

CREMIGEL BASE

FICHA DE SEGURIDAD

Este producto es una mezcla de:

Base body milk natural
Carbopol

PART A – Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product

1) Information on product identity

- Name of the product: BASE BODY MILK 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:

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

1. Table

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*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 cm²

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/cm².

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

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_p (%): 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 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 24.14 mg/kg bw/day for Softening Face Cream for Normal Skin. Face surface area was emphasised as 565 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 FINAL PRODUCT, %	NOAEL mg/kg/day	REFERENCES	SED mg/kg bw/day	Retention Factor	Da _a , μm/cm ²	Da _p , (%)	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, Ethylhexylglycerin, CIR	0,2173	1	-	100	2301
Ethylhexylglycerin	0,1000	50	Expert Panel Meeting, September 26-27, 2011.	0,0241	1	-	100	2071
Lecithin	0,0135	1000	Notification of grass 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, Carol S Johnston, Frank J Kelly, Kalus Kraemer, Lester Packer, Sampath Parthasarathy, Hermut 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, Carol S Johnston, Frank J Kelly, Kalus Kraemer, Lester Packer, Sampath Parthasarathy, Hermut 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 decollete 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.

GEL HIDRATANTE BASE CARBOPOL

FICHA DE SEGURIDAD

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : GEL HIDRATANTE BASE CARBOPOL

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : GEL HIDRATANTE BASE CARBOPOL

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Gran Velada.S.L
Pol. Montecillo, Nave 3D, 50520 Magallón (Zaragoza) ESPAÑA
Telf. +34 976 86 74 74
contacto@granvelada.com

1.4. Emergency telephone number

Emergency number: Servicio de Información Toxicológica: 91 562 04 20

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP], Globally Harmonized System [GHS] and Work Health and Safety Regulations, Schedule 6

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP], Globally Harmonized System [GHS] and Work Health and Safety Regulations, Schedule 6

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to CLP, GHS & WHS S.6
Aqua	(CAS No) 7732-18-5 (EC no) 231-791-2	q.s. 100	Not classified
Propane-1,2-diol	(CAS No) 57-55-6 (EC no) 200-338-0	0.5 - < 2	Not classified
Carbomer	(CAS No) 9003-01-4	0.3 - < 1	Not classified

Name	Product identifier	%	Classification according to CLP, GHS & WHS S.6
Triethanolamine	(CAS No) 102-71-6 (EC no) 203-049-8	0.3 - < 1	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT RE 2, H373
Mixture of Benzyl Alcohol and Methylchloroisothiazolineone and Methylisothiazolinone		0.05 - < 0.10	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
 First-aid measures after skin contact : Wash skin with plenty of water.
 First-aid measures after eye contact : Rinse eyes with water as a precaution.
 First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire; Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning : Take up liquid spill into absorbent material.
up Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool. Keep away from heat and direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Propane-1,2-diol (57-55-6)	
Local name	Propane-1,2-diol
WEL TWA (mg/m ³)	10 mg/m ³ particulates 474 mg/m ³ total vapour and particulates
WEL TWA (ppm)	150 ppm total vapour and particulates

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protective equipment:

Safety glasses. Gloves.

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment



Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rai
SDS	Safety Data Sheet
vPvB	Very Persistent and Very Bioaccumulative

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Sensitisation — Skin, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H335	May cause respiratory irritation
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product