

## PRODUCT REGULATORY INFORMATION

ES.05-PG.01-FOR.04 Rev.01



Product name: **GREEN TEA - ECO<sup>1</sup>** (Code: 4861000G)

Manufacturer: **PROVITAL, S.A.**

Version and date: **v. 15 – APR/2023**

## PRODUCT INFORMATION

### INCI name of the ingredients:

PCPC		Origin of the raw material	Geographical origin*
Glycerin	40 - 60 %	Vegetal	---
Water	40 - 60 %	Mineral	---
Camellia Sinensis Leaf Extract <sup>1</sup>	2 - 5 %	Vegetal	China
<i>Preservatives</i>			
Potassium Sorbate	0,2000 - 0,3000 %	Synthetic	---
Sodium Benzoate	0,2000 - 0,3000 %	Synthetic	---

\* Provital 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 PROVITAL, minimizing the environmental impact of the activities and managing resources sustainably and responsibly. In PROVITAL we contribute to social, occupational, environmental and economic improvements in our surrounding area.

**GMO-Status:** Ingredients used in the manufacture of Provital 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 set out by the European Commission, the ingredients of this product are not classified as nanomaterials.

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**Microplastic particles:** None of the ingredients contained in this product are classified as microplastic particles according to the definition proposed by the ECHA (European Chemicals Agency), and also does not contain intentionally added microplastic particles or release intentional or unintentionally microplastic particles into the environment.

**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 / Palm Kernel Oil:** Up to our knowledge and according to the information given by our suppliers, this product is not derived from and does not contain Palm Oil or Palm Kernel Oil.

**Irradiation:** This product has not been subject of ionizing radiation (with gamma or x-ray radiation) during or after the manufacturing process by or on behalf of this company.

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

**Silicones:** According to the manufacturing process and raw material used this product does not contain any type of silicones.

## ALLERGENS

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**Cosmetic allergens:** The following table shows the results of allergen analysis using GC-MS (GasChromatography/Mass Spectrometry)

Cosmetic allergens identified in Regulation (CE) No 1223/2009	Value (ppm)
Amyl cinnamal (CAS n° 122-40-7)	< 0.01*
Amylcinnamyl alcohol (CAS n° 101-85-9)	< 0.01*
Benzyl alcohol (CAS n° 100-51-6)	< 0.01*

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Benzyl salicylate(CAS n° 118-58-1)	< 0.01*
Cinnamyl alcohol (CAS n° 104-54-1)	< 0.01*
Cinnamal (CAS n° 104-55-2)	< 0.01*
Citral (CAS n° 5392-40-5)	< 0.01*
Coumarin (CAS n° 91-64-5)	< 0.01*
Eugenol (CAS n° 97-53-0)	< 0.01*
Geraniol (CAS n° 106-24-1)	< 0.01*
Hydroxy-citronellal (CAS n°107-75-5)	< 0.01*
Isoeugenol (CAS n°97-54-1)	< 0.01*
Anisyl alcohol(CAS n°105-13-5)	< 0.01*
Benzyl benzoate(CAS n° 120-51-4)	< 0.01*
Benzyl cinnamate (CAS n° 103-41-3)	< 0.01*
Citronello(CAS n° 106-22-9)	< 0.01*
Farnesol (CAS n° 4602-84-0)	< 0.01*
Hexyl cinnamaldehyde (CAS n°101-86-0)	< 0.01*
d-Limonene (CAS n°5989-27-5)	< 0.01*
Linalool (CAS n° 78-70-6)	< 0.01*
Methyl heptin carbonate (CAS n°111-12-6)	< 0.01*
a-Cetone (CAS n°127-51-5)	< 0.01*
Oak moss extract (CAS n°90028-68-5)	< 0.01*
Threemoss extract (CAS n°90028-67-4)	< 0.01*

\*Limit of detection

**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

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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:** According to our knowledge and in accordance with the information received from our suppliers, glycerin used in this product is from vegetal origin, with a minimum purity of 99.5%, USP grade, complies with the Ph. Eur. and contains < 0.1% of Diethylene Glycol (Diglycol) and < 0.1% of Ethylene Glycol. This product does not contain any glycol ether such as DEGEE, EDGME, EGBA and 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.

**Formaldehyde:** This product does not contain formaldehyde as an ingredient, and none of its compounds is capable of generating it.

**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.

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

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**Pesticides:** This product has been manufactured from certified organic plants, therefore no pesticides have been added during their cultivation.

**PFAS:** The content of per- and polyfluoroalkyl substances (PFAS) is not analyzed on this product. However, according to the raw materials used and the manufacturing process, the presence of PFAS substances in this product is not expected to be found.

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

**Theophylline:** The Theophylline content is not analyzed on this product. However, according to the raw materials used and the manufacturing process, the presence of Theophylline in this product is not expected to be found; and in case of eventual presence, they would be considered as technically unavoidable traces following the Good Manufacturing Practices.

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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. Submission Code on NMPA platform: 141847-01564-1497
Korea	Yes	
Canada	Yes	

### Chemical legislation

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**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
Glycerin	---	Exempt (Annex V, paragraph 9)
Water	---	Exempt Annex IV
Camellia Sinensis Leaf Extract <sup>1</sup>	---	Exempt due to the fact it is commercialized in quantity less than 1 ton per year
Potassium Sorbate	01-2119950315-41-xxxx	---
Sodium Benzoate	01-2119460683-35-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 (AIIIC)	Canada (DSL)	China (IECSC)	Japan (ENCS, ISHL)	Philippines (PICCS)	USA (TSCA)
Glycerin	Yes	Yes	Yes	Yes	Yes	Yes
Water	Yes	Yes	Yes	Yes	Yes	Yes
Camellia Sinensis Leaf Extract <sup>1</sup>	Yes	Yes	Yes	No	Yes	No
Potassium Sorbate	Yes	Yes	Yes	Yes	Yes	Yes
Sodium Benzoate	Yes	Yes	Yes	Yes	Yes	Yes

### Other legislations and standards

**COSMOS Standard:** This product is certified to the COSMOS-Standard for Natural and Organic Cosmetics (in accordance with its 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: 50,90%
- Natural Origin Index/Natural Origin Content: 99,60%
- Organic Index/Organic Content: 31,90%

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- Organic Origin Index/Organic Origin Content: 31,90%

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 complies with the NATRUE Standard for Natural and Organic Cosmetics (in accordance with the latest version), but it is not certified.

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

**Kosher:** This product meets Kosher requirements, but It is not 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.

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