EVALUATION OF THE EFFICACY OF A COSMETIC PRODUCT

CHECKING ITS ACCEPTABILITY AFTER APPLICATION UNDER NORMAL CONDITIONS OF USE

OBJECTIVE ASSESSMENT OF ITS QUALITIES AND EFFICACY

In use test with clinical control by a dermatologist and with instrumental evaluation

Short Report

This report is a summary of the report 780613.A, and reflects all data concerning the study developed with the product.

I . OBJECTIVE

The aim of the present study was to assess the **biological repair / regeneration efficacy,** as well as to check the **acceptability** and assess the **qualities** and **efficacy** of the product **CREME FACIAL LEITE DE BURRA, BATCH 330127/A 655** after application under the normal conditions of use planned by the Sponsor.

The subjective **qualities and efficacy** of the products were assessed, at the end of the study, using a target questionnaire.

This study allows to justify the claim "adjunct in the repair / regeneration".

II . DATES OF STUDY

Beginning: June 24th, 2013
End: July 23th, 2013

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 40 years,

b) Gender: male and female,

c) Phototype (Fitzpatrick) : I to IV,

d) Type of skin: all types of skin.

IV. METHODOLOGY

IV.1.Assessment of the efficacy

The instrumental efficacy data are expressed in numbered data and are submitted to a suitable statistical treatment. A 95% level of significance was adopted. The subjective data of efficacy are submitted to a suitable statistical treatment.

IV.2. Checking of the acceptability

The results were mainly expressed as descriptive data and do not require a statistical treatment. The test products been well accepted by the subjects, under these experimental conditions, by extrapolation it should be safe for human health when applied by a great panel of consumers.

IV.3. Experimental conditions of use of the test product

The experimental conditions, defined by protocol, were the following ones:

Experimental area(s)	Product directions of use	Application(s) at the Institute	Application(s) at home Frequency/duration
Arm (randomized by subject)	***Phase 1:*** Application of SLS 1% in occlusive patch Finn Chamber standard ® for 24H, in both arms. ***Phase 2:*** Application of CREME FACIAL LEITE DE BURRA, **by the subject**, on clean skin by gentle digital massage until complete absorption, in one arm, randomly defined, twice a day.	First application (Volunteers' education and trainee application)	From D1 to D28 Application, twice a day (morning -after bath, evening – at bedtime) for 28 +/- 2 consecutive days (4 weeks)

IV.4. Study schedule

		Week 1				Week 2			Week 3			Week 4		
	Inclusion	D1	D2	D3	D5	D8	D10	D12	D15	D17	D19	D22	D24	D26
Information + consent	●													
Inclusion/Non-inclusion Criteria	●													
Study														
Biometric measurement		●	●	●	●	●	●	●	●	●	●	●	●	●
Application of test product			●	●	●	●	●	●	●	●	●			
Application of SLS 1%		●												
Clinical evaluation		●	●			●			●			●		●
Questionnaire												●		

V . RESULTS

V.1. Results from the dermatological evaluation

Evaluation periods	Cutaneous reactions related with the test product	% of subjects exhibiting clinical signs ascribable to the test product
D1 post - application	None	0%
D2	None	0%
D8	None	0%
D15	None	0%
D22	None	0%
D26	None	0%

V.1. Results from the questionnaire asked to the volunteers and observation of the individual observation sheet

Volunteers codification	Sensations of discomfort noted by the volunteers at home	Number and % of subjects exhibiting sensations of discomfort ascribable to the test product
/	None	0%

V.3. Hydration evaluation

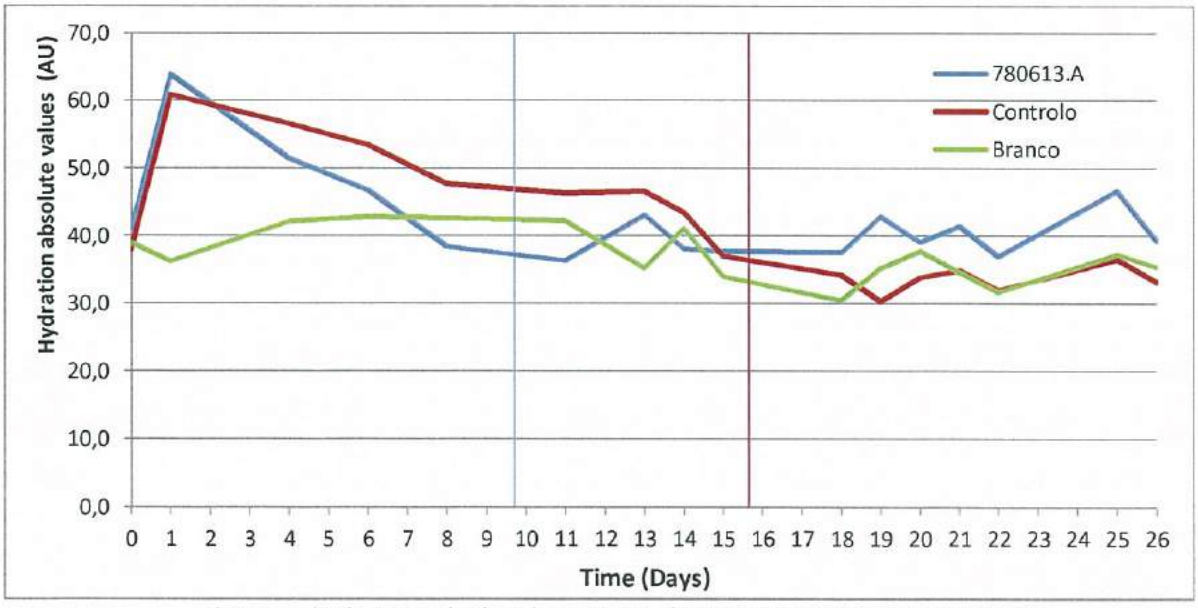

Figure 1 - Skin hydration (AU) evolution during the study (means values of 15 subjects).
The vertical lines represent the mean of days of recovery obtained in the application zone (blue) and control (red).

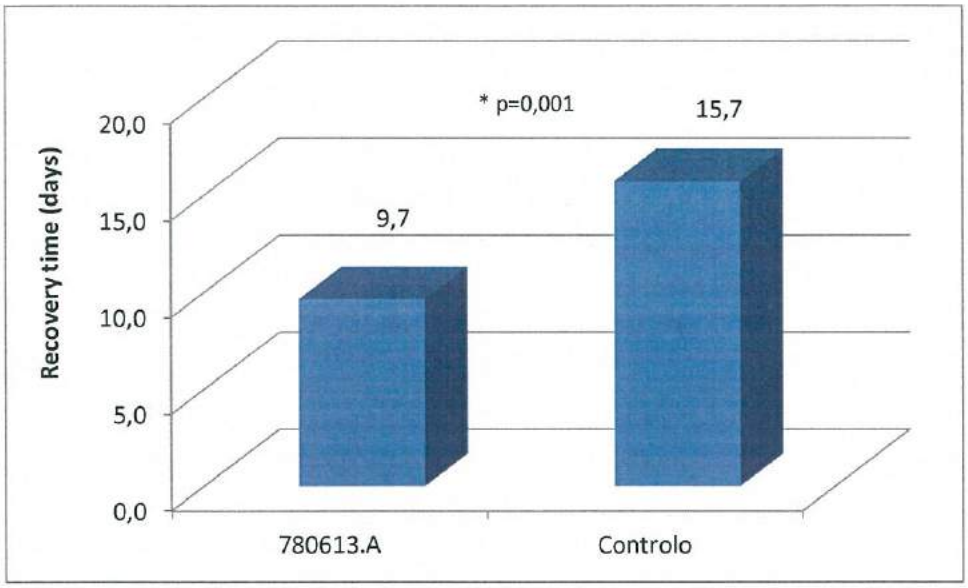

Figure 2 Recovery time of the skin obtained with and without the product **CREME FACIAL LEITE DE BURRA**. Also shown is the statistical comparison against the control (*: p<0,05; N.S.: Non-significant)

V.4. Trans Epidermal Water Loss Evaluation

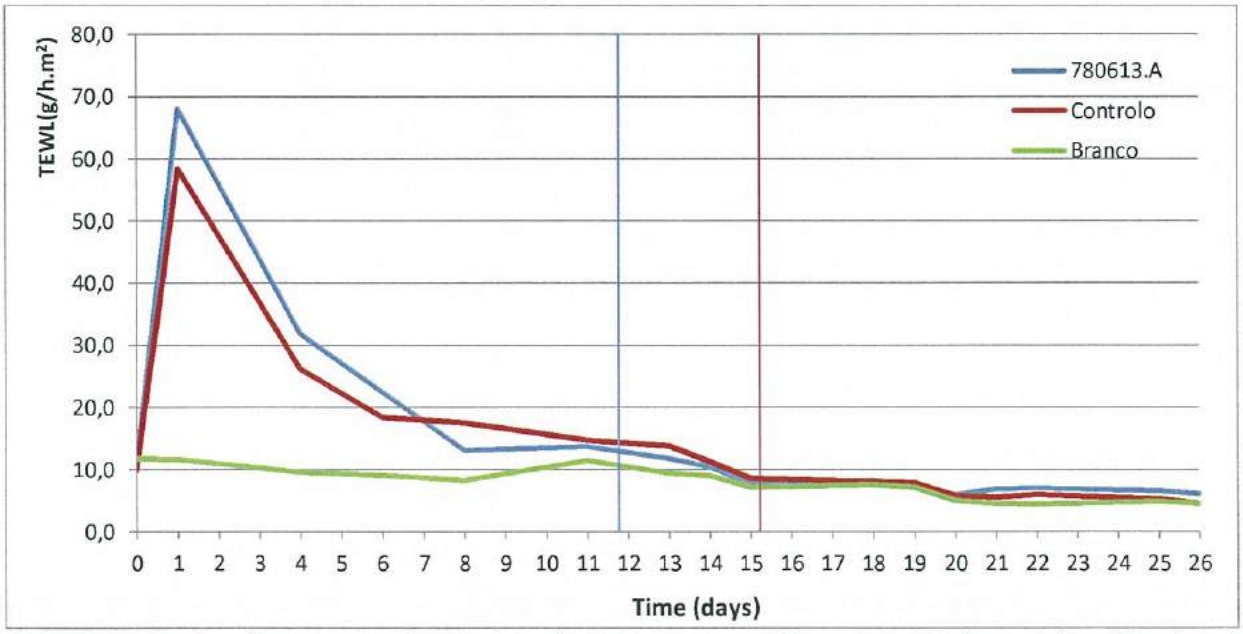

Figure 3 Trans Epidermal Water Loss Evaluation during the application time of the product study (means values of 15 subjects). The vertical lines represent the mean of days of recovery obtained in the application zone (blue) and control (red).

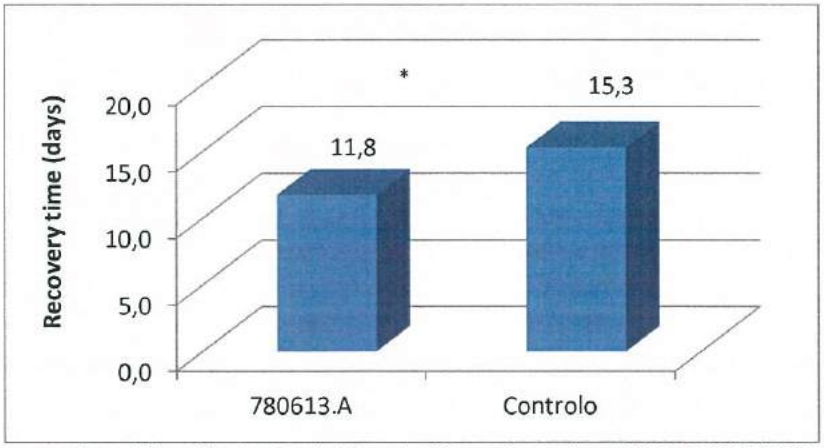

Figure 4 Recovery time of the skin obtained with and without the product **CREME FACIAL LEITE DE BURRA**.
Also shown is the statistical comparison against the control (*: p<0,05; N.S.: Non-significant)

V.5. Evaluation of the microcirculation and Erythema

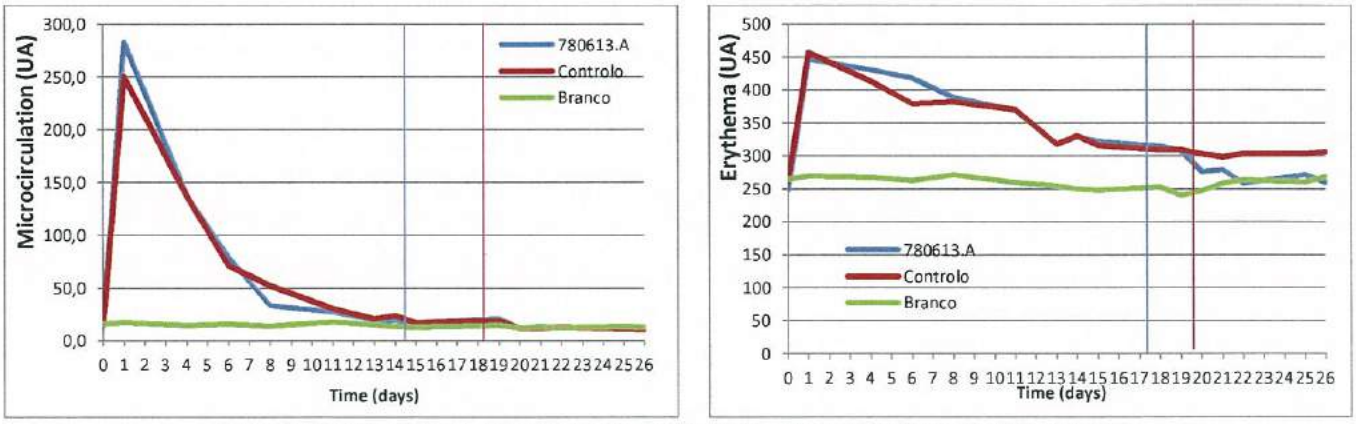

Figure 5 Microcirculation and Erythema Evaluation during the application time of the product.
The vertical lines represent the mean of days of recovery obtained in the application zone (blue) and control (red).

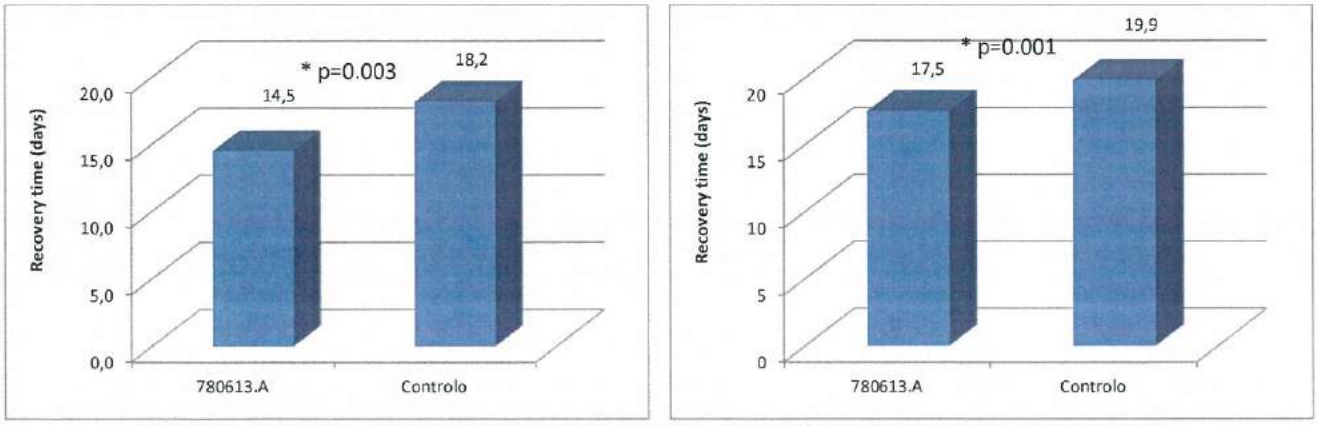

Figure6 Recovery time of the skin obtained with and without the product **CREME FACIAL LEITE DE BURRA**.
Also shown is the statistical comparison against the control (*: p<0,05; N.S.: Non-significant)

Table 1 - Summary results of the % change in relation with Day0, for each variable

780613.A vs control	% Var	Recovery difference (days)
Hydration	-38.6	-6.0
TEWL	-23.0	-3.5
Microcirculation	-20.2	-3.7
Erythema	-11.8	-2.4

VI . CONCLUSION

According to the standard experimental conditions and protocol and after statistical analysis we concluded that:

The product **CREME FACIAL LEITE DE BURRA, BATCH 330127/A 655** accelerates significantly, in 6.0 days, the recovery of skin hydration after one application of SLS for 24 hours.

The product **CREME FACIAL LEITE DE BURRA, BATCH 330127/A 655** accelerates significantly, in 3.5 days, the recovery of the skin barrier, assessed by Trans Epidermal Water Loss after one application of SLS for 24 hours.

The product **CREME FACIAL LEITE DE BURRA, BATCH 330127/A 655** accelerates significantly, in 3.7 days, the recovery of blood flow, measured by Laser Doppler Flowmetry (microcirculation variable) after one application of SLS for 24 hours.

The product **CREME FACIAL LEITE DE BURRA, BATCH 330127/A 655** accelerates significantly, in 2.4 days, the recovery of erythema after one application of SLS for 24 hours.

These results show that the product **CREME FACIAL LEITE DE BURRA, BATCH 330127/A 655** is an aid in skin recovery.

The product **CREME FACIAL LEITE DE BURRA, BATCH 330127/A 655** showed no irritative reaction, so the product has a very good skin compatibility.

Pedro C+T. 2/8/2013

Scientific Manager : Pedro CONTREIRAS PINTO

I the undersigned, Pedro CONTREIRAS PINTO, declare that:
- the final report was examined on August 2nd, 2013,
- the results reported accurately and completely reflect the raw data of the study.

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