

# ACEITE DE ROMERO

## INFORMACIÓN REGULATORIA DEL PRODUCTO (PRI)

### PRODUCT INFORMATION

#### INCI name of the ingredients:

PCPC		Origin of the raw material	Geographical origin*
Helianthus Annuus (Sunflower) Seed Oil	95 - 99 %	Vegetal	---
Rosmarinus Officinalis (Rosemary) Leaf Extract	1 - 5 %	Vegetal	Spain, Tunisia
<i>Antioxidants</i>			
Ascorbyl Palmitate	0,0050 - 0,0150 %	Vegetal	---
BHT	0,0300 - 0,0400 %	Synthetic	---

\* GRAN VELADA reserves the right to change the geographical origin in the case of having any supplying problems

**Animal Testing:** This product has not been the subject of animal testing for cosmetic purposes by or on behalf of this company.

**Sustainability/Social Responsibility:** This product has been developed following the CSR policy of GRAN VELADA, minimizing the environmental impact of the activities and managing resources sustainably and responsibly. In GRAN VELADA we contribute to social, occupational, environmental and economic improvements in our surrounding area.

**GMO-Status:** Ingredients used in the manufacture of GRAN VELADA products do not come from genetically modified organisms (GMO).

**BSE-Status:** This product does not contain any material derived from tissues included on the list of Specified Risk Materials laid down in Decision 97/534/EC concerning transmissible bovine spongiform encephalopathy (BSE). Subsequent directives 97/1/EC, 98/16/EC and 2000/6/EC are also contemplated.

**Nanomaterials:** According to the definition of nanomaterial in accordance with REACH legislation set out in the 2011 European Commission recommendation (2011/696/EU) and the definition proposed by the Cosmetic Regulations (EC) No. 1223/2009 (Chapter I, Article 2), the ingredients of this product are not classified as nanomaterials.

**CMR-Status:** According to our knowledge none of the ingredients contained in this product is classified as carcinogenic, mutagenic or toxic for reproduction in accordance with Annex VI of Regulation (EC) No. 1272/2008 and its latest updates, therefore the presence of substance classified as CMR in this product is not expected to be found, and the eventual presence of traces of these substances would be technically unavoidable following the Good Manufacturing Practices.

**California Proposition 65:** The ingredients contained in this product are not listed by the State of California as substances that may cause cancer or other reproductive harm, according to the latest updated list.

**VOC ( Volatile Organic Compounds ):** According to European Commission Directive 99/13/EC, the ingredients of this product are not classified as VOC (Volatile Organic Compounds).

**Palm Oil:** According to the information given by our raw material supplier, the ingredient Ascorbyl Palmitate used in this product is derived from Palm oil RSPO certified, through the Mass Balance and Segregated Supply Chain Models (MB/SG).

**Presence of formol:** This product does not contain formol and is not able to give formaldehyde.

**Latex:** According to the manufacturing process and raw material used this product does not contain latex.

## ALLERGENS

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**Cosmetic allergens:** The raw materials and the method of production used, permit to assure that the product contains less than 20 ppm of total limonene and linalool. These substances are considered as allergenic by the current European cosmetics legislation.

**Food Allergens:** According to the European Parliament and Council Regulation (EU) No. 1169/2011, the following substances have been identified as main responsible for food allergies or intolerances.

Substances or products causing allergies or intolerances listed in Annex II of Regulation (EU) No. 1169/2011	Presence
Cereals containing gluten (namely: wheat, rye, barley, oats, spelled, kamut or their crossbred varieties)	No
Crustaceans	No
Eggs	No
Fish	No
Peanuts	No
Soybeans	No
Milk (including lactose)	No
Nuts, namely almonds, hazelnuts, walnuts, cashews, pecans, Brazil nuts, pistachios, macadamia nuts or Australian nuts	No
Celery	No
Mustard	No
Sesame	No
Sulfur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO <sub>2</sub> .	No
Lupin	No
Molluscs	No

**Gluten- Status:** According to Regulation (EU) N° 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food, a food can be considered "gluten-free" if gluten content does not exceed 20 ppm. According to this definition, this product can be considered gluten-free.

## IMPURITIES

**Aflatoxin:** This product complies with aflatoxin limits set out in the United States Pharmacopeia (USP), section 561.

**Diethylene glycol/glycol ethers:** This product does not contain Diethylene Glycol or any glycol ethers, such as DEGEE, EDGME, EGBA or DEDGME.

**1,4 dioxane:** The 1,4 dioxane content is not analyzed on this product. However, according to the raw materials used and the manufacturing process, the presence of 1,4 dioxane in this product is not expected to be found.

**Phthalates:** This product does not contain phthalates such as Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP), Diethylhexyl phthalate (DEHP), Diisononyl phthalate (DINP), Di-n-octyl phthalate (DNOP), Diisodecyl phthalate (DIDP) and Diethyl phthalate (DEP).

**Heavy metals:** Heavy metal content is not analyzed on this product. However, according to the raw materials used and the production process, the eventual presence of total heavy metals in this product would be technically unavoidable and lower than 10 ppm.

**Pesticides:** This product complies with residual pesticide limits set out in the European Pharmacopoeia, cv, chapter 2.8.13.

**Residual Solvents:** This product complies with residual solvent limits set out in the European Pharmacopoeia, cv, chapter 5.4.

## REGULATORY INFORMATION

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### Cosmetic legislation

**Europe:** This product complies with Regulation (EC) No. 1223/2009 and it does not contain any substance prohibited for use in cosmetics.

#### Other areas:

Country/Area	YES/NO	Remarks
USA	Yes	
Japan	Yes	
Australia	Yes	
MERCOSUR	Yes	
ASEAN	Yes	
China	Yes	This product can be used in China, according to the latest version of the IECIC list.
Korea	Yes	
Canada	Yes	

### Chemical legislation

**Europe:** This product complies with EC Regulation No. 1907/2006 (REACH) and its latest adaptations. Furthermore, none of its ingredients are classified as SVHC (Substances of Very High Concern) or as PBT/vPvB (Persistent, Bioaccumulative and Toxic Substances) according to the latest updated list.

The following table shows registration status (REACH) of components in this product:

INCI	Registry	Registration exemption
Helianthus Annuus (Sunflower) Seed Oil	---	Exempt (Annex V, paragraph 9)
Rosmarinus Officinalis (Rosemary) Leaf Extract	---	Exempt due to the fact it is commercialized in quantity less than 1 ton per year
Ascorbyl Palmitate	01-2120769098-41-xxxx	---
BHT	01-2119565113-46-xxxx	---

Exempt substances per tonnage will be registered within the periods imposed by the REACH if they exceed 1 ton per year

#### Other areas:

INVENTORIES	Australia (AIC)	Canada (DSL)	China (IECSC)	Japan (ENCS, ISHL)	Philippines (PICCS)	USA (TSCA)
Rosmarinus Officinalis (Rosemary) Leaf Extract	Yes	Yes	Yes	No	Yes	No
Helianthus Annuus (Sunflower) Seed Oil	Yes	Yes	Yes	No	Yes	Yes
Ascorbyl Palmitate	Yes	Yes	Yes	Yes	Yes	Yes
BHT	Yes	Yes	Yes	Yes	Yes	Yes

#### Other legislations and standards

**Cosmos Standard:** This product is not certified and it is not compliant with the Cosmos Standard for Natural and Organic Cosmetics (in accordance with the latest version).

**ISO16128 Standard:** According to the definitions and calculation methods established in the ISO16128 standard (Part 1 and Part 2), the resulting naturalness indexes for this product are the following:

- Natural Index/Natural Content: 99,95%
- Natural Origin Index/Natural Origin Content: 99,97%
- Organic Index/Organic Content: 0%
- Organic Origin Index/Organic Origin Content: 0%

These values correspond to the calculation method defined in ISO 16128 guidelines and may vary from other organic and natural product guidelines and calculation systems.

**Natrue Standard:** This product is not certified, and it is not compliant with the NATRUE Standard for Natural and Organic Cosmetics (in accordance with the latest version).

**Halal:** This product meets Halal requirements and it is certified.

**Vegan:** This product does not contain raw material from animal origin, and none processing aid from animal origin are used during the manufacturing process, therefore this product meets Vegan requirements, but it is not certified.

**CITES:** This product is not affected by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

**Nagoya Protocol and ABS legislations:** This product is not affected by the Nagoya Protocol due to its launch date, because no R+D studies have been conducted and/or because of the origin of its raw materials. However, it is the obligation of the responsible of the finished cosmetic to check if the activities performed with this ingredient are affected in any country by the Nagoya Protocol or equivalent ABS legislation.

Note: This information is provided in good faith merely for informative purposes. GRAN VELADA has taken reasonable care to ensure that it is correct and reliable. However, due to the fact that this information is prepared using data provided by sources over which GRAN VELADA does not always have control and whose verification and collation is not always possible, GRAN VELADA assumes no responsibility for damages, losses or expenses arising from the use of this information, including those derived from the existence of possible intellectual property rights, in particular patent rights. GRAN VELADA reserves the right to modify and/or update the information provided herewith and assumes no obligation to communicate these changes. This information does not relieve the customer of their obligation to ensure regulatory compliance of their product. This document has been issued electronically and is valid without signature. For more information, please contact your local GRAN VELADA representative.