evaluation of results by volunteers after 3 weeks. Relative frequency in scale of level of satisfaction (n=22).

Subjective tolerance evaluation after 3 weeks of use:

100% of volunteers did not indicate any undesirable symptom after product use (Figure 20).

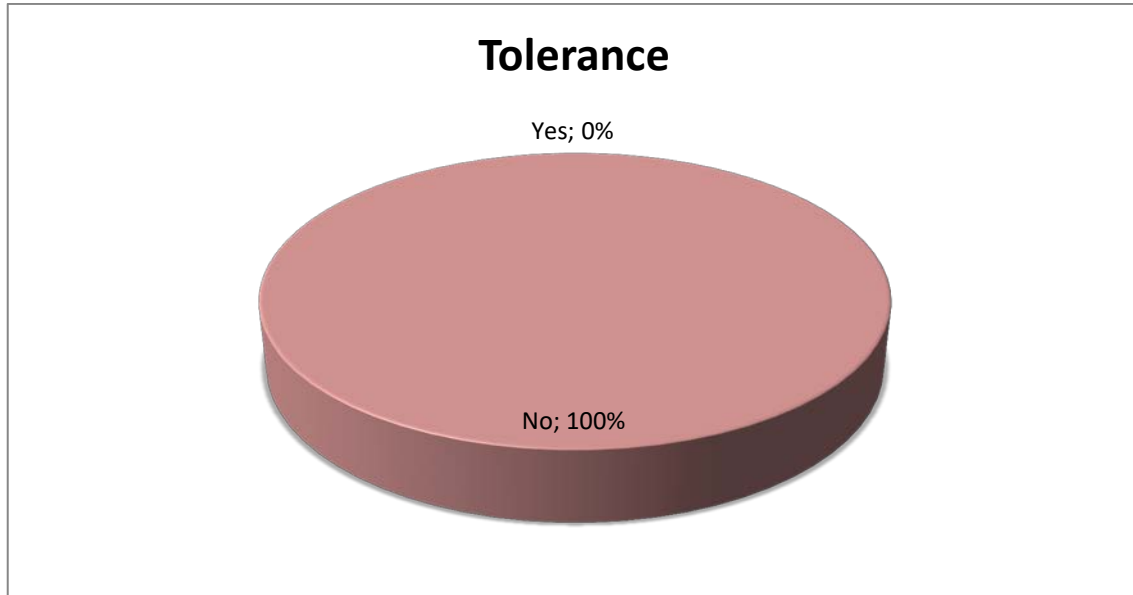


Figure 20. Subjective evaluation of the appearance of undesirable symptoms after 3 weeks of product use (n=22).

Subjective evaluation about future use of the product:

- **Satisfaction of expectations**

Volunteers were asked whether they considered the product meet with their expectations of a good soap sponge. 100% of them thought that the product was fulfilling their expectations (Figure 21).

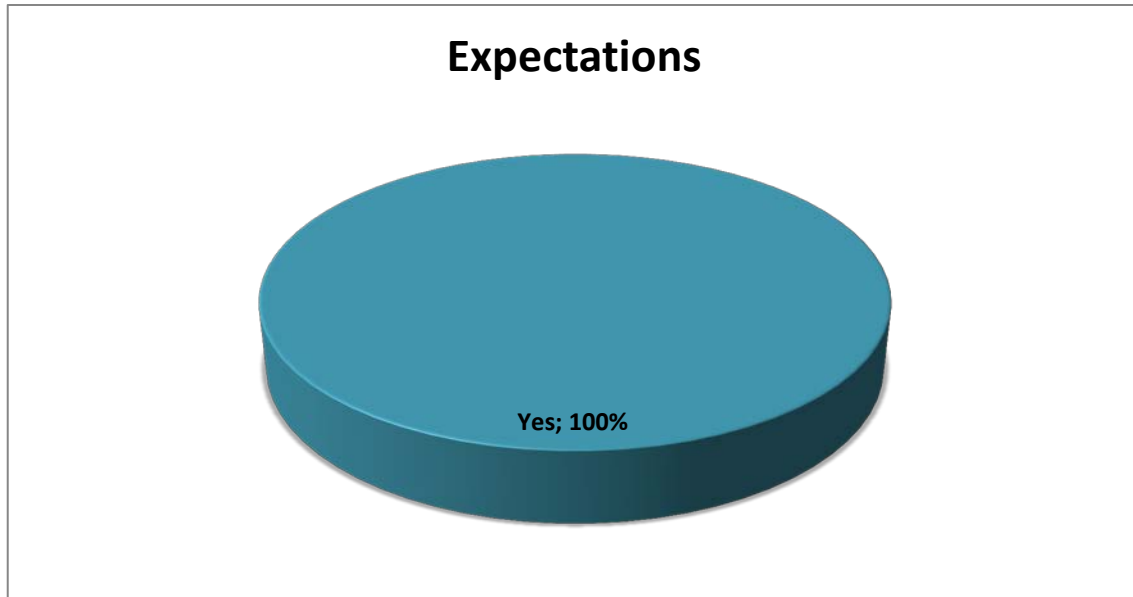


Figure 21. Subjective evaluation about fulfilment of expectations by volunteers after 3 weeks. Relative frequency in scale of fulfilment (n=22).

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

- "It leaves a cleaning feeling and have a good smell",
- "It is a very good product, especially the days of menstruation"
- "The feeling of cleanliness is lasting"
- "It refreshes the area".

- **Purchase intention**

Volunteers were asked whether they would purchase the product instead of their habitual one for a price they consider fair. 68% answered that they would surely buy it, 27% probably yes and 5% didn't know (Figure 22).

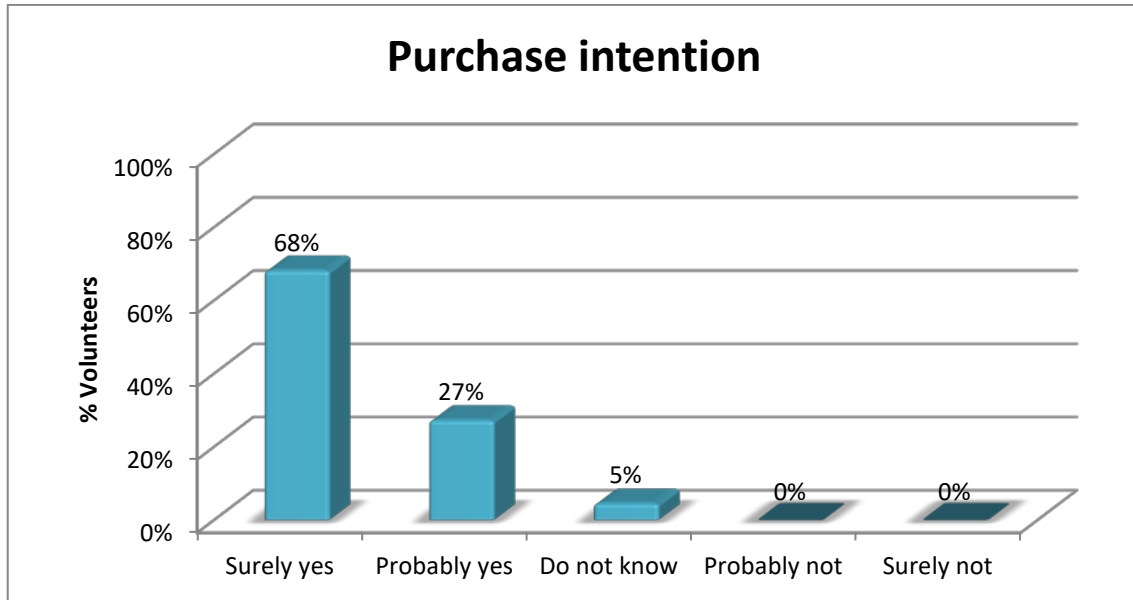


Figure 22. Subjective evaluation on purchase intention instead of the habitual product (n=22).

10. CONCLUSION

This study had as objective to evaluate the acceptability, subjective efficacy and tolerance for the product **ESPONJA JABONOSA**, on 20 volunteers. The study was done in 22 volunteers.

According to the clinical examination carried out by the dermatologist and the gynaecologist, none of the volunteers presented any alterations related with product use. As for the subjective evaluation of the product tolerance, none of the volunteers indicated undesirable symptoms during product use.

Regarding subjective evaluation about organoleptic characteristics and general opinion, most of the volunteers were satisfied with the product. 100% of the volunteers were satisfied with color, texture and ease of application and use. 95% of volunteers were satisfied with the product in general, the product appearance, and resistance and suitability of packaging. 91% of volunteers were satisfied with product smell and attractiveness of packaging.

As for the subjective efficacy of the product, most of the volunteers had a positive opinion. 100% of the volunteers indicated that the product left a cleaning sensation, maintained a good intimate hygiene, was ideal for sensitive skin and suitable for daily use. 95% of the volunteers believed that the product was easy and comfortable to use. 91% of the volunteers indicated that the product had a soft and pleasant texture.

100% of the volunteers is satisfied in a greater or lesser degree with the qualification of the result of the product.

The product met expectations of a good soap sponge for 100% the volunteers and 95% would be willing to buy it instead of their habitual one for a price they consider fair.

The product can claim:

“Tested under dermatologic control”

“Tested under gynaecologic control”

11. DOCUMENT CONSERVATION AND SAMPLES

The following documents will be stored in the Zurko Research archive:

- Signed informed consents.
- Final Report.
- Documents provided by the sponsor.

The documents will be stored during 5 years. After 5 years the sponsor will be asked about the possibility of extension because of the commercialization of the tested element.

The sample of the tested product will be stored in the Zurko Research archive for samples, during 1 year.

12. BIBLIOGRAPHIC 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 García 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).

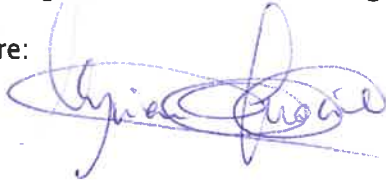
- The results here presented reflect accurately and completely the raw data of the study.

Signature:



Gynaecologist/a: Miriam Gracia Segovia. Medical license number: 285115922

Signature:



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

Signature:



Director of the study: María Barbero Calderón, Pharmacist. I, the undersigned, María Barbero Calderón, 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:



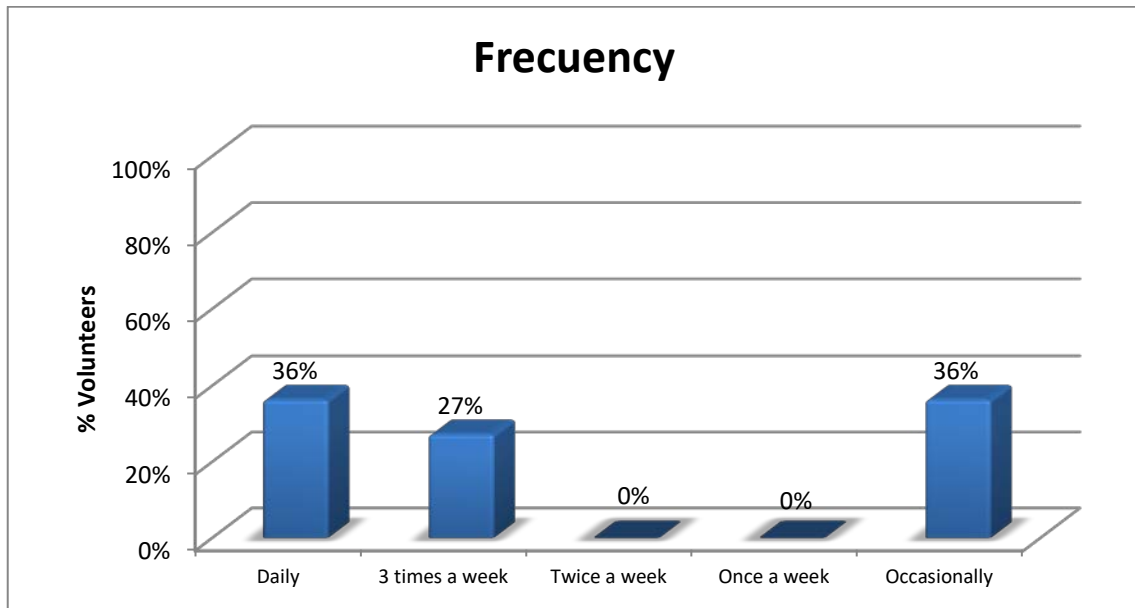
ANNEXES

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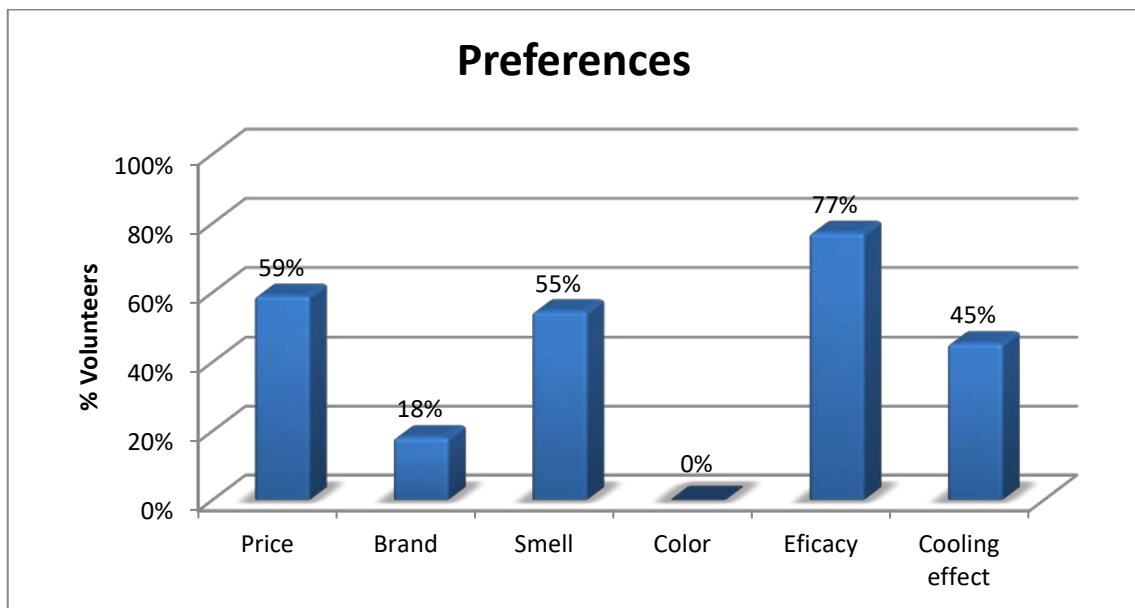
Annex I. Information about volunteers

Volunteers		Age (Years)	Gender (F=female, M=male)	Type of skin (S= sensitive, R= resistant)	Habitual use	Habitual product
Ref.	Acronym					
1	V1	38	F	S	No	-
2	V2	31	F	S	Yes	Chilly
3	V3	34	F	S	No	-
4	V4	55	F	S	Yes	Deliplus
5	V5	48	F	R	No	-
6	V6	54	F	S	Yes	Chilly
7	V7	49	F	S	Yes	Chilly
8	V8	24	F	R	No	-
9	V9	35	F	R	Occasionally	Chilly
10	V10	56	F	S	Yes	Deliplus
11	V11	54	F	R	No	-
12	V12	59	F	R	No	-
13	V13	67	F	S	No	-
14	V15	50	F	S	No	-
15	V16	59	F	S	No	-
16	V17	64	F	S	Occasionally	Deliplus
17	V18	67	F	S	No	-
18	V19	48	F	S	Yes	Deliplus
19	V20	42	F	S	Yes	Chilly
20	V21	45	F	S	No	-
21	V22	33	F	S	Occasionally	Deliplus
22	V23	27	F	S	Occasionally	Deliplus

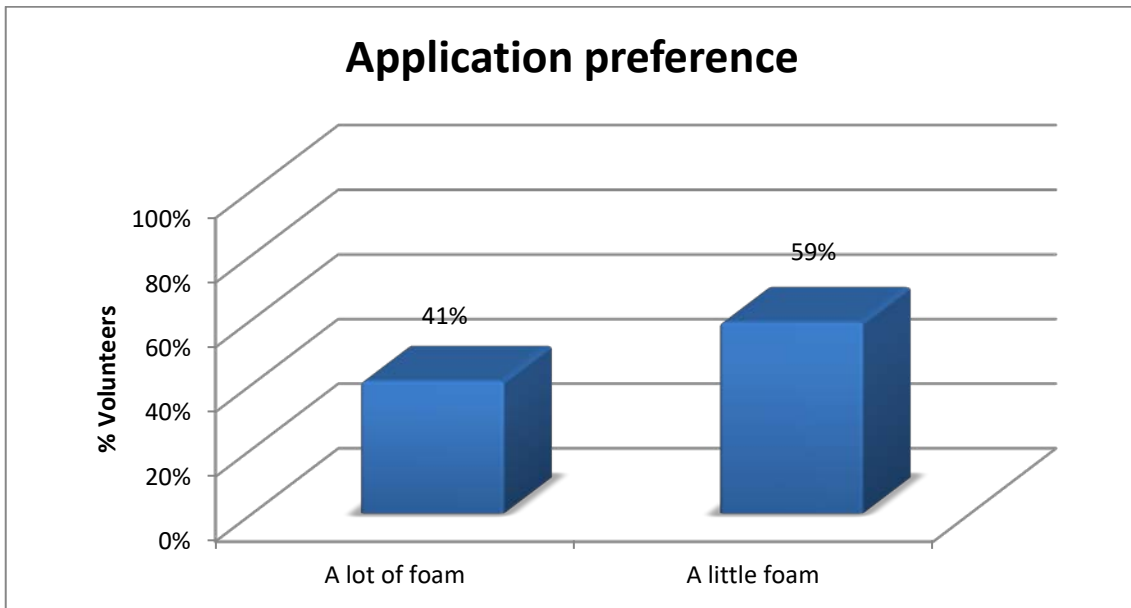
Frequency of use of habitual product (n=11)



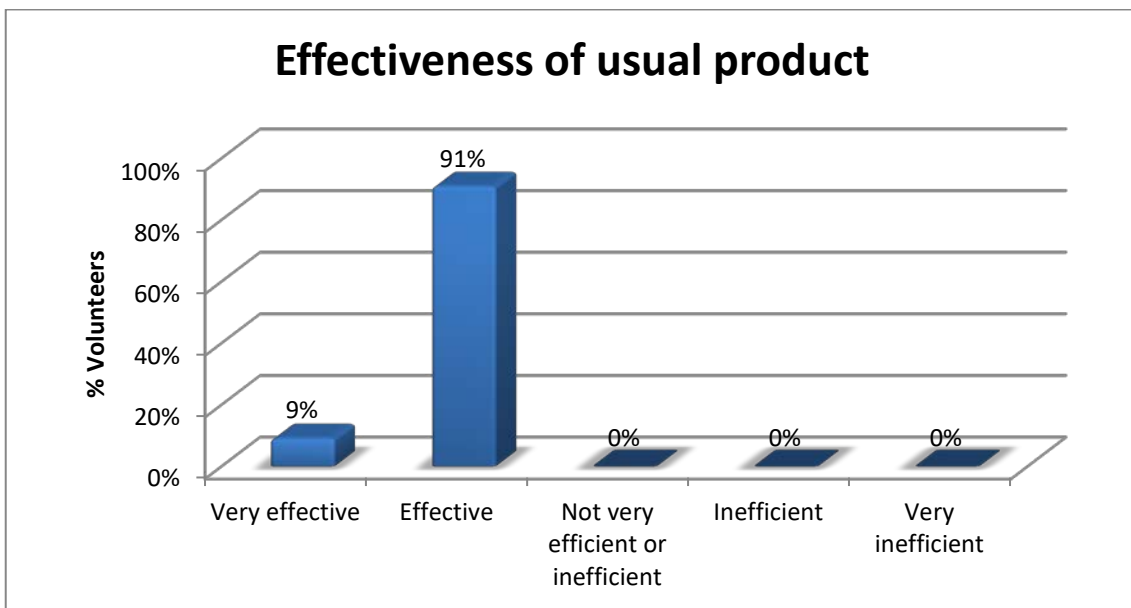
Consumption preferences in this kind of products (n=22)



Application preference (n=22)



Effectiveness of usual product (n=11)



Price of usual product (n=11)

