

## 5432-HYDROLYSED COLLAGEN

### 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

#### 1.1. Identification of the substance or preparation.

Name: Hydrolysed collagen

Bulk code: 5432

Internal code: 405277

Valid from bulk batch: 0116402

#### 1.2. Synonyms.

No information available.

### 2. DESCRIPTION.

Appearance: Powder/microgranulate.

Colour: White (dry), colourless/slightly yellowish (aqueous solution).

Odour: Neutral.

Origin: Marine.

Geographical origin of the product: Manufactured in Europe.

Origin of the raw material:

Species	Area of origin
Pangasius hypophthalmus	Asia
Tilapia / Oreochromis niloticus	North and South America, Asia
Catfish	Europe, North America, Asia
Cod / Gadus morhua	Europe
Haddock / Melanogrammus aeglefinus	Europe
Nile perch / Lates niloticus	Africa
Cobia / Rachycentron canadum	North America
Redfish / Sebastes	Europe

### 3. COMPOSITION/INFORMATION ON COMPONENTS.

CAS: 92113-31-0

EINECS: 295-635-5

INCI: Hydrolysed collagen

Composition: 100% hydrolysed collagen. Collagen is considered a natural, soluble protein according to European Regulation 853/2004/EC. The product contains type I collagen (95-97%) and type III collagen (3-5%).

**Method of production:** Dehydrated animal-protein product. The collagen is made via processes that do not alter the primary chemical structure of the native natural collagen present in the fish's skin.

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For more information, see the analysis report.

**Solubility:** The product is soluble in an aqueous liquid medium.

**5. PROPERTIES/USES.**

Cosmetic use.

Food use.

The product is not considered a food additive, according to European, US and Canadian regulations.

Collagen is a food ingredient produced exclusively from the skin of fish suitable for human consumption.

Collagen complies with the definition of a natural food ingredient according to the ISO's technical specification for food ingredients to be considered natural.

**6. DOSAGE.**

Food use:

- Anti-aging effect, improved skin suppleness, musculoskeletal improvements: from 2.5 to 10 g/day.

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

Store at room temperature in a cool, dry place in a tightly closed container, away from sunlight and ignition sources.

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

**BSE/TSE:**

The product is free of BSE/TSE since it comes exclusively from fish skin as a starting raw material.

Therefore, there is no risk of BSE/TSE and there are no special regulatory requirements concerning BSE in this type of collagen.

**GMOs:**

Collagen manufacturing does not involve genetically modified materials.

All raw materials used to produce collagen come from animals that have been certified as suitable for human consumption by officially authorised veterinarians.

The aforementioned product is made exclusively from animal raw material and, as such, is free from GMOs.

The additives and processing aids used in the process do not come from genetically modified products either.

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Collagen is not subject to specific GMO labelling requirements according to Regulation (EC) No. 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

**CMR:**

The product does not present a CMR risk.

**SVHC:**

The product does not contain SVHC.

**NANOMATERIALS:**

No nanomaterials are used in the product and it does not need to be labelled as a nanomaterial.

**IRRADIATION:**

The product has not undergone any type of ionising radiation and does not contain radioactivity. The product has a radioactivity control plan in place.

**RESIDUAL SOLVENTS:**

The product is compliant with the following analysis:

- European Pharmacopoeia 5.4. "Residual Solvents"
- General Chapter <467> USP "Residual Solvents"
- Part of the ICH Guide Q3C "Residual Solvents"
- European Directive 2009/32/EC on residual solvents in foodstuffs.

**PESTICIDES:**

Collagen is a highly purified protein made from healthy raw materials obtained from animals suitable for human consumption. The aforementioned collagen is not affected by European regulation 396/2005/EC on pesticides.

The regulations applicable to collagen in Europe do not consider the risk of pesticide in gelatine.

No pesticides are used in the process to produce the aforementioned product.

The collagen manufacturing process (with extractions and purifications) leads to a final purified collagen that is not considered hazardous regarding contamination due to pesticides. Consequently, the aforementioned product does not present any risks regarding contamination due to pesticides.

**IMPURITIES:**

- Dioxins: All the fish skins the manufacturer purchases to produce collagen come from healthy animals that are suitable for human consumption. Dioxins only accumulate in fatty tissues. As collagen is a pure protein that contains less than 0.02% of fat, the level of dioxin that could be present in the collagen is very low, much less than 1 ng TEQ/kg. European Regulation (EC) No. 1881/2006 of 19 December 2006 sets out maximum levels for dioxins and PCBs in meat, meat products and animal fat from ruminants, poultry, pigs and fish, and also in milk and eggs. The Regulation's maximum levels do not apply to foodstuffs containing less than 2% of fat, such as collagen. This regulation confirms that collagen must be considered safe in terms of the risk of

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dioxins and PCBs. The manufacturer has a periodic control plan in place, through which the results of the analyses carried out confirm that the level of dioxins is below the acceptable limit of 3.5 pg/g for fish products and their derivatives.

- Melamine: Melamine is not used in the product manufacturing process. Furthermore, the manufacturer has established an annual control plan for melamine and cyanuric acid, and the results obtained are below the quantification limits.
- Mycotoxins: The product does not present a risk of contamination due to mycotoxins.

**HEAVY METALS:**

The product's specification complies with the applicable limit values for heavy metals (Regulation 853/2004/EC).

Metal catalysis is not used in the product's manufacturing process. Furthermore, no catalysts are added to the collagen.

**ALLERGENS:**

- **Food allergens:** The product does not contain any of the allergens detailed in Annex II to European Regulation 1169/2011/EC, except for fish and related products. The product does not contain gluten, nor is it likely to suffer cross-contamination with gluten during the manufacturing process.
- **Cosmetic allergens:** The product does not contain any of the allergens listed in Annex III of Regulation (EC) 1223/2009.

**TESTED ON ANIMALS:**

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

**RSPO:**

Not applicable.

**ISO 16128:**

Not applicable.

**REACH:**

Exempt from registration for being natural polymers.

Gelatine and collagen are not classed as hazardous in accordance with Directive 67/548/EEC and Regulation 1272/2008/EC.