

# CREMA FACIAL BASE NATURAL

## FICHA DE SEGURIDAD

### 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 FACIAL BASE NATURAL
- Intended use: Face care
- Manufacturer/distributor: “Gran Velada”

##### 2) Product descriptions

- 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	77,7875
Prunus Amygdalus Dulcis Oil	8007-69-0	Emollient	10,0000
Persea Gratissima Oil	8024-32-6	Emollient, humectant	3,9960
Glycerin	56-81-5	Humectant	3,0250
Sodium Polyacrylate	9003-04-7	Emollient, emulsion stabilising, viscosity controlling	1,0500
PPG-1-PEG-9 Lauryl Glycol Ether	-	Emulsifyng	1,0000
Panthenol	81-13-0	Skin conditioning	0,4875
Chamomilla Recutita Extract	84082-60-0	Active Component	0,5000
Cetearyl Alcohol	67762-27-0	Emulsion Stabilising	0,5000
Stearic Acid	57-11-4	Emulsifyng	0,3000
Parfum	-	Fragrance	0,5000
Phenoxyethanol	122-99-6	Preservative	0,9000
Ethylhexylglycerin	70445-33-9	Preservative, skin conditioning	0,1000
Lecithin	8002-43-5	Emollient	0,0135
Ascorbyl Palmitate	137-66-6	Antioxidant	0,0135
Helianthus Annuus Seed Oil	8001-21-6	Emollient	0,0135
Tocopherol	54-28-4	Antioxidant	0,0135
Alcohol	64-17-5	Solvent	0,0135

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

Physical/chemical characteristics

2. table

ANALYSIS RESULTS	SPECIFICATION
Appearance	Medium viscous emulsion
Colour	White
Odour	Cucumber, fresh
Solubility in water	Easily mixed
pH (20% water solution)	5.5-8.5
Heavy metals, ppm	0 to 10
Neto volume, ml	50.0 +/- 4.5

## 3. Microbiological quality

Microbiological purity criteria must comply with the Regulation (EC) No 1223/2009 of the European parliament and of the council of 30 November 2009 on cosmetic products (Article 12), Regulation of the Cabinet of Ministers of the Republic of Latvia on 02.07.2013. №. 354 “Kosmētikas līdzekļu būtisko prasību nodrošināšanas kārtība” (“Assurance procedures for cosmetic products essential requirements”, Annex III).

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 0.5 g or 0.5 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 0.1 g or 0.1 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 0.5 g or ml of a cosmetic product of *Category 1* and in 0.1 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/0.1 g	$<1 \cdot 10^3$
Molds and yeasts 0.1 g, <i>Candida Albicans</i>	absent
Pathogens and opportunistic: - <i>Staphylococcus aureus</i> , 0.1g - <i>Pseudomonas aeruginosa</i> , 0.1g - <i>Enterobacteriaceae</i> , 0.1g	absent

Microbiological tests are showing that Softening Face Cream for Normal Skin complies with requirements.

#### 4. Impurities, traces, informations about the packaging material

Product is packaged in white and suitable for cosmetic container with pump and cap, which meets following requirements:

REACH Statement (Regulation EC 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals). Product does not test to the absence of SVHC's (Substance of Very High Concern).

Certified according to ISO9001:2008 and ISO14001:2004 standards, related to environmental management to help organizations minimize how their operations (processes, etc.) negatively affect the environment; comply with applicable laws, regulations, and other environmentally oriented requirements, and continually improve in the above.

Certified according to OSHAS18001:2007 to control and improve health and safety performance and do so with occupational health and safety management systems (OHSMS).

Heavy Metals are not part of the recipe (EU regulation 94/62/EC and amendment 2013/2/EU).

#### 5. Normal and reasonably foreseeable use

- 1) The product label information: Volume, ingredients, distributor information, shelf-life, a brief description.
- 2) The warnings on the product label: Store in a cool dry place. Protect from direct sunlight.
- 3) Normal and reasonably foreseeable application amount and total area of the skin contact: Face area
- 4) Using directions and frequency of applications: For all skin types. In morning and evening apply a small amount on cleansed and moist face, neck and decollete and massage gently.

## 6. Exposure to the cosmetic product

Product type: Cosmetic Leave-on product

IFRA category: Class 5

Exposure: Direct dermal contact

The sites of application: ½ area head female

The surface areas of application: 565 cm<sup>2</sup>

Estimated amount of product applied: 1.54 g

The duration and frequency of use: 2.14/day

Retention factor: 1.0 [SCCNFP/0321/00]

Calculated amount product/application: 1.54 g/d

Calculated relative amount product/weight/day (as mg/kg/day): 24.14

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 µg/cm<sup>2</sup>.

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

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

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

**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<sub>p</sub> (%):** Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions

A is 24.14 mg/kg bw/day for Softening Face Cream for Normal Skin. Face surface area was emphasised as 565 cm<sup>2</sup> 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 24.14 mg/kg bw/day for Softening Face Cream for Normal Skin. Face surface area was emphasised as 565 cm<sup>2</sup> 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 FINAL PRODUCT, %	NOAEL mg/kg/day	REFERENCES	SED mg/kg bw/day	Retention Factor	Da <sub>a</sub> , µm/cm <sup>2</sup>	Da <sub>p</sub> , (%)	MoS
Aqua	78,2875	-	-	18,8986	1	-	100	-
Prunus Amygdalus Dulcis Oil	10,0000	-	-	2,4140	1	-	100	-
Persea Gratissima Oil	3,9960	-	-	0,9646	1	-	100	-
Glycerin	3,0250	10000	OECD SIDS Initial Assessment Report for SIAM 14 Glycerol, Paris, France, 26-28 March 2002	0,7302	1	-	100	13694
Sodium Polyacrylate	1,0500	-	-	0,2535	1	-	100	-
PPG-1-PEG-9 Lauryl Glycol Ether	1,0000	safe	Safety Assessment of Alkyl PEG/PPG Ethers as Used in Cosmetics. Cosmetic Ingredient Review, Jan 20, 2013	0,2414	1	-	100	-
Panthenol	0,4875	safe	Opinion of the Scientific Committee on Food the Tolerable Upper Intake Level of Pantothenic Acid 17 April 2002	0,1177	1	-	100	-
Chamomilla Recutita Extract	0,5000	-	-	0,1207	1	-	100	-
Cetearyl Alcohol	0,5000	200	SIAM 22, 19-21 April 2006, SID INITIAL ASSESSMENT PROFILE	0,1207	1	-	100	1657
Stearic Acid	0,3000	7500	Human&Environmental Risk Assessment on ingredients of European household cleaning products, Fatty Acid Salts, June, 2002	0,0724	1	-	100	103563
Phenoxyethanol	0,9000	500	UNEP Publications; OECD SIDS Ethylene Glycol Phenyl Ether, CAS No: 122-99-6.	0,2173	1	-	100	2301
Ethylhexylglycerin	0,1000	50	Ethylhexylglycerin. CIR Expert Panel Meeting. September 26-27, 2011.	0,0241	1	-	100	2071
Lecithin	0,0135	1000	Notification of gras determination for soy lecithin phosphatidylserine complex, Lipogen products (9000) LTD. November 29, 2005	0,0033	1	-	100	306852
Ascorbyl Palmitate	0,0135	800	Vitamins E and C are safe across a broad range of intakes 12. John N Hathcock, Angelo Azzi, Jeffrey Blumberg, Tammy Bray, Annette Dickinson, Balz Frei, Ishwari Lal, Lal, Carol S Johnston, Frank J Kelly, Kalus Kraemer, Lester Packer, Sampath Parthasarathy, Henmut Sies and Maret G Traber. Am J Clin Nutr April 2005 vol. 81 No.4 736-745.	0,0033	1	-	100	245482
Helianthus Annuus Seed Oil	0,0135	-	-	0,0033	1	-	100	-
Tocopherol	0,0135	800	Vitamins E and C are safe across a broad range of intakes 12. John N Hathcock, Angelo Azzi, Jeffrey Blumberg, Tammy Bray, Annette Dickinson, Balz Frei, Ishwari Lal, Lal, Carol S Johnston, Frank J Kelly, Kalus Kraemer, Lester Packer, Sampath Parthasarathy, Henmut Sies and Maret G Traber. Am J Clin Nutr April 2005 vol. 81 No.4 736-745.	0,0033	1	-	100	245482
Alcohol	0,0135	2400	SIDS Initial Assessment Report For SIAM 19, Berlin, Germany, 19-22 October 2004	0,0033	1	-	100	736445

## 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 49th Amendment, Limits in the finished products. Category 5, %	Wording of conditions of use and warnings
Phenoxyethanol	Maximum concentration in ready for use preparation 1%	0.900	-	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.

The information contained in the file are as follows:

1. Certification of Analysis or Specifications of Final Product;
2. Certification of Analysis and Specifications of Ingredients;
3. Label Information for Final Product;
4. Safety Data Sheet of Ingredients (MSDS);
5. Formulation of the Product;
6. Packaging Quality Certificate (TDS/MSDS).

## 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, Prunus Amygdalus Dulcis, Simmondsia Chinensis Seed Oil, Sodium Polyacrylate, PPG-1-PEG-9 Lauryl Glycol Ether, Panthenol, Aloe Barbadensis Extract, Helianthus Annuus Seed Oil (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) Informations on the label of the product: Volume, ingredients, distributor information, shelf-life, a brief description.
- 2) The warnings on the product label: Store in a cool dry place. Protect from direct sunlight.
- 3) Using directions and frequency of application: For all skin types. In morning and evening apply a small amount on cleansed and moist face, neck and décollete and massage gently.

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