

## EVALUATION OF THE HYDRATION EFFICACY OF A COSMETIC PRODUCT

### AFTER APPLICATION UNDER DEFINED CONDITIONS IN NORMAL SUBJECTS

#### ACUTE HYDRATION - 4H

#### Objective evaluation of the hydration by "capacitance" method

##### *Short Report*

*This report is a summary of the report 770613.S, and reflects all data concerning the study developed with the product.*

## I . OBJECTIVE

The aim of the present study is to assess the **hydration efficacy**, after a single application of the cosmetic product **SABONETE LEITE DE BURRA**, batch n° 130606, in healthy human volunteers.

The experimental design considers the specific application conditions of the product. In this context, it adopts a widely used study model, which involves the application and measurement of skin hydration over time by "corneometry". This approach, allows for the quantitative description of such hydration, as well as a comparison against defined controls.

The hydration efficacy of the product is assessed:

- objectively and quantitatively, by instrumental measurements of the skin hydration taken in the forearm, with a Corneometer® (Cutometer® dual MPA 580), before and after treatment.

This study allows to justify the claim "hydration during 4h".

## II . DATES OF STUDY

**Beginning:** June 24<sup>th</sup>, 2013

**End:** July 2<sup>nd</sup>, 2013

The protocol and test conditions were reviewed by the Internal Review Board (**opinion n° 465/13 from June 21<sup>st</sup>, 2013**) and the standard protocol was submitted to the Ethical Commission of PhD Trials (**opinion n° 001/2012 from January 26<sup>th</sup>, 2012**).

### III . SUBJECTS

Fifteen (15) subjects were included in the study. There were neither withdrawals nor exclusion. The efficacy and compatibility of the test product was, therefore, assessed in fifteen (15) subjects, corresponding to these specific inclusion criteria:

- a) Age: 18 to 65 years,
- b) Gender: male and female,
- c) Phototype (Fitzpatrick) : I to V,
- d) Type of skin: all types of skin.

### IV. METHODOLOGY

#### IV.1. Experimental area and sites of application of the test products

The chosen area of experiment was the forearm.

The area of application and control were randomly selected by the researcher.

The test product was applied by the researcher to one of the sites localized by a clockwise distribution, altering of one rank from a subject to another.

#### IV.2. Experimental conditions of application of the test products

Product name	Product directions of use	Quantity to be applied	Environmental conditions
<b>SABONETE LEITE DE BURRA, batch nº 130606</b>	In the study centre, by a technician, with the help of a finger cot by slight massage till its complete penetration, on an area of 2,5 x 2,5 cm (6,25cm <sup>2</sup> ) in the forearm – side determined according to a randomization	2mg/cm <sup>2</sup>	All measurements involve a prior acclimatisation period and are performed in a controlled environment (21 °C ± 1°C, 45% ± 10%).

The amount of applied product was measured using a disposable syringe.

In order to ensure uniformity of test procedures on all volunteers, application of the test product was carried out by the researcher.

### V . RESULTS

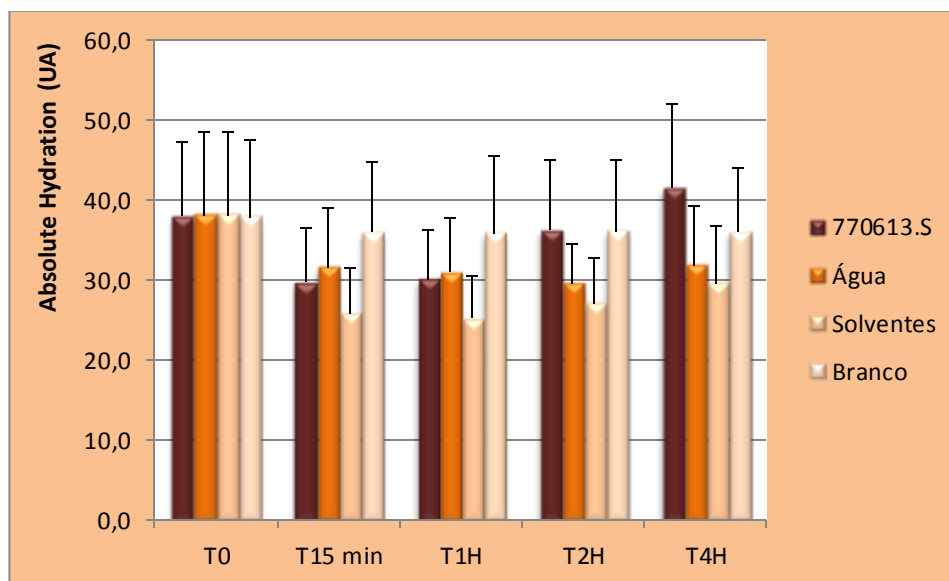
#### V.1. Results from the dermatological evaluation

There is no cutaneous reactions related with the test product in any volunteer.

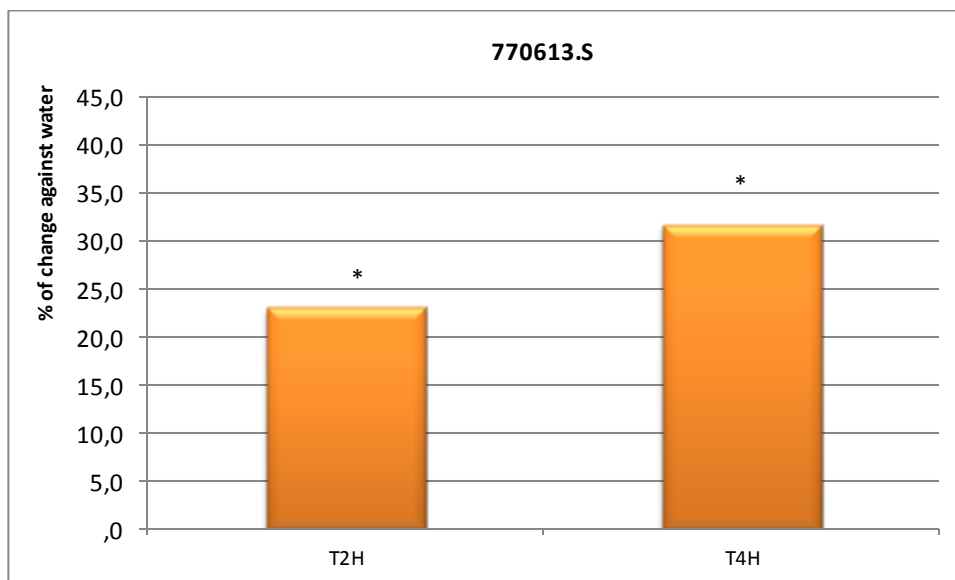
## V.2. Results from the questionnaire asked to the volunteers and observation of the individual observation sheet

There is no sensations of discomfort noted by the volunteers at home.

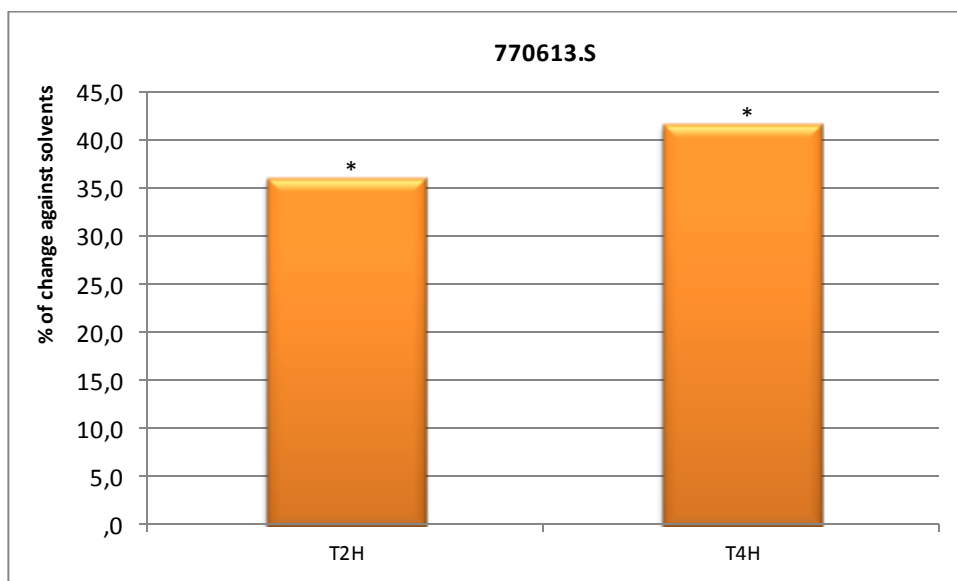
## V.3. Hydration evaluation



**Figure 1** - Skin hydration (AU) evolution during the study. Mean + sd values of all the volunteers (n=15).



**Figure 2** - % Change against the control “water”. Mean values of all the volunteers. Also shown is the statistical comparison against water, obtain with absolute values (\*:  $p < 0,05$ ; N.S.: Non-significant)



**Figure 3** - % Change against the control "solvent". Mean values of all the volunteers. Also shown is the statistical comparison against water, obtain with absolute values (\*:  $p < 0,05$ ; N.S.: Non-significant)

## VI . CONCLUSION

Under the experimental standardized conditions adopted and after all the statistical analysis we concluded that:

The product **SABONETE LEITE DE BURRA, batch nº 130606** presented a statistically increase of 23,1% in the skin hydration after 2H of application when compared with the control "water" and 36,0% with the control "solvent" comparison.

The comparison against the water and solvent control shows a statistically significant at 4H by 31,7% and 41,6%..

These results show that product **SABONETE LEITE DE BURRA, batch nº 130606** reinforces skin hydration after 2H and after 4H of application.

The product **SABONETE LEITE DE BURRA, batch nº 130606** showed no irritative reaction, so the product has a very good skin compatibility.

### Scientific Manager : Pedro CONTREIRAS PINTO

I the undersigned, Pedro CONTREIRAS PINTO, declare that:

- the final report was examined on August 2<sup>nd</sup>, 2013,
- the results reported accurately and completely reflect the raw data of the study.