

PRODUCT REGULATORY INFORMATION

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Product name: **STRIOVER™** (Code: 7291000G)

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

Version and date: **v. 03 – NOV/2019**

PRODUCT INFORMATION

INCI name of the ingredients:

PCPC [CTFA]		Origin of the raw material	Geographical origin*
Water	40 - 60 %	Mineral	---
Glycerin	40 - 60 %	Vegetal	---
Astragalus Membranaceus Root Extract	1,5 - 2,5 %	Vegetal	China
Codonopsis Pilosula Extract	1,5 - 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 prepared in accordance with the United Nations Sustainable Development Goals and the CSR policy of PROVITAL GROUP, minimising the environmental impact of the activities undertaken and managing the resources in a sustainable and responsible manner. At PROVITAL GROUP, we contribute towards the social, occupational, environmental and economic improvement of our environment.

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 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.

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.

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

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.

ALLERGENS

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

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

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Benzyl alcohol (CAS nº 100-51-6)	< 0.01*
Benzyl salicylate(CAS nº 118-58-1)	< 0.01*
Cinnamyl alcohol (CAS nº 104-54-1)	< 0.01*
Cinnamal (CAS nº 104-55-2)	< 0.01*
Citral (CAS nº 5392-40-5)	< 0.01*
Coumarin (CAS nº 91-64-5)	< 0.01*
Eugenol (CAS nº 97-53-0)	< 0.01*
Geraniol (CAS nº 106-24-1)	< 0.01*
Hydroxy-citronellal (CAS nº107-75-5)	< 0.01*
Isoeugenol (CAS nº97-54-1)	< 0.01*
Anisyl alcohol(CAS nº105-13-5)	< 0.01*
Benzyl benzoate(CAS nº 120-51-4)	< 0.01*
Benzyl cinnamate (CAS nº 103-41-3)	< 0.01*
Citronellol(CAS nº 106-22-9)	< 0.01*
Farnesol (CAS nº 4602-84-0)	< 0.01*
Hexyl cinnamaldehyde (CAS nº101-86-0)	< 0.01*
Lilial (CAS nº 80-54-6)	< 0.01*
d-Limonene (CAS nº5989-27-5)	< 0.01*
Linalool (CAS nº 78-70-6)	< 0.01*
Methyl heptin carbonate (CAS nº111-12-6)	< 0.01*
a-Cetone (CAS nº127-51-5)	< 0.01*
Oak moss extract (CAS nº90028-68-5)	< 0.01*
Threemoss extract (CAS nº90028-67-4)	< 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

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Sesame	No
Sulfur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO ₂ .	No
Lupin	No
Molluscs	No

Gluten- Status: According to Regulation (EU) No. 41/2009 regarding gluten intolerance (celiac disease), 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

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

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

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

1,4 dioxane: This product complies with 1,4 dioxane limits set out in the European Pharmacopoeia, cv, chapter 5.4.

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, USP grade 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.

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.

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

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MOSH/MOAH: The content of mineral oil aromatic hydrocarbons (MOAH) and mineral oil saturated hydrocarbons (MOSH) it is not analyzed in this product, however, according to the raw material and the manufacturing process used, its presence it is not expected to be found in this product.

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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	
Australia	Yes	Astragalus Membranaceus Root Extract and Codonopsis Pilosula Extract are exempt from registration, if complies with the current regulatory scheme for industrial chemicals requirements.
MERCOSUR	Yes	
ASEAN	Yes	
China	Yes	This product can be used in China, according to the latest version of the IECIC list.
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
Water	---	Exempt Annex IV
Glycerin	---	Exempt (Annex V, paragraph 9)
Astragalus Membranaceus Root Extract	---	Exempt due to the fact it is commercialized in quantity less than 1 ton per year
Codonopsis Pilosula Extract	---	Exempt due to the fact it is commercialized in quantity less than 1 ton per year
Potassium Sorbate	01-2119950315-41-xxxx	---

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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 (AICS)	Canada (DSL)	China (IECSC)	Japan (ENCS, ISHL)	Philippines (PICCS)	USA (TSCA)
Water	Yes	Yes	Yes	Yes	Yes	Yes
Glycerin	Yes	Yes	Yes	Yes	Yes	Yes
Astragalus Membranaceus Root Extract	No	No	No	No	No	No
Codonopsis Pilosula Extract	No	No	No	No	No	No
Sodium Benzoate	Yes	Yes	Yes	Yes	Yes	Yes
Potassium Sorbate	Yes	Yes	Yes	Yes	Yes	Yes

Other legislations

Cosmos certificate: This product complies with the COSMOS standard for Natural and Organic Cosmetics (in accordance with the latest version), but it is not certified.

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

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

Vegan Certificate: 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: 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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