



**MEDCIN INSTITUTO DA PELE**

pesquisa clínica

e conceitos em

dermatologia

**Clinical and Instrumental Study for the Dermatological  
Evaluation of Safety and Efficacy:**

**Breast Firming Effect**

**...: FINAL REPORT :...**

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**Product: Bust Serum**

**Sponsor: DANIELLE ROCHES – TALIKA.**

**Institution: Medcin Instituto da Pele S/C Ltda.**

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*July 2009*

**Clinical and Instrumental Study for the Dermatological Evaluation of Safety and Efficacy: Breast Firming Effect.**

**Addor, F.A.S.; Silva, V.M.**  
Medcin Instituto da Pele – Clinical Investigation Section.

Predictive clinical trials for proving the in-use and instrumental safety and efficacy of the breast firming effect for **Bust Serum** product sponsored by **DANIELLE ROCHES – TALIKA**.

**Sponsor:** DANIELLE ROCHES – TALIKA.

**Product:** Bust Serum.

**Studied formula:** The quantitative formula supplied by the manufacturer that is attached to this report, stamped and signed by Medcin.

**Name of the technician in charge:** Alexis de Brosses.

**Sample receipt date:** 04/27/09.

**Trial period:** 05/12/09 to 07/02/09.

**Trial code:** 5629-09.



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## REQUESTING RESEARCHER

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### SPONSOR:

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## STUDY SYNOPSIS

Clinical and instrumental study for the dermatological evaluation of in-use safety and efficacy of breast firming effect, **Bust Serum** product, company **DANIELLE ROCHES - TALIKA**.

## OBJECTIVE

- To prove the safety of using of this formulation under normal conditions.
- To evaluate the instrumental, clinical and subjective efficacy of the abovementioned formulation as to the breast firming effect.

## TRIAL DURATION

Final report: duration 42 days.

## ETHICAL CONSIDERANTIONS

This study was conducted according to Good Clinical Practices (GCP) standards, the international standards for researches involving human subjects (Declaration of Helsinki) the National Health Council resolution no. 196, dated October 10, 1996, as amended.

## SUBJECT SCREENING

### I. STUDY POPULATION

Thirty seven female subjects were invited and subsequently selected to participate in the evaluations when the following inclusion and exclusion criteria were met:

#### Inclusion

- 18 to 40 year-old female subjects;
- BMI within 20-25;
- Complaint of flaccid breast;
- Skin without lesions at the site to be tested;
- Agree to comply with trial procedures and go to the clinic on the days and times on which the clinical and instrumental evaluations are scheduled;
- Signed informed consent form.

#### Exclusion

- Pregnancy / lactation;
- Use of anti-inflammatory / immunosuppressive drugs;
- History of atopy / allergies;
- Pathologies leading to immunosuppression, such as diabetes, HIV, etc.;
- Endocrine pathologies, such as thyroid diseases, diabetes, ovarian or adrenal gland disorders;
- History of reactions to cosmetic products;
- Intense sun exposure within 15 days before the evaluation;
- Active skin lesions at the site to be evaluated;
- Esthetical treatments within 3 weeks before screening;
- Dermatological treatments within 3 weeks before screening;
- Regular use of skin firming products.

## MATERIAL

### I. TEST SAMPLE

The company **DANIELLE ROCHES – TALIKA** has supplied the sponsor with the evaluated samples in identified containers.

The remaining samples were disposed of to landfills or incinerated at a certificated site according to a prior arrangement with the sponsor; the retention samples remained stored up to the expiration threshold or for 1 year.

The containers with the evaluated samples delivered by the sponsor received a label with the following content:

*TRIAL NUMBER: 5629-09*  
*STUDY TYPE: Breast firming efficacy*  
*MEDCIN INSTITUTO DA PELE*  
*PHONE: (011) 3654.3849*

## METHODOLOGY

All subjects invited to take part in the study were clinically evaluated according to the inclusion and exclusion criteria after they have read and signed the Informed Consent Form.

### 1. METHODOLOGY FOR EVALUATION

The screened subjects were primarily evaluated by the dermatology specialist to check whether the inclusion and exclusion criteria have been met and for the overall dermatological evaluation of breast firmness. A Case Report Form was created for each female subject and it was supplied and filled out by the researcher. Data were recorded in such case report form.

Then the clinical research assistant handled out questionnaires in order to evaluate how the volunteer feel about her breasts, according to the score in 1 to 10 (10 = flawless) and also questioned if it would be in her interest undergoing a treatment for the volume, which lifts and make the breasts firmer. After such questions were made, the breasts were anthropometrically measured:

- from nipple to the homolateral anterior axillary line (now on simply referred to as anterior axillary line);
- from nipple to clavicle;
- from nipple to inframammary fold.

Standardized pictures were taken in three different positions, at 0°, 45° from right and left sides. Such pictures were filed for future comparisons. After the pictures were taken, the subjects were referred to the instrumental evaluation in order to check breast skin firmness/elasticity through Cutometry (Cutometer MPA 580 (Courage&Khazaka). Such procedures were performed in the beginning of the study, in the interim evaluation and in the study end. After the instrumental measures were performed, the samples were distributed along a copy of the Informed Consent Form with the information relevant to the mode of use that was previously defined by the sponsor.

In case of underlying disease, the subjects were instructed to come to Medcin in order they were evaluated by the dermatologist.

A  $\pm$  2 day window was allowed for subject return during the interim and final evaluations.

New dermatological evaluations, both subjective and instrumental, were performed during the interim analysis (T 28) and in the study end by T42. The data were dully input in the case report forms.

### I. TYPES OF EVALUATION

#### 1. Safety evaluation:

The evaluation was performed by the investigator physician in the beginning (T0), the intermediate evaluation (T28) and in the end of the study (T42) or in case of underlying disease.

#### 2. Clinical and subjective efficacy evaluations:

**Clinical:** The evaluation followed a 5-point scale for the following items: moisturizing, volume, firmness and skin overall aspect, and a 4-point scale for breast lifting effect, being the extreme points defined for each item in order to guide the standardized analysis conducted in the beginning (T0), the intermediate evaluation (T28) and in the end of the study (T42), where increasing ratings represent an improvement in the item being evaluated.

**Subjective:** Table 1 below shows the evaluated items and the study time points:

**Table 1: Items evaluated at each study time point.**

	Questionnaire about interest on treatment for volume, lifting and making breasts firm	Grade from 1 to 10 for breasts	Moisturizing	Firmness	Breast overall aspect	Lifting effect	Volume	Final perception
T0	Yes	Yes	No	No	No	No	No	No
T28	No	Yes	Yes	Yes	Yes	Yes	Yes	No
T42	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes

The items in table 1 underwent a standardized evaluation according to the 1-4 scale in the beginning (T0) and intermediate evaluation (T28) and in the end of the study (T42). A questionnaire about product perception was also answered, comprising skin texture after product application, and to know whether the package is easy to use, whether the subject liked it, whether the product improves breast volume, whether the subject is satisfied with the cares provided by the product and whether she would buy the product whatever the price would be. Such evaluations were monitored by the clinical research assistant.

### 3. Instrumental Efficacy Evaluations:

#### 3.1 PERMANENT EQUIPMENT

Cutometer MPA 580 (Courage&Khazaka).

#### 3.2 SUPPLIES

Samples of study product.

#### 3.3 METHODOLOGICAL PROCEDURES

##### 3.3.1 – ENVIRONMENTAL CONDITIONS

The following environmental conditions were applied to subjects for at least 20 (twenty) minutes before the evaluations could start and during the study course:

- Temperature:  $T = 20 \pm 2^{\circ}\text{C}$
- Relative Humidity:  $\text{RU} = 40 \pm 5\%$

##### 3.3.2 – AREA OF APPLICATION

For each subject there was delimited area that was treated and a control area; the selected treated area was the breast external face, at the nipple level and the selected control area was the forearm internal face. The treated area was applied the test product according to the mode of use provided by the sponsor, the control area received no type of treatment.

##### 3.3.3 – MEASUREMENTS

The instrumental measurements were taken in triplicate before product application (T0), after 28 (T28) and 42 days (T42) of product continuous use. For the calculation, we used an average of these 3 measurements.

##### 3.3.4 – CRITERIA FOR EVALUATION

The values of R0 and R7 parameters are expressed in arbitrary values (equipment-specific) from 0,000 to 1,000 (cut metric units).

In case the parameter R0 increases or reduces ( $>$  or  $<$  10%) with the use of the product, this means skin firmness has increased or reduced, respectively; because the skin gives pose higher resistance to equipment suction.

If the parameter R7 increases or reduces ( $>$  or  $<$  10%) with product use, this means the elasticity has increased or reduced, respectively. This happens because a more elastic skin returns to the original point in a more effective way (both qualitatively and quantitatively).

For this study, parameters R0 and R7 are used, they are the ones that best represent the skin firmness and elasticity data, respectively.

## RESULTS

### I – SAFETY CLINICAL EVALUATION

Thirty seven subjects were invited and enrolled for the conduction of this study, among them, 03 withdrew just after the initial evaluation for personal reasons not related to the study, and 04 did not return for the intermediate and final evaluation for the same reasons as stated above.

From these 30 subjects returning for the final evaluation after 42 days on product use, none of them reported skin adverse reaction under dermatological monitoring.

**Table 2:** Results obtained on T42 on 37 (thirty seven) subjects.

Subject number	T42	Subject number	T42
01	0	20	0
02	0	21	0
03	0	22	0
04	Withdrew	23	0
05	Withdrew	24	0
06	0	25	0
07	0	26	0
08	0	27	0
09	0	28	0
10	0	29	0
11	0	30	Did not return
12	0	31	Withdrew
13	Did not return	32	0
14	0	33	Did not return
15	0	34	0
16	0	35	Did not return
17	0	36	0
18	0	37	0
19	0		

**KEY:**

0 = NO REACTION

R1 = REACTION NOT RELATED TO THE PRODUCT

R2 = REACTION PROBABLY NOT RELATED TO THE PRODUCT

R3 = REACTION PROBABLY RELATED TO THE PRODUCT

R4 = REACTION DEFINITELY RELATED TO THE PRODUCT

I1\* = MILD IN INTENSTITY

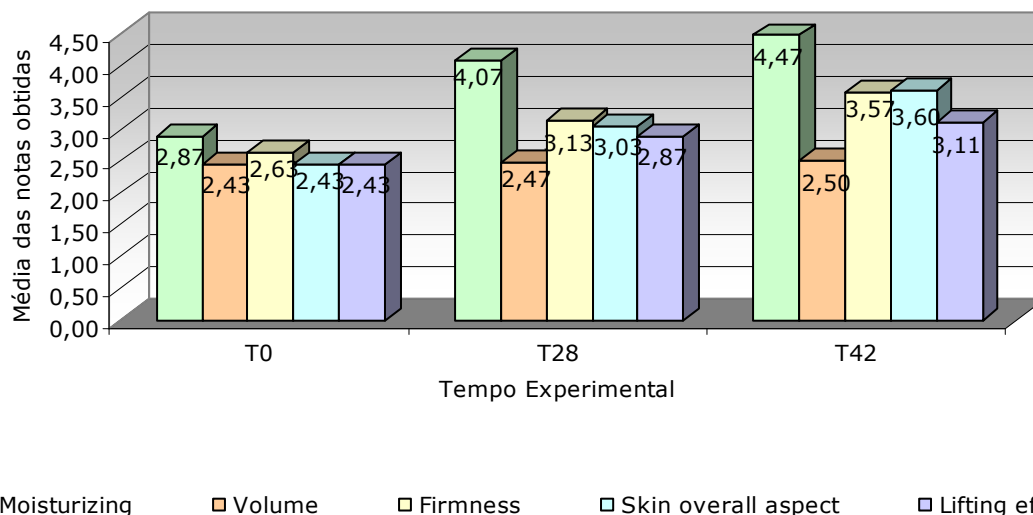
I2\* = MODERATE IN INTENSITY

I3\* = SEVERE IN INTENSITY

\*according to standard scale – please see Attachment A

## II – EFFICACY CLINICAL EVALUATION

The chart 1 shows the means obtained initially (T0), in the intermediate evaluation (T28) and in the end of the study (T42), according to the clinical evaluation criteria:



**Chart 1** Obtained averages through the clinical evaluation in study time points.

The obtained results were statically evaluated through Student's T-test and the results are presented in table 3 below:

**Table 3:** Statistical analysis of the clinical evaluation.

Evaluation items	Student's T-test			* Conclusion
	T0 - T28	T0 - T42	T28 - T42	
Moisturizing	< 0.0001	< 0.0001	0,0001	Significant **
Volume	0.3256	0,1608	0,3256	Not Significant **
Firmness	< 0.0001	< 0.0001	0,0007	Significant **
Skin overall aspect	< 0.0001	< 0.0001	< 0.0001	Significant **
Lifting effect	0.0015	< 0.0001	0,0311	Significant **

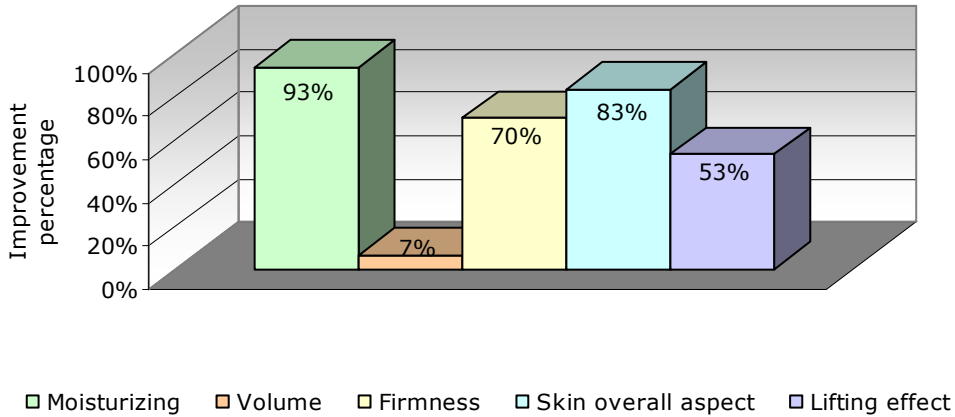
\* Significance level: 5%

\*\* Hypothesis: There is no difference between study time points.

n = 30

As can be noted, according to the dermatological evaluation, there was a statistically significant improvement for moisturizing, firmness, skin overall aspect and the lifting effect after the product was used for 42 days.

The chart 2 below shows the percentage of subjects with some clinical improvement (mild, moderate or intense) in the end of the study (T42).

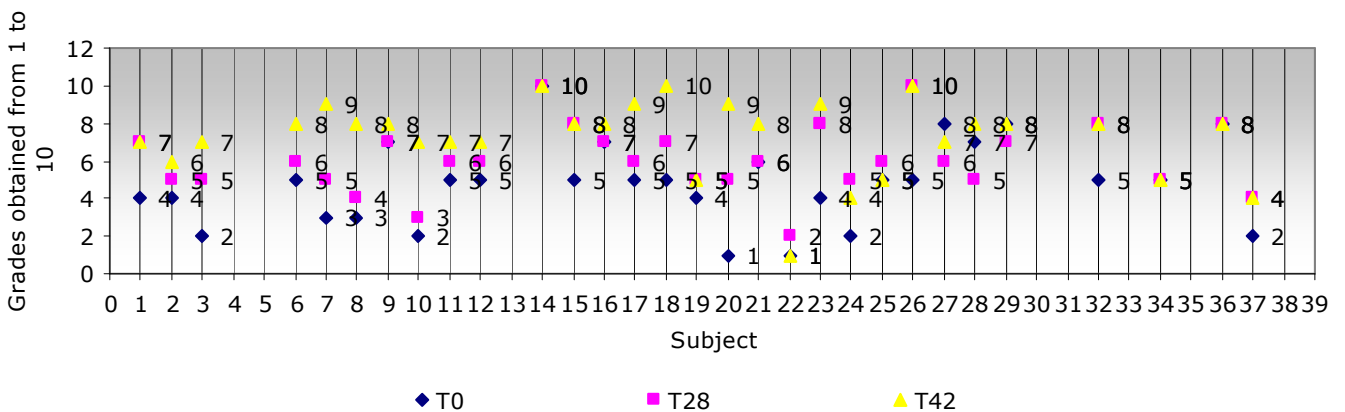


**Chart 2:** Percentage of subjects experiencing improvement in each item according to clinical evaluation.

### III – SUBJETIVE EVALUATION

By the initial evaluation, 100% of enrolled subjects stated having interest for a treatment for volume, which augments the breast and makes them firmer.

The chart 3 below shows the grades from 1 to 10, being 10 for flawless breasts, obtained by the initial (T0), in the intermediate evaluations (T28) and in the end of the study (T42). The subjects with numbers 4, 5 and 31 withdrew at the beginning of the study and the subjects 13, 30, 33 and 35 did not return for the intermediate and final evaluation:

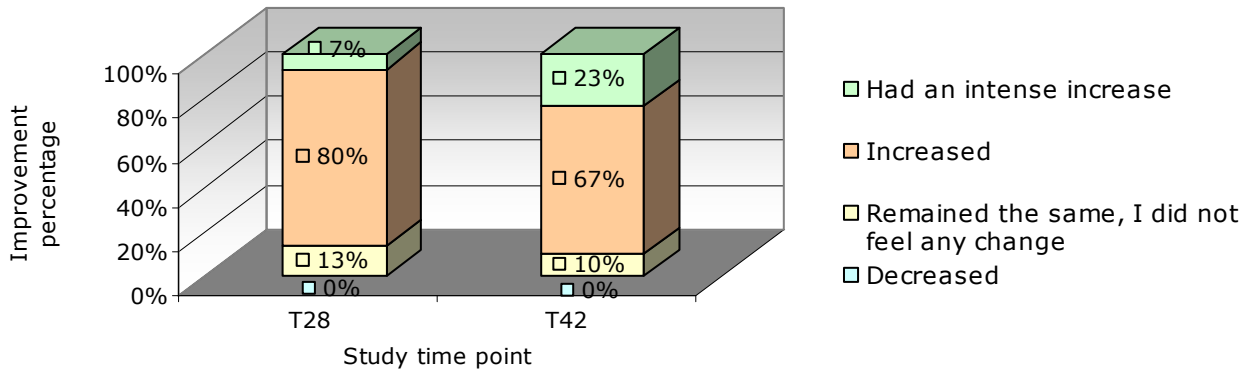


**Chart 3:** Grades obtained through self evaluation in each subject in T0, T28 and T42. The percentage of subjects attaining any improvement degree was 70% (p value – 0.0002, P<0,05) in both time points .

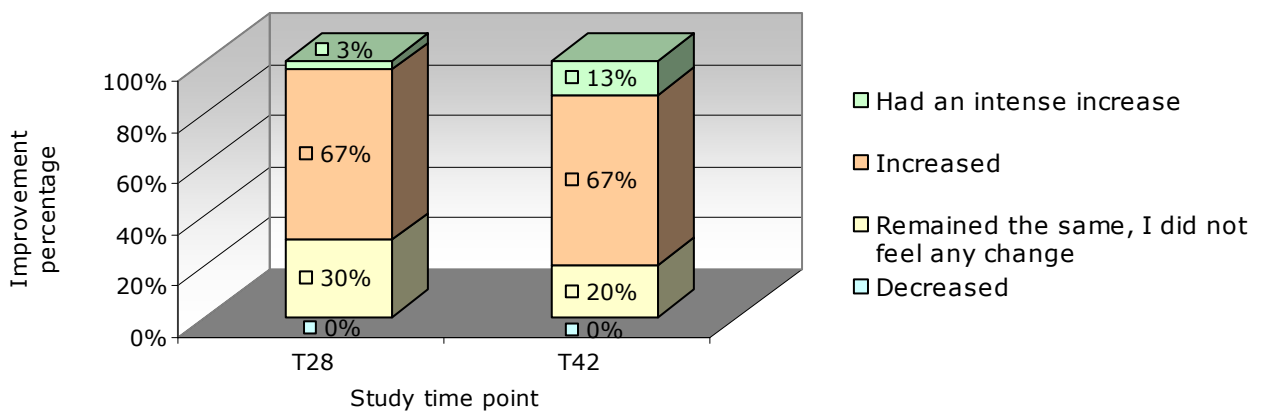
**Note:** The volunteers 14, 34 and 36 maintained the same values in T0, T28 and in T42.

The following charts compare the percentage obtained in the intermediate evaluation (T28) and in the final evaluation, according to the subjective evaluation criteria:

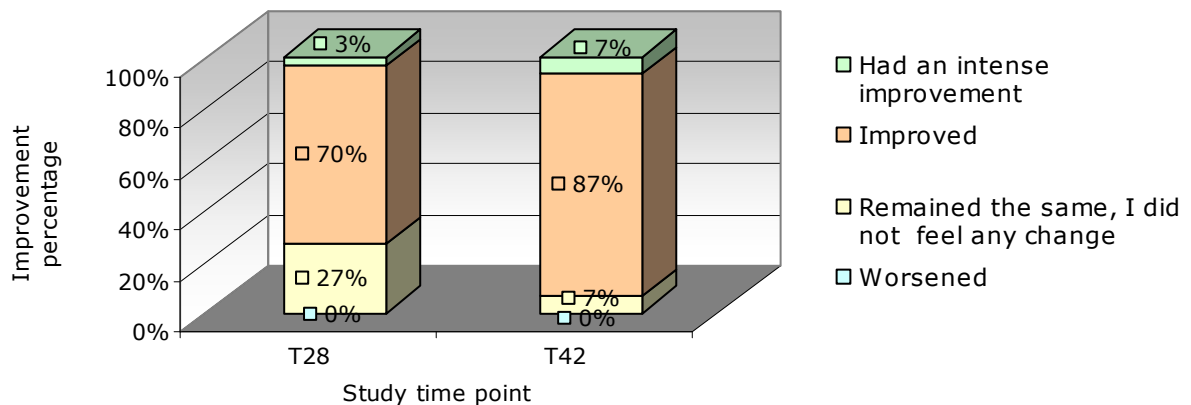
**Chart 4: MOISTURIZING** – Upon product use the moisturizing of my breast skin:



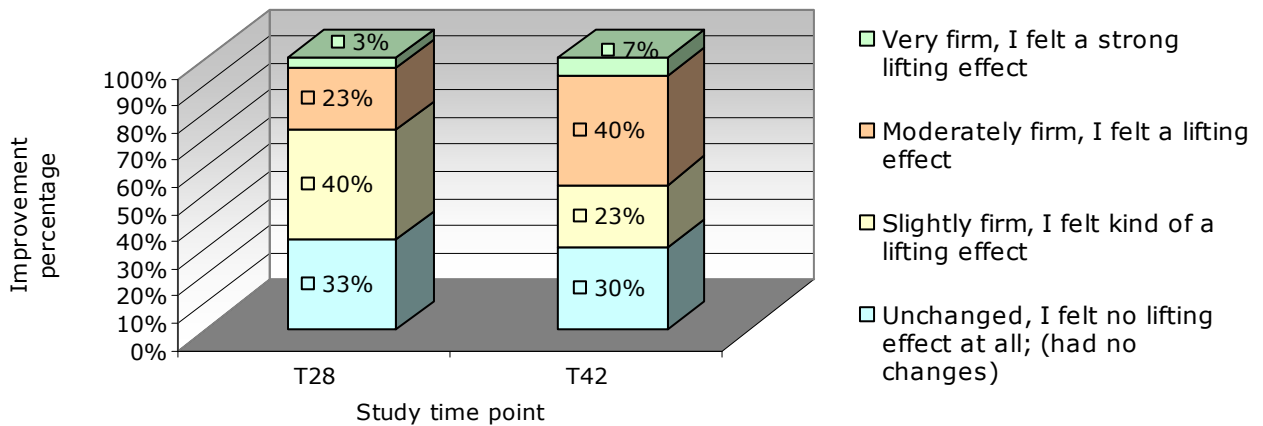
**Chart 5: FIRMNESS** – Upon product use I felt the firmness of um breast skin to (more resistant, less flaccid skin):



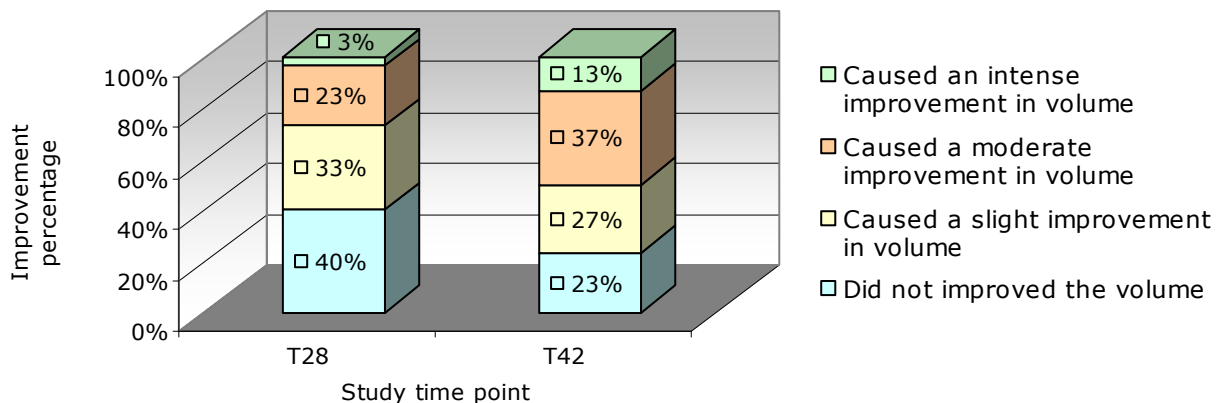
**Chart 6: BREAST GENERAL APPEARANCE** – Considering my breast general appearance after I used the product, I noticed that:



**Chart 7: TENSILE EFFECT AFTER PRODUCT APPLICATION / LIFTING EFFECT** – Immediately after I applied the product I noticed my breasts got:



**Chart 8: VOLUME** – As to the volume of my breast just after the product was used, I noticed the product:



The obtained results were statically evaluated through Student's T-test and the results are presented in table 4 below:

<b>Table 4:</b> Statistical analysis of the subjective evaluation.		
<b>Evaluation items</b>	<b>Student's T-test</b>	<b>* Conclusion</b>
	<b>T28 – T42</b>	
Moisturizing	0,0314	Significant **
Volume	0,0087	Significant **
Firmness	0,0563	Not significant **
Skin overall aspect	0,0169	Significant **
Lifting effect	0,1328	Not significant **

\* Significance level: 5%

\*\* Hypothesis: There is no difference between study time points.

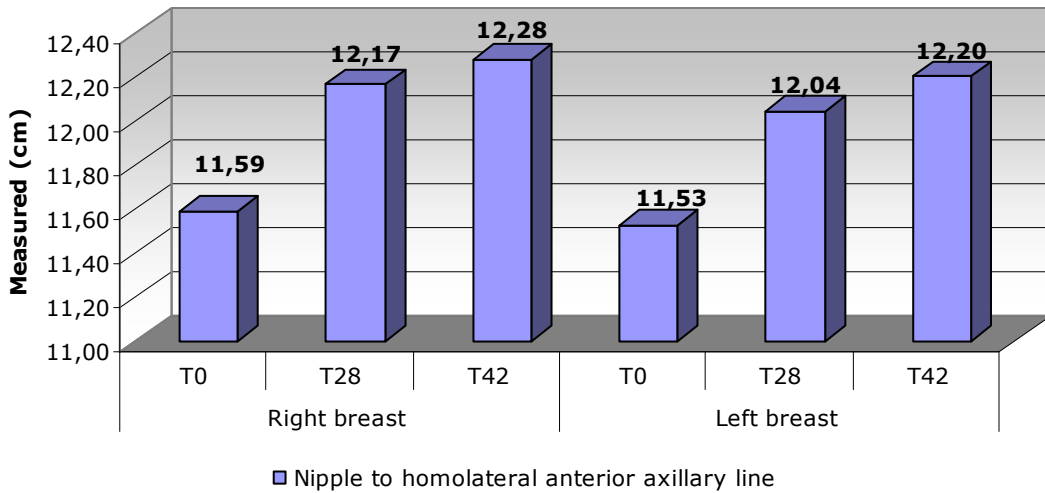
n = 30

As can be noted, according to the subjective evaluation, there was a statistically significant improvement for moisturizing, volume and skin overall aspect after the product was used for 42 days.

#### IV - ANTHROPOMETRIC MEASUREMENTS

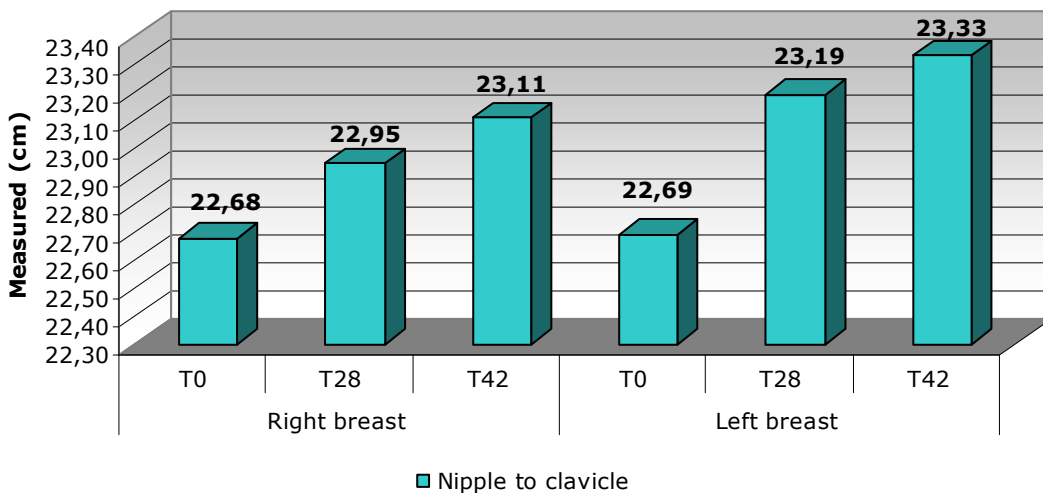
Breast anthropometric measurements were performed at the study beginning (T0), in the intermediate evaluation (T28) and in the end of the study (T42).

The chart 9 below shows the averages obtained in the initial (T0), in the intermediate evaluations (T28) and in the end of the study of the anthropometric measurements from "nipple to homolateral anterior axillary line" of subject breasts:



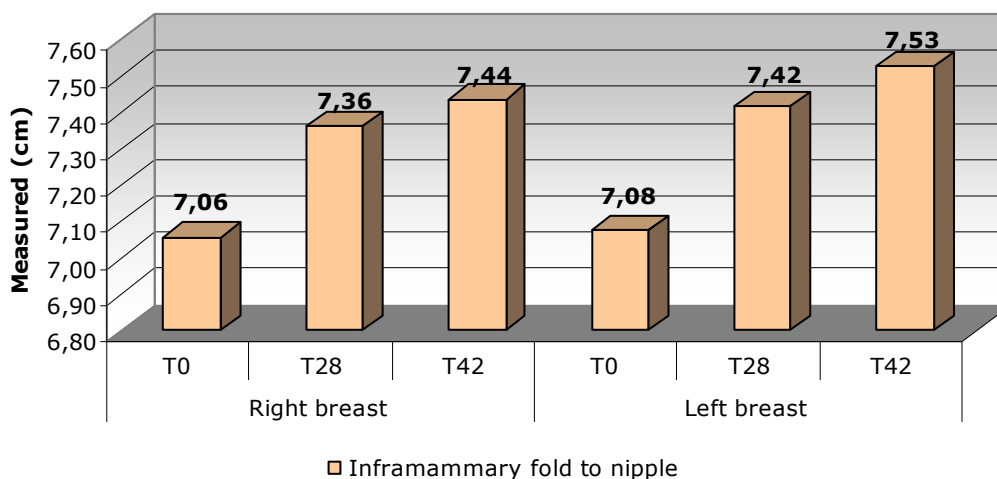
**Chart 9** Averages obtained through anthropometric measurements from "nipple to the homolateral anterior axillary line" of subjects left and right breasts.

The chart 10 below shows the averages obtained in the initial (T0), in the intermediate evaluations (T28) and in the end of the study of the anthropometric measurements from "clavicle to nipple" of subject breasts:



**Chart 10:** Averages obtained through anthropometric measurements from "clavicle to nipple" of subjects right and left breasts.

The chart 11 below shows the averages obtained in the initial (T0), in the intermediate evaluations (T28) and in the end of the study) of the anthropometric measurements from "inframammary fold to nipple" of subject breasts:



**Chart 11:** Averages obtained through anthropometric measurements from "inframammary fold to nipple" of subjects right and left breasts.

The obtained results were statically assessed through Student's T-test and the results are presented in tables 5 and 6 below:

**Table 5:** Statistical results obtained through Student's T-test on time point T28.

Evaluation items	Breast	Student's T-test	* Conclusion
Nipple to homolateral axillary line	Right	0,0006	Significant **
	Left	0,0004	Significant ****
Clavicle to nipple	Right	0,0548	Not significant **
	Left	0,0168	Significant **
Nipple to inframammary fold	Right	0,0002	Significant **
	Left	<0,0001	Significant **

\* Significance level: 5%

\*\* Hypothesis: There is no difference between study time points.

n = 30

As we can see through table 5, according to the performed anthropometric measurements, there were statistically significant measurements for the distance from "clavicle to nipple" in the left breast, from "nipple to the homolateral anterior axillary line" and from "nipple to inframammary fold" in both breasts

**Table 6:** Statistical results obtained through Student's T-test on time point T42.

Evaluation items	Breast	Student's T-test	* Conclusion
Nipple to homolateral axillary line	Right	0,0001	Significant **
	Left	0,0005	Significant **
Clavicle to nipple	Right	0,0115	Significant **
	Left	0,0040	Significant **
Nipple to inframammary fold	Right	0,0001	Significant **
	Left	0,0002	Significant **

\* Significance level: 5%

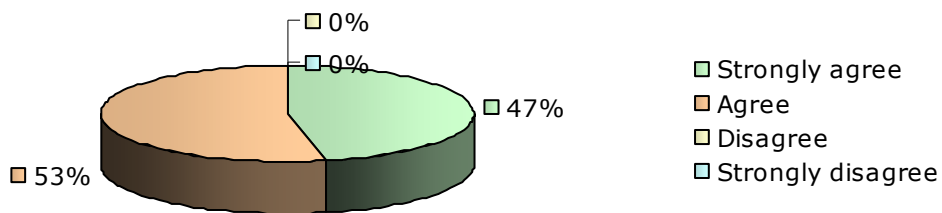
\*\* Hypothesis: There is no difference between study time points.

n = 30

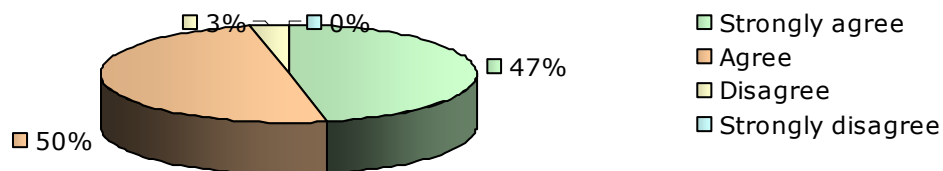
According to table 6, all evaluated parameters were statistically significant after 42 days of use of the product.

## V - FINAL PERCEPTION

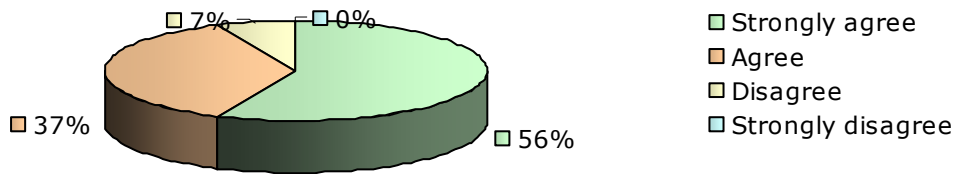
### The texture was pleasant?



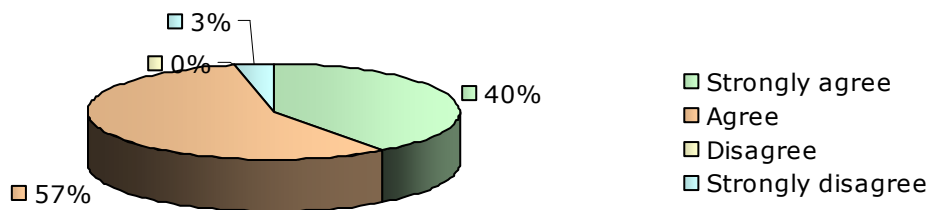
### The product application was easy?



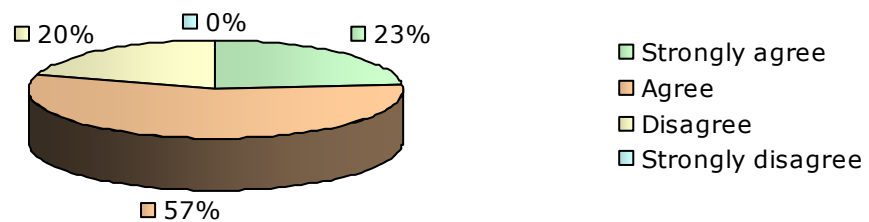
**The product was easy to use?**



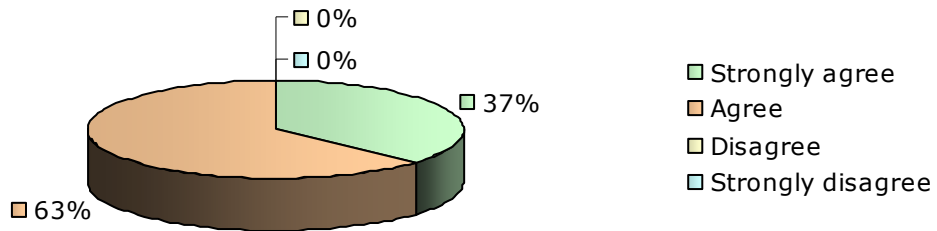
**The packaging is pleasant?**



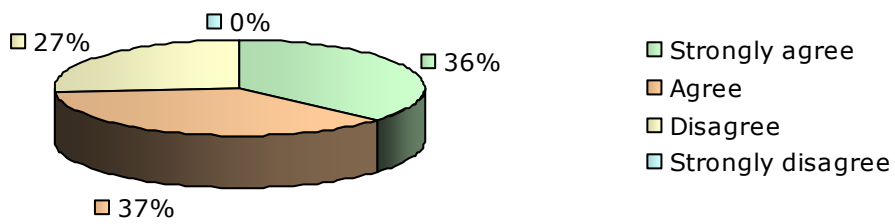
**Cosmetics results after using:**



**Are you satisfied of this care product?**



**Would you buy this product (whatever is price)?**

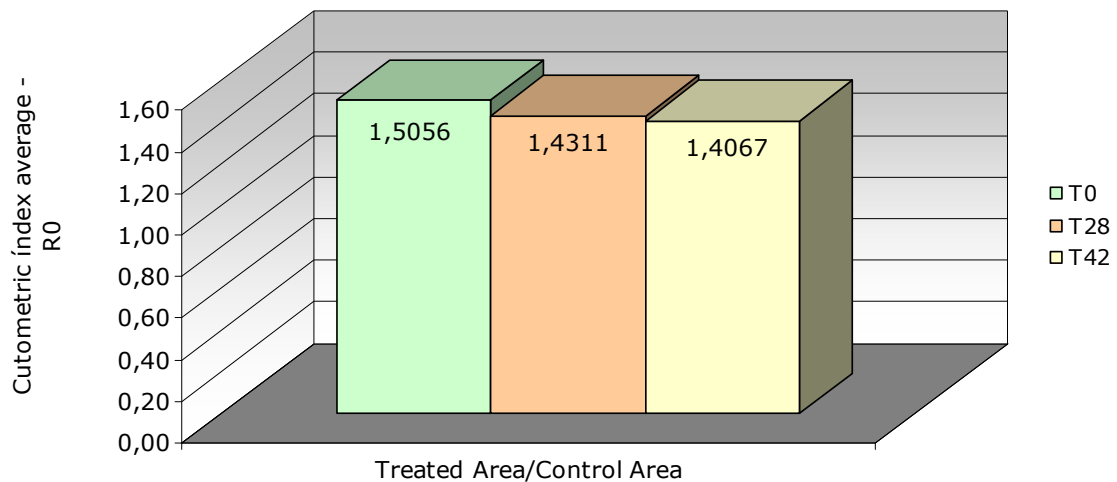


## VI - INSTRUMENTAL EVALUATIONS (CUTOMETRY)

### I. SKIN FIRMNESS – R0 PARAMETER

For R0, the smaller the value, the higher the skin firmness (according to item 3.3.4 – Criteria for Evaluation).

Please find below the 12 bar chart for averages of ratios between values for treated and control areas (Treated Area / Control Area) for the R0 variable:



**Chart 12:** Comparison between averages of ratios between the values for treated area and control area for the R0 variable.

Please find below the table 7 with the comparison test and the percentage of change from T0 to T28 and T0 to T42 for the averages of ratios between values of treated area and control area:

**Table 7:** Comparison test and the percentage of change from T0 to T28 and T42 time points for the averages of ratios between values for treated area and control area.

Area	Variation	Student's T-test	Conclusion*
Treated Area / Control Area (1 <sup>st</sup> evaluation - T28)	-4,95%	0,6265	Not significant **
Treated Area / Control Area (2 <sup>nd</sup> evaluation - T42)	-6,57%	0,3800	Not significant **

\* Significance level: 5%

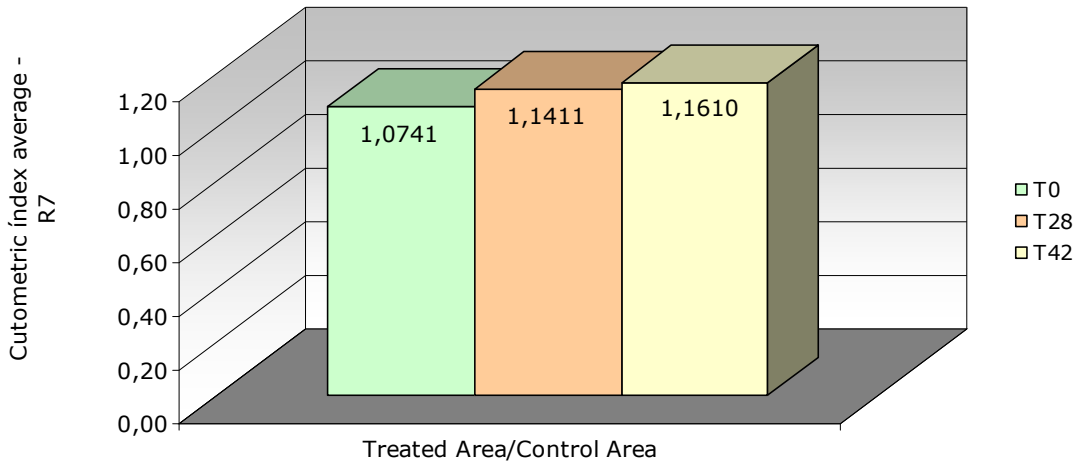
\*\* Hypothesis: There is no difference between study time points.

n = 30

## II. SKIN ELASTICITY – R7 PARAMETER

For the parameter R7 the higher the values, the higher the skin elasticity (according to item 3.3.4 – Criteria for Evaluation).

Please find below the 13 bar chart for averages of ratios between values for treated and control areas (Treated Area / Control Area) for the R7 variable:



**Chart 13:** Comparison between averages of ratios between the values for treated area and control area for the R7 variable.

Please find below the table 8 with the comparison test and the percentage of change from T0 to T28 and T0 to T42 for the averages of ratios between values of treated area and control area:

**Table 8:** Comparison test and the percentage of change from T0 to T28 and T42 time points for the averages of ratios between values for treated area and control area.

Area	Variation	Student's T-test	Conclusion*
Treated Area / Control Area (1 <sup>st</sup> evaluation - T28)	6,24%	0,2192	Not significant **
Treated Area / Control Area (2 <sup>nd</sup> evaluation - T42)	8,09%	0,1885	Not significant **

\* Significance level: 5%

\*\* Hypothesis: There is no difference between study time points.

n = 30

## DISCUSSION

### Safety evaluation

The evaluated product has shown to be safe for human use at the manufacturer-recommended area, and caused neither irritation nor sensitivity reactions in the population of subjects evaluated.

### Clinical Evaluation

Through clinical evaluation can be observed a statistically significant improvement for the items moisturizing, firmness, skin global aspect and lifting effect, as compared to the initial time point T0. The rate of subjects with some degree of clinically observed improvement after the product was used for 42 days was 93% for moisturizing, 70% for firmness, 83% for skin global aspect and 53% for lifting effect.

### Subjective evaluation

Subjective evaluation: a progressive improvement was also seen in all evaluated items:

<b>Percentage of subjects with improvement in both T28 e T42 in the items evaluated.</b>		
	<b>T28</b>	<b>T42</b>
<b>Moisturizing</b>		
Increase	80%	67%
intense increase	7%	23%
<b>Firmness</b>		
Increased	67%	67%
intense increase	3%	13%
<b>Skin overall aspect</b>		
Improved	70%	87%
intense improvement	3%	7%
<b>Lifting</b>		
Slightly firm, I felt kind of a lifting effect	40%	23%
Moderately firm, I felt a lifting effect	23%	40%
Very firm, I felt a strong lifting effect	3%	7%
<b>Volume</b>		
Caused a slight improvement in volume	33%	27%
Caused a moderate improvement in volume	23%	37%
Caused an intense improvement in volume	3%	13%

Through the table above it can be observed that the subjective evaluation showed statistically significant improvement, with 23% of the subjects presented intense moisturizing ( $P = 0.0314$ ) and 13% showed strong growth in the volume of breasts ( $P = 0, 0087$ ).

### Anthropometric measurements

There was a statistically significant improvement in all parameters evaluated after 42 days of use the product.

### **Final perception**

In the final perception, it can be noticed positive results: 100% of subjects showed that the texture was pleasant and were satisfied with the product care, 97% of subjects showed that the application of the product was easy and considered the packaging of it pleasant and 93% of subjects declared that the product was easy to use. In "intention to purchase the product whatever is price," 73% of subjects expressed intention to buy the product.

### **Instrumental Evaluation**

R0 parameter refers to the property dermal viscosity, which is noticed through its firmness; the higher the dermal density and integrity, the stronger and the more resistant to suction the skin is; therefore, the lower the R0 value, the firmer the skin will be. The product has shown a 6,57% improvement in dermal viscosity in subject breasts, translated into improved firmness after the use.

R7 parameter refers to skin elasticity, that is, whether its ability to immediately retract after device traction (suction) is faster; thus, the higher R7 the higher the elasticity is, it can recover fast from the deformity caused by suction. Such property is linked to elastic fibers. The product has shown a 8,09% improvement in dermal elasticity of subject breasts after continuous use.

Despite of the results were not statistically significant, both parameters has shown a progressive improvement in both evaluations, suggesting that the continuous using could provide a better result.

## CONCLUSION

The product **Bust Serum** sponsored by company **DANIELLE ROCHES – TALIKA**, was assessed from 05.12.2009 to 07.02.2009 under the following clinical study protocol:

- Clinical and Instrumental Study for the Dermatological Evaluation of Safety and Efficacy: Breast Firming Effect.

In the conditions under which the product described above was evaluated and referring to the studied subject population the data enables the following conclusions:

- The product described above has shown to be safe for human use at the manufacturer-recommended area, and caused no definitively established irritation or sensitivity reactions in the population of subjects evaluated;
- According to the recommendations of *Guia para Avaliação de Segurança* (ANVISA, 2003), the product may be considered dermatologically tested;
- The product showed efficacy in the cosmetic treatment to improve moisturizing, firmness, tensile effect and skin overall aspect, observed through the dermatological evaluation;
- The percentage of subject with improvement in volume of the breasts were statistically significant ( $P= 0,0087$ ).
- The anthropometrical measurements with the use of the product promoted a breast growing effect, statistically significant after 42 days of use.

This report is exclusively intended for the internal and regulatory use by company **DANIELLE ROCHES – TALIKA**, and must not be released to whatever communication vehicle without the written authorization from the author.

Osasco, July 17<sup>th</sup>, 2009.



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**ATTACHMENTS**

**ATTACHMENT A: Scale for the assessment of intensity of reaction**

Clinical Sign	Grade	Classification
<b>Erythema</b>	<b>0</b>	None
	<b>1</b>	Mild (Poorly noticeable, borderline and non-edematous)
	<b>2</b>	Moderate (Between mild and intense)
	<b>3</b>	Intense (defined as clear and delimited border edematous erythema)
<b>Scaling</b>	<b>0</b>	None
	<b>1</b>	Mild (fine, bran-like, poorly noticeable scaling)
	<b>2</b>	Moderate (Between mild and intense)
	<b>3</b>	Intense (gross scaling, detachment of large sheets of epidermis)
<b>Vesiculation</b>	<b>0</b>	None
	<b>1</b>	Mild
	<b>2</b>	Moderate (Between mild and intense)
	<b>3</b>	Intense
<b>Edema</b>	<b>0</b>	None
	<b>1</b>	Mild
	<b>2</b>	Moderate (Between mild and intense)
	<b>3</b>	Intense

**ATTACHMENT B:** *Instructions for subjects in the study*

**Mode of use:**

- Apply on a daily basis, by the morning or by the evening, on breast base, then massage with large moves making an 8 up to neck level. Do not cause spots, it is not clammy.

**Cautions:**

- Keep container tightly closed.
- Keep out of the reach of children;
- In case of contact with eyes, rinse and seek Medcin medical team.

**During the test period do not forget to:**

- Inform the doctor about the use of any drug product or cosmetic product;
- Avoid changing hygiene products. Eg.: Moisturizing creams, toilet soaps, deodorants, etc.;
- Avoid sun exposure for tanning purposes;
- Product must only be used during the study period, and only on the specified days.

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