

**EVALUATION OF THE HYDRATION EFFICACY  
OF A COSMETIC PRODUCT**

**AFTER APPLICATION UNDER DEFINED CONDITIONS  
IN NORMAL SUBJECTS**

**ACUTE HYDRATION - 8H**

**Objective evaluation of the hydration by “capacitance” method**

*Summary Report*

*This report is a summary of the report 4150416.C, and reflects all data concerning the study developed with the product.*

**OBJECTIVE**

The aim of the present study is to assess the **hydration efficacy** at 30 minutes, 2H, 4H and 8H, of the product **DMC Creme Mãos Donkey Milk** after a single application in healthy human volunteers.

**II . DATES OF STUDY**

**Beginning:** 28/4/2016

**End:** 29/4/2016

**III . SUBJECTS**

- **Number of volunteers defined in the protocol : 10**
- **Number of volunteers who performed the study: 10** (10 included volunteers, no exclusions and no drop-outs).
- **Specific inclusion criteria :**
  - age: 18-65 years old,
  - gender: female
  - phototype (Fitzpatrick): I to IV,
  - dry skin (Level  $\leq$  40 AU).

**IV. METHODOLOGY**

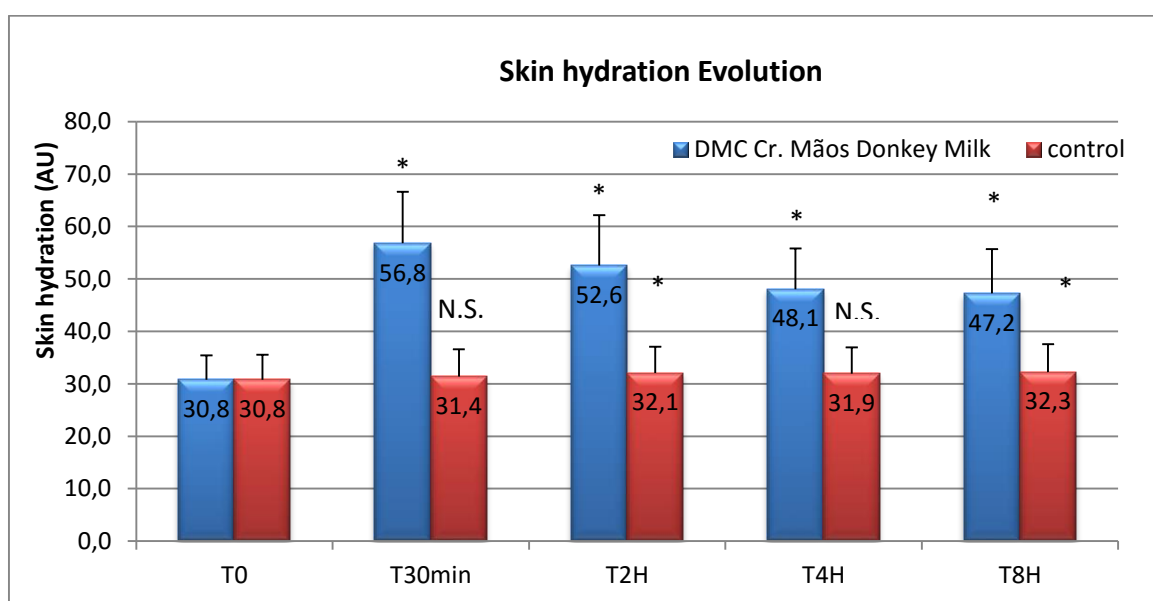
The experimental conditions and protocol schedule were as follow:

Product name	Product directions of use	Quantity to be applied	Environmental conditions
<b>DMC Creme Mãos Donkey Milk</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 $\pm$ 1°C, 45% $\pm$ 10%).

	Inclusion	T0	T1 min	Start of counting time	T30min	T2H	T4H	T8H	
Clinical history, informed consent	•								
Verification of inclusion/exclusion criteria	•								
Basal Hydration Measurement		•							
Application of tested product and control			•						
Biometric measurements					•	•	•	•	

## V . RESULTS

Results were as follows:



**Figure 1** - Skin hydration (AU) evolution during the study. Mean + sd values of all the volunteers (n=10). Also shown is the statistical comparison against the control (\*: p<0,05; N.S.: Non-significant)

**Table I** – Summary results of the evolution of the Hydration values during the study (T30 min)

	n	T0	T30min	p-value <sup>1</sup> (time effect)	% change
<b>Treated area</b>	10	30.8 ± 4.6	56.8 ± 9.8	0.005	85.6%
<b>Non-treated area</b>	10	30.8 ± 4.7	31.4 ± 5.2	0.610	2.0 %
<b>p-value<sup>1</sup> (product effect)</b>	-	1.000	0.005		
<b>% change<sup>2</sup></b>	-	0.3%	82.3%		

1 – Wilkoxon Test regarding D0: p < 0.05 : significant; 0.05 ≤ p < 0.10: close to significativity ; p ≥ 0.10 : non significant

2 – Product effects statistical comparisons were performed between the %changes obtained at T30m on the treated area vs % changes obtained at non-treated area

Table II – Summary results of the evolution of the Hydration values during the study (T2H)

	n	T0	T2H	p-value <sup>1</sup> (time effect)	% change
<b>Treated area</b>	10	30.8 ± 4.6	52.6 ± 9.6	0.005	70.7%
<b>Non-treated area</b>	10	30.8 ± 4.7	32.1 ± 5.0	0.036	4.2%
<b>p-value<sup>1</sup> (product effect)</b>	-	1.000	0.005		
<b>% change<sup>2</sup></b>	-	0.3%	64.0%		

1 – Wilcoxon Test regarding D0: p < 0.05 : significant; 0.05 ≤ p < 0.10: close to significativity ; p ≥ 0.10 : non significant

2 – Product effects statistical comparisons were performed between the %changes obtained at T2H on the treated area vs % changes obtained at non-treated area

Table III – Summary results of the evolution of the Hydration values during the study (T4H)

	n	T0	T4H	p-value <sup>1</sup> (time effect)	% change
<b>Treated area</b>	10	30.8 ± 4.6	48.1 ± 7.8	0.005	56.9%
<b>Non-treated area</b>	10	30.8 ± 4.7	31.9 ± 5.0	0.114	3.8%
<b>p-value<sup>1</sup> (product effect)</b>	-	1.000	0.005		
<b>% change<sup>2</sup></b>	-	0.3%	51.9%		

1 – Wilcoxon Test regarding D0: p < 0.05 : significant; 0.05 ≤ p < 0.10: close to significativity ; p ≥ 0.10 : non significant

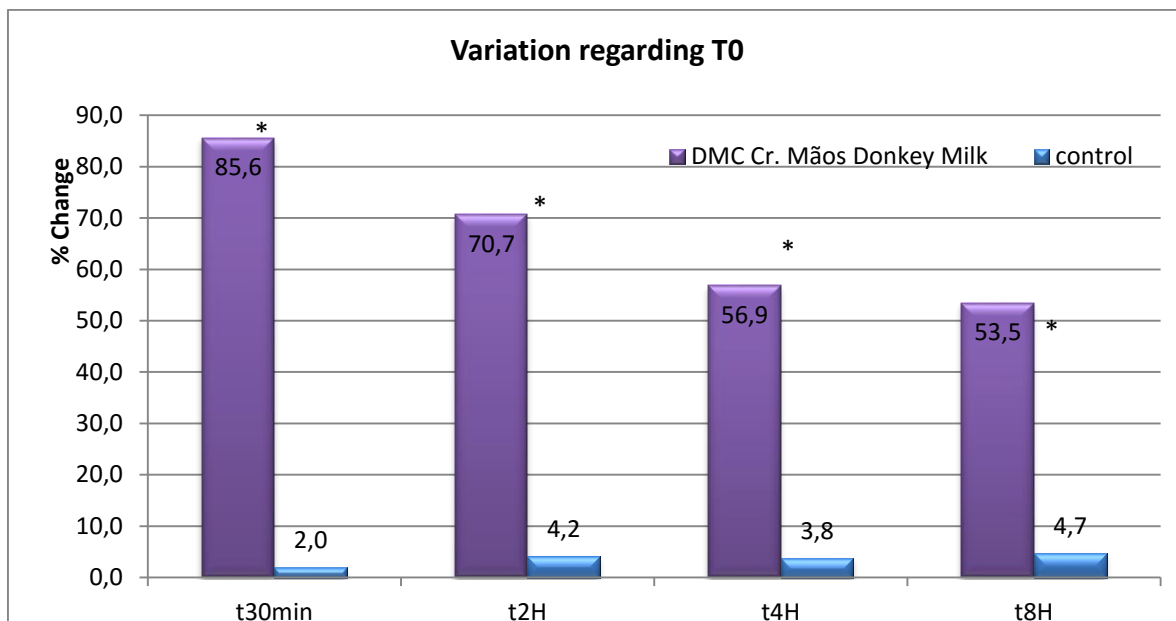
2 – Product effects statistical comparisons were performed between the %changes obtained at T4H on the treated area vs % changes obtained at non-treated area

Table IV – Summary results of the evolution of the Hydration values during the study (T8H)

	n	T0	T8H	p-value <sup>1</sup> (time effect)	% change
<b>Treated area</b>	10	30.8 ± 4.6	47.2 ± 8.5	0.005	53.5%
<b>Non-treated area</b>	10	30.8 ± 4.7	32.3 ± 5.3	0.037	4.7%
<b>p-value<sup>1</sup> (product effect)</b>	-	1.000	0.005		
<b>% change<sup>2</sup></b>	-	0.3%	47.0%		

1 – Wilcoxon Test regarding D0: p < 0.05 : significant; 0.05 ≤ p < 0.10: close to significativity ; p ≥ 0.10 : non significant

2 – Product effects statistical comparisons were performed between the %changes obtained at T8H on the treated area vs % changes obtained at non-treated area



**Figure 2** - % Change against Basal, for each product and control sites. Mean values of all the volunteers. Also shown is the statistical comparison between products (\*:  $p < 0,05$ ; N.S.: Non-significant)

## VI . CONCLUSION

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

The product **DMC Creme Mãos Donkey Milk** presented a statistically increase of 85.6% in the skin hydration after 30 minutes of application and a statistically increase of 70.7%, 56.9% and 53.5% in the skin hydration after 2H, 4H and 8H of application.

The comparison against the blank control shows that this increase is statistically significant both at 30 minutes, after 2H, after 4H and after 8H of application.

These results show that product **DMC Creme Mãos Donkey Milk** reinforces skin hydration after 30 minutes, after 2H, after 4H and after 8H of application.

**Signatures and dates:**

**Investigator/Scientific Manager: Pedro CONTREIRAS PINTO**

I the undersigned, Pedro CONTREIRAS PINTO, declare that the overall conduct of the study was carried out under my responsibility having in mind the basic principles and spirit of Good Clinical Practices (“Avis aux promoteurs et aux investigateurs pour les essais cliniques des médicaments” : principes généraux – FR.OB – 1987, international recommendations ICH E 6, step 4, of 1/5/1996 and general principals of the Portuguese law 46/2004 from August 19<sup>th</sup>).