

5432-HYDROLYZED COLLAGEN

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1. Identification of the substance or preparation.

Name: Hydrolyzed collagen

Bulk code: 5432

Internal code: 405277

Valid from bulk lot: 130822

1.2. Synonyms.

No data available.

2. DESCRIPTION.

Appearance: Powder/ microgranulate .

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

Odor: Neutral.

Origin: Marine

Geographical origin of the product: Made in Europe.

Origin of 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 aeglephinus	Europe
Nile perch / Lates niloticus	Africa
Cobia / Rachycentron canadum	North America
Redfish / Sebastes	Europe

3. COMPOSITION/INFORMATION OF COMPONENTS.

Ingredients: 100% fish collagen

CAS: 92113-31-0

EINECS: 295-635-5

INCI: Hydrolyzed collagen

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

5432-HYDROLYZED COLLAGEN

Method of obtaining: Dehydrated substance of animal protein type. Collagen is manufactured through processes that do not alter the primary chemical structure of the native natural collagen present in fish skin.

4. PHYSICAL-CHEMICAL DATA.

For more detailed information, please refer to the analysis bulletin.

Solubility: The product is soluble in aqueous liquid medium.

5. PROPERTIES/USES.

Cosmetic use.

Food use.

6. DOSAGE.

No data available

7. OBSERVATIONS.

The documentation corresponding to the regulatory part of the product that is available for it is the one we reflect below.

NUTRITIONAL INFORMATION:

Please see the following nutritional information for this product:

	Typical values per 100 g
Energy	1593 kJ
Energy	381 kCal
Protein	95 g
Moisture	4,7 g
Carbohydrates	0
of which sugars	0
Totals Fats	0
of which saturated fats	0
of which trans fatty acids	0
Ash	0,3 g
of which sodium	0,1 g
Dietary Fibers	0
Vitamins	0

5432-HYDROLYZED COLLAGEN

ALLERGENS:

- **Food allergens:** In accordance with European Regulation 1169/2011/EC and in relation to allergens in ingredients, a list of the main allergens that must be labelled has been drawn up. Below you will find this list and the answers regarding our products mentioned above that comply with the regulations:

Allergen products	Contains	Free from
Eggs and egg and products thereof		X
Crustaceans and products thereof		X
Fish and products thereof	X	
Soya and products thereof		X
Peanut and products thereof		X
Milk and dairy products (including lactose)		X
Shellfruit and products thereof		X
Cereals with gluten (i.e. wheat, rye, barley, oat, epeautre, kamut and their hybrids) and products thereof		X
Sesame seeds, sesame and products thereof		X
Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO ₂		X
Celery and products thereof		X
Mustard and products thereof		X
Mollusks (gastropods, bivalves, etc.) and products thereof		X
Lupins and products thereof		X

STORAGE:

Store at room temperature in a cool, dry place, protected from light, with the container tightly closed and away from sources of ignition.

SHELF LIFE:

5 years. For more detailed information, please consult the analysis bulletin.

5432-HYDROLYZED COLLAGEN

LEGAL REQUIREMENTS:

The above mentioned product complies with EC Regulation 178/2002 and EC Regulation 852/2004.

The product complies with Regulation (EC) 1169/2011 regarding allergens.

BSE/TSE:

The product is BSE/TSE free as it is derived exclusively from fish skin as the starting raw material.

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

GMO:

Collagen manufacturing does not involve genetically modified materials.

All raw materials used for collagen production come from animals that have been **certified** as fit for human consumption by officially authorized veterinarians.

The aforementioned product is made exclusively from animal raw material, and as such, it is GMO-free. Neither the additives nor the processing aids used in the process come from genetically modified products.

Collagen is not subject to specific GMO labeling requirements according to Regulation (EC) No 1830/2003 on the traceability and labelling of GMOs and the traceability of products derived from them.

CMR:

The product does not present CMR risk.

SVHC:

The product does not contain SVHC substances.

NANOMATERIALS:

nanomaterials are used in the product and it is not susceptible to labelling as a nanomaterial .

IRRADIATION:

The product has not been treated with any type of ionizing radiation and does not contain radioactivity.

The product has a radioactivity control plan.

RESIDUAL SOLVENTS:

The product complies with the following analyses:

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

5432-HYDROLYZED COLLAGEN

PESTICIDES:

Collagen is a highly purified protein produced from healthy raw materials from animals fit for human consumption. The collagen mentioned above is not affected by the European regulation 396/2005/EC on pesticides.

The regulations applicable to collagen in Europe do not take into account the risk of pesticides in gelatin.

No pesticides are used in the production process of the above mentioned product.

The collagen manufacturing process (with extractions and purifications) leads to a purified final collagen, which is not considered hazardous with regard to pesticide contamination. Consequently, the above-mentioned product does not present any hazard regarding pesticide contamination.

IMPURITIES:

- **Dioxins:** All fish skin purchased by the manufacturer to produce collagen comes from healthy animals fit for human consumption. Dioxins accumulate only in fatty tissues. Since collagen is a pure protein containing less than 0.02% fat, the level of dioxin that could be present in collagen is very low, much less than 1 ng TEQ/kg. The European Regulation (EC) No 1881/2006 of 19 December 2006 establishes maximum levels of dioxins and PCBs in meat, meat products and animal fat from ruminants, poultry, pigs and fish and also in milk and eggs. The maximum levels of the Regulation are not applicable to food products containing less than 2% fat, such as collagen. This regulation confirms that collagen should be considered safe with regard to the risk of dioxins and PCBs. The manufacturer has a periodic monitoring plan, in which the results of the analyses confirm that the level of dioxins is below the acceptable limit of 3.5 pg /g for fishery products and their derivatives.
- **Melamine :** Melamine is not used during the manufacturing process of the product. In addition, the manufacturer has established an annual control plan on melamine and cyanuric acid and the results obtained are below the quantification limits.
- **Mycotoxins :** The product does not present a risk of contamination by mycotoxins .

HEAVY METALS:

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

The product is not manufactured using metal catalysis for its production. In addition, no catalytic agent is added to the collagen.

ALLERGENS:

- **Cosmetic allergens:** The product does not contain any of the allergenic substances 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.

5432-HYDROLYZED COLLAGEN**ISO 16128:**

Not applicable.

REACH:

Exempt from registration because they are natural polymers.

Gelatine and collagen are not classified as hazardous under Directive 67/548/EEC and Regulation 1272/2008/EC.