

CREMA BASE HIDRATANTE

FICHA DE SEGURIDAD

COSMETIC PRODUCT SAFETY REPORT

PART A – Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product

1) Information on product identity

- Name of the product: Crema base hidratante
- Intended use: Body care
- Manufacturer/distributor: Gran Velada

2) Product description

- Preparation, consistency, possibly emulsion type: O/W emulsion
- Quantitative and qualitative composition of the cosmetic product:

Description of the ingredients:

1. table

INCI NAME	CAS No	FUNCTION	CONCENTRATION FINAL PRODUCT, %
Aqua	7732-18-5	Solvent	83,9000
Glycerin	73398-61-5	Emollient, humectant	5,0000
	56-81-5	Humectant	2,0000
Cetyl Alcohol	67762-27-0	Emulsifying	3,0000
Glyceryl stearate	31566-31-1	Emulsifying	3,0000
Peg-100 Stearate	9004-99-3	Emulsifying	1,0000
Synthetic Beeswax		Viscosity	1,0000
Phenoxyethanol	122-99-6	Preservative	0,8100
Ethylhexylglycerin	70445-33-9	Preservative	0,0900
Chlorphenesin	104-29-0	Preservative	0,2000

2. Physical/chemical characteristic and stability of the cosmetic product

1) Physical/chemical characteristics

2. table

ANALYSIS RESULTS	SPECIFICATION
Appearance	Homogeneous mass
Colour	White
Odour	Natural
Solubility in water	Easily mixed
pH (10% water solution)	5.5-8.5
Colloidal stability	Stable
Thermostability	Stable
Net weight, g	50000.00±150

2) Stability of the cosmetic product

Stability testing was conducted on finished product packaged in the transparent and suitable for cosmetic jar with aluminium cap. The frequency of testing was initial and at the shelf-life (24 months) sufficient to establish the stability profile of the product. Stability testing was lasted for 24 months. Storage condition used was at 25 °C, and parameters investigated were: appearance, odour and colour. All values obtained confirmed the shelf-life proposed.

Challenge test was shown that a well preserved product should remain growth-free six inoculation cycles and thereby the product has a shelf-life 24 months.

Taking into account these two tests body cream “Hidrante” realization time is 24months.

3. Microbiological quality

Consequently, two separate categories of cosmetic products are defined in the microbiological quality control limits:

Category 1: Products specifically intended for children under 3 years, to be used in the eye area and mucous membranes.

Category 2: Other products.

It is generally accepted that for cosmetics classified in *Category 1*, the total viable count for aerobic mesophilic microorganisms should not exceed 10^2 cfu/g or 10^2 cfu/ml when tested in 1 g or 1 ml of the product.

For cosmetics classified in *Category 2*, the total viable count for aerobic mesophilic microorganisms should not exceed 10^3 cfu/g or 10^3 cfu/ml when tested in 1 g or 1 ml of the product.

Escherichia Coli, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered the main potential pathogens in cosmetic products. These specific potential pathogens must not be detectable in 1 g or ml of a cosmetic product of *Category 1* and in 1 or ml of a Cosmetic product of *Category 2*.

This product evaluated according to *Category 2*.

3. table

Parameters	Specification
Total aerobic mesophile plate count, max. CFU/1 g	<1*10 ³
Molds and yeasts 1 g, <i>Candida Albicans</i>	absent
Pathogens and opportunistic: - <i>Staphylococcus aureus</i> , 1g - <i>Pseudomonas aeruginosa</i> , 1g - <i>Enterobacteriaceae</i> , 1g	absent

Microbiological tests are showing that body cream “Hidrante” complies with requirements.

4. Impurities, traces, information about the packaging material

Product is packaged in a bucket with lid.

High Concern).

5. Normal and reasonably foreseeable use

1)The product label information: Weight, ingredients, distributor information, shelf-life, a brief description.

2)The warnings on the product label: Store in a tightly closed original packing. Protect from direct sunlight.

3)Normal and reasonably foreseeable application amount and total area of the skin contact: Area body-area

4) Using directions and frequency of applications: apply a thin layer to cleansed skin.

6. Exposure to the cosmetic product

Product type: Cosmetic Leave-on product

IFRA category: Class 5A

Exposure: Direct dermal contact

The sites of application: area body- area head female

The surface areas of application: 15670 cm²

Estimated amount of product applied: 7.82 g

The duration and frequency of use: 2.28/day

Retention factor: 1.0 [SCCNFP/0321/00]

Calculated amount product/application: 7.82 g

Calculated relative amount product/weight/day (as mg/kg/day): 123.2

The normal reasonably foreseeable exposure route: Dermal Route, uptake by diffusion

Exposed population: Adults

7. Exposure of the substances

Dermal absorption of test substance reported in $\mu\text{g}/\text{cm}^2$:

$$\text{SED} = \frac{\text{DA}_a (\mu\text{g}/\text{cm}^2) \times 10^{-3}\text{mg}/\mu\text{g} \times \text{SSA} (\text{cm}^2) \times \text{F} (\text{day}^{-1})}{60 \text{ kg}}$$

Dermal absorption reported as percentage of the amount of substance applied:

$$\text{SED} = \text{A} (\text{mg}/\text{kg}/\text{day}) \times \text{C} (\%) / 100 \times \text{DA}_p (\%) / 100$$

SED (mg/kg bw/day): Systematic Exposure Dosage

A (mg/kg bw/day): Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and frequency of application

C (%): the Concentration of the ingredient under study in the finished cosmetic product on the application site

DA_p (%): Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions

A is 123.2 mg/kg bw/day for body cream “Hidrante”. Body surface area was emphasised as 15670 cm² and adult’s body weight was accepted 60 kg (Base on the The SCCS’s Notes of Guidance for The Testing of Cosmetic Ingredients and their Safety Evaluation 11th Revision) when this value is calculated.

8. Toxicological profile of the substances

1) Toxicological profile of the substances involved in the formula

- Calculation of Margin of Safety (MoS)

$$\text{MoS} = \text{NOAEL}/\text{SED}$$

A is 123.2 mg/kg bw/day for body cream “Hidrante”. Body surface area was emphasised as 15670 cm² and an adult’s body weight was accepted 60 kg (Base on the The SCCS’s Notes of Guidance for The Testing of Cosmetic Ingredients and their Safety Evaluation 11th Revision) when this value is calculated.

4. table

INCI NAME	CONCENTRATION	NOAEL	REFERENCES	SED mg/kg	Retention	Da _a	Da _p , (%)	MoS
Aqua	839000	-	-	1033648	1	-	100	-
	50000	2500	GRAS Notice (GRN) No. 449	61600	1	-	100	406
Glycerin	20000	10000	SIAM 14 Glycerol, Paris, France, 26-28 March 2002	24640	1	-	100	4058
Cetaryl Alcohol	30000	750	SIAM22, 1821 April 2006, SIDS INITIAL ASSESSMENT PROFILE	36860	1	-	100	203
Glyceryl stearate	30000	safe	Glyceryl monostearate is safe for use in cosmetic formulations (Int. J. Toxicol., 2004)	36860	1	-	100	-
Peg-100 Stearate	10000	safe	Safety Assessment of PEG Diesters as Used in Cosmetics	12320	1	-	100	-
Synthetic Beeswax	10000	safe	ED-A	12320	1	-	100	-
Phenoxyethanol	08100	500	UNEP Publications; OECD SIDS Ethylene Glycol Phenyl Ether, CAS No: 122-99-6.	09979	1	-	100	501
Ethylhexylglycerin	00800	50	Ethylhexylglycerin. CIR Expert Panel Meeting. September 26-27, 2011.	01109	1	-	100	451
Chlorphenesin	02000	100	ED-A	02164	1	-	100	406

2) Control of substances compliance with regulations:

List of substances which cosmetic products must not contain except subject to the restrictions laid down (Regulation (EC) No. 1223/2009 Of the European Parliament and of the Council of 30 November 2009 on cosmetic products)

5. table

Substance INCI Name	Restrictions (Limit of product specified in the regulations)	Concentration of substance in finished products (%)	IFRA 51 th Amendment, Limits in the finished products. Category 5A, %	Wording of conditions of use and warnings
-	The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ol style="list-style-type: none"> 1. 0.001% in leave-on products; 2. 0.01% in rinse-off products. 	-	-	Conforms
Phenoxyethanol	Maximum concentration in ready for use preparation 1%	0.9000	-	Conforms

9. Undesirable effects and serious undesirable effects

Any adverse reactions and serious adverse effects have been reported.

10. Information on the cosmetic product

Other relevant information, e.g., existing studies from human volunteers or the duly confirmed and substantiated findings of risk assessments carried out in other relevant areas.

PART B – Cosmetic Product Safety Assessment

1. Assessment conclusion

The safety assessment report of this product is prepared for adults use. MoS>100 is found almost for all raw materials except Aqua, Glyceryl Stearate, PEG-100 Stearate, Synthetic Beeswax, (not known any adverse effect on human health). The calculation was performed assuming that dermal absorption is 100%. With this case study, it is evaluated that the use of these raw materials in this product are safe.

The ingredients of the product are permitted ingredients for cosmetics. All raw materials are not toxic under normal and reasonably unforeseeable conditions of use at this concentration. The product does not contain prohibited substances listed in annexes of Regulation (EC) No. 1223/2009. The product contains allergens that exceeds the limits specified in the regulation. These allergens have to be indicated in the list of ingredients. Composition of the product complies with requirements of the Cosmetic Regulations.

Following review of the information provided for the above product and its ingredients, the product is safe for the intended application and complies with EC Regulation 1223/2009.

This safety assessment for human health is based upon information available at this date. Reviews of this assessment will be made as and when new information becomes available.

2. Labelled warnings and instructions of use

- 1) Information on the product: Weight, ingredients, distributor information, shelf-life, a brief description.
- 2) The warnings on the product label: Store in a tightly closed original packing. Protect from direct sunlight.
- 3) Using directions and frequency of application: apply thin layer to cleansed skin.

3. Reasoning

This report is prepared based on the Regulation (EC) No. 1223/2009 of the European Parliament and of Council of 30 November 2009 on cosmetic product and the SCCS's Notes of Guidance for testing of Cosmetic Ingredients and their Safety Evaluation 11th Revision.

Attached information and documents (MSDS's TDS's, Stability Reports etc) and the references at end of the report are also used on the safety assessment.