

## 94168-WATER-SOLUBLE COLLAGEN

**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1. Identification of the substance or preparation**

Name: Water-soluble collagen

Bulk code: 94168

Internal code: 405209

Valid from bulk batch: 0115342

**1.2. Synonyms**

No information available.

**2. DESCRIPTION**

Appearance: Liquid

Colour: Opalescent

Odour: Almost odourless/characteristic

Origin: The product is manufactured from raw materials of strictly animal (marine) origin

Geographical origin: Republic of Equatorial Guinea

**3. COMPOSITION/INFORMATION ON COMPONENTS**

CAS: 9007-34-5

EINECS: 232-697-4

INCI: Soluble Collagen

**Components:** Aqueous native collagen solution obtained from the fish species *Solea Solea*.

Collagen content: approximately 0.3%

Hydroxyproline content: &gt; 0.025 g/100 g

Water q.s. 100%

Preservative: Phenoxyethanol approximately 2%

**4. PHYSICO-CHEMICAL DATA**

For more information, see the analysis report.

**Solubility:** Soluble in water in any proportion. Insoluble in oils and fats.**5. PROPERTIES/USES**

Cosmetic use.

It is recommended for use in cosmetic formulations (excluding oral hygiene products, paediatric cosmetic products and those intended for use during pregnancy and breastfeeding).

It is a skin moisturiser that is usually added into emulsions, serums and gels.

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**6. DOSAGE**

2.0–5.0 %

It is recommended to add at the end of the formulation, at temperatures below 27°C.

**7. REMARKS****STORAGE:**

Store at a controlled temperature, in a refrigerator, in a dry place, protected from sunlight in a hermetically sealed container. A slight deposit may form at the bottom of the container, so it is recommended to shake it before use.

The documentation available related to the product's regulatory compliance is included below.

**BSE/TSE:**

The product does not contain and does not come into contact with “animal risk materials” as defined in Regulation (EC) 1069/2009: Class 1 and 2 materials and ingredients derived therefrom. It also does not contain, derive from and does not come into contact with “specified risk materials” as defined in the EU “Guidance note on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products” (EMA/410/01 rev.3). The product does not come into contact with animal risk materials/specified risk materials.

**GMOs:**

The product does not contain genetically modified organisms (GMOs).

**CMR:**

It does not contain substances classified as Class 1A, 1B or 2 carcinogenic, mutagenic or toxic for reproduction (CMR), according to Regulation (EC) 1272/2008 and its amendments, nor substances listed by the IARC or by the NTP, and thus they are not expected to be present. However, trace levels (technically unavoidable when following good manufacturing practices) of such substances may be present.

**SVHC:**

The product does not contain any of the substances listed as SVHCs in the latest ECHA Candidate List update, nor does it contain substances listed in Annex XIV to REACH or Annex XVII to the Restricted Substances List, and all products used during the manufacturing process comply with REACH requirements.

**MICROPLASTICS:**

The product is not a polymer, nor does it contain polymers as defined in Article 3 (5) of Regulation (EC) 1907/2006. Consequently, the product does not fall within the definition of microplastics and does not contain microplastics.

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**94168-WATER-SOLUBLE COLLAGEN****VOCs:**

The product is compliant with Directive (EU) 2010/75 of the European Parliament and of the Council of 24 November 2010 on industrial emissions and California air pollution control laws.

**IRRADIATION:**

The product has been radiosterilised with gamma rays during or after manufacture.

**COLOURANTS/PRESERVATIVES:**

The product may contain restricted substances (i.e., authorised preservatives, colourants, etc.) listed in other annexes to the European Cosmetics Regulation under the limits and within the conditions set forth in the following annexes:

- Annex IV: List of colourants allowed in cosmetic products.
- Annex V: List of preservatives that cosmetic products may contain.
- Annex VI: List of UV filters that cosmetic products may contain.

The presence of such restricted substances (if any) and the levels of use are mentioned in the product safety data sheet.

**RESIDUAL SOLVENTS:**

No solvent listed in Appendix 1 to the Harmonised ICH Guideline (Guideline for residual solvents Q3C (R), updated 22 April 2021) or diethylene glycol is used. Based on the manufacturing process, significant levels of solvents (Class 1, Class 2 and Class 3 and all other solvents) are not expected to be present. However, there may be undetectable and technically unavoidable trace levels resulting from good manufacturing practices.

**HEAVY METALS:**

In accordance with ICH Q9 and based on current knowledge of the ingredient manufacturing process (catalyst if any/reagents, equipment) and the environment (GMP), heavy metals are not expected to be present (except technically unavoidable traces derived from good manufacturing practices).

**ALLERGENS:**

- **Food allergens:** According to Regulation (EU) 1169/2011 and the US Food Allergen Labelling and Consumer Protection Act of 2004 (Public Law 108-282, Title II) and its amendments, the product may contain fish and related products. The presence of other allergens included in these regulations, such as gluten, are not expected to be present. Still, trace levels (technically unavoidable derived from the manufacturing process) of other food allergens may be present.
- **Cosmetic allergens:** The product does not contain, or contains unquantifiable traces of, any of the 26 allergenic substances listed in Annex III to Cosmetic Products Regulation (EC) 1223/2009. The product does not contain any of the prohibited substances listed in Annex II to Regulation (EC) 1223/2009. The product may contain restricted substances (i.e., authorised preservatives, colourants, etc.) listed in other annexes to the European Cosmetics Regulation under the limits and within the set conditions:
  - Annex III: List of substances that cosmetic products must not contain except subject to the restrictions and conditions laid down.



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The presence of such restricted substances (if any) and the levels of use are mentioned in the product safety data sheet.

**VEGAN:**

The product contains fish, so it is not suitable for vegan consumption.

**TESTED ON ANIMALS:**

The product has not been tested on animals for cosmetic purposes.

**CITES:**

The species of origin do not require CITES declaration.

**ISO 16128:**

Based on the calculations defined in ISO 16128-1 and 16128-2, the natural content of the product is:

- Natural content (NC): 0%
- Natural origin content (NOC): 0%
- Organic content (OC): 0%
- Organic origin content (OOC): 0%

**REACH:**

Fully complies with Regulation (EC) 1907/2006 (REACH) as all substances are excluded from the regulation and/or are exempt from registration and/or are registered.

**COSMETICS REGULATIONS:**

Status of ingredient regulations for cosmetic and personal care applications.

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<b>EUROPE</b> (European Cosmetic Regulation 1223/2009 and its amendments)	Approved
<b>U.S.A.</b> (FD&C Act— 21 CFR 700 to 740)	Approved
<b>CANADA</b> (Food and Drugs Act and Cosmetic Regulations)	Approved
<b>MERCOSUR:</b> Argentina, Brazil, Paraguay and Uruguay; with association agreements with Chile and Bolivia (Regulation for Personal Hygiene Products, Cosmetics & Perfumes)	Approved
<b>AUSTRALIA</b> (Notification & Assessment Act 1989, as amended—TGA)	Approved
<b>JAPAN</b> (Pharmaceutical Affairs Law - regulations for cosmetics)	Approved
<b>KOREA</b> (Cosmetics Law - Korea Food & Drug Administration KFDA)	Approved
<b>TAIWAN</b>	Approved
<b>ASEAN:</b> Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, VietNam (ASEAN Cosmetic Directive)	Approved
<b>INDIA</b> (provisions of Indian Drug and Cosmetic Act)	Approved
<b>Commonwealth of Independent States (CIS)</b> Official members: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Uzbekistan Unofficial associate members: Turkmenistan, Ukraine	Approved
<b>Gulf Cooperation Council (GCC)</b> Official members: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE (United Arab Emirates)	Approved
U.S.A.: Substances that are regulated under other federal regulations, including food additives, drug, cosmetics ... are not subject to TSCA including food additives, drug, cosmetics ... are not subject to TSCA regulation. Canada: Substances not listed on DSL or NDSL can be imported in Canada in quantities not exceeding 100 kg per 12-month period and per importer. In addition, substances not listed in DSL or NDSL, but listed in the "in-commerce list" (ICL) can be freely used in Products Regulated Under the Food and Drugs Act (F&DA). In addition, substances considered as "Natural" according Health Canada's definition are exempted from New Substances regulation.	
Australia: Substances Introduced at 1% or less in cosmetics are exempted from AICS listing. Otherwise, substances not listed on AICS can be imported in Australia in quantities not exceeding 10 kg per 12-month period and per importer. In addition, in the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act), an industrial chemical which meets the definition of 'a naturally-occurring chemical' is taken to be on the Australian Inventory of Chemical Substances (AICS), whether listed or not, and therefore does not require notification as a new chemical prior to manufacture or importation into Australia.	

### REGULATORY STATUS OF THE INGREDIENT FOR BORDER-LINE APPLICATIONS

	Status	Denomination	Identifier	Additional information
<b>AUSTRALIA</b> Therapeutic goods (TGA)	Approved	Collagen	52976	Available for use as an Active Ingredient in: Biologicals, Export Only, Prescription Medicines Available for use as an Excipient Ingredient in: Biologicals, Export Only, Listed Medicines, Prescription Medicines
<b>JAPAN</b> QUASI-DRUGS	Approved	Water-soluble Collagen	503070	No limit
<b>AUSTRALIA:</b> Australia has a two-tiered system for the regulation of medicines, including complementary medicines: Registered Medicines: higher risk medicines must be registered on the Australian Register of Therapeutic Goods (ARTG), which involves individually evaluating the quality, safety and effectiveness of the product. Listed Medicines: lower risk medicines containing pre-approved, low-risk ingredients. Ingredients must be evaluated and included in the Therapeutic Goods (Permissible Ingredients) Determination before they can be used listed medicines.				
<b>JAPAN:</b> Quasi-drugs include Mouth wash products (for disinfection of the mouth); Deodorants; Talc powder (with active ingredient); Hair-growth products; Depilatories; Hair dyes (oxidative); Bath preparations (with active ingredients); Permanent wave products; Medicated cosmetics (including anti-dandruff shampoos and rinses, Leave-on acne products for prevention of acne, anti-chapping and anti-frostbite lotions, whitening products and anti-bacterial products); Medicated toothpastes ...				



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### COSMETIC INVENTORIES:

NATIONAL INVENTORIES					
	U.S.A. (TSCA)	Canada (DSL/NDSL)	Australia (AICS)	China (IECSC)	Other inventories
Soluble Collagen	Listed	DSL listed	Listed	Listed	Collagens (TSCA, DSL, EINECS, AICS, ECL, PICCS, ASIA-PAC, NZIoC) (or Peptones (English, French) (TSCA, DSL, AICS, ECL, PICCS, ASIA-PAC, NZIoC))
U.S.A.: Substances that are regulated under other federal regulations, including food additives, drug, cosmetics ... are not subject to TSCA regulation. "Naturally occurring substances" are not subject to Premanufacture Notice reporting. Canada: Substances not listed on DSL or NDSL can be imported in Canada in quantities not exceeding 100 kg per 12-month period and per importer. In addition, substances not listed in DSL or NDSL, but listed in the "in-commerce list" can be freely used in Products Regulated Under the Food and Drugs Act (F&DA). In addition, substances considered as "Natural" according Health Canada's definition are exempted from New Substances regulation. Australia: Substances Introduced at 1% or less in cosmetics are exempted from AICS listing. Otherwise, substances not listed on AICS can be imported in Australia in quantities not exceeding 10 kg per 12-month period and per importer. In addition, in the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act), an industrial chemical which meets the definition of 'a naturally-occurring chemical' is taken to be on the Australian Inventory of Chemical Substances (AICS), whether listed or not, and therefore does not require notification as a new chemical prior to manufacture or importation into Australia.					

### CSAR:

The product is approved according to China's Hygienic Standard for Cosmetics and listed in the IECIC 2015. CSAR is not available.