

90851-SODIUM HYALURONATE**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1 Identification of the substance or preparation**

Name: Sodium Hyaluronate

Bulk code: 90851

Internal code: 405029

Batch valid from: 0113192

1.2 Synonyms

Sodium hyaluronate/Hyaluronic Acid

2. DESCRIPTION

Appearance: Powder or granulate.

Colour: White or almost white.

Odour: Odourless.

Origin: Synthetic

Country of origin: China

3. COMPOSITION/INFORMATION ON COMPONENTSFórmula molecular: $(C_{14}H_{20}NO_{11}Na)_n$

CAS: 9067-32-7

EINECS: 232-678-0

Method of production: The starting material (glucose and soy peptone) is fermented by adding yeast powder (Thalli), generating a crude product. This product is dissolved and filtered to carry out an extraction. The precipitate obtained is dehydrated and dried, to proceed to refining the hyaluronic acid. This is inspected and finally packaged.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: Soluble in water and insoluble in ethanol.**5. PROPERTIES/USES**

Cosmetic use.

Oral use.

Not suitable for the manufacture of food supplements or foods.

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The product exhibits such functions as water retention, lubrication, viscosity, and good biocompatibility. Therefore it helps promote joint health and helps restore skin moisture and improve skin health.

6. DOSAGE

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

STORAGE:

Store at a controlled temperature between 2 and 8°C, in a dry place in a tightly closed container. Protect from sunlight and moisture.

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

BSE-TSE:

The product does not contain ingredients of ruminant origin or materials derived from or exposed to ruminants affected by, or quarantined from, transmissible spongiform encephalopathy (TSE) or bovine spongiform encephalopathy (BSE). Therefore, it is compliant with EU Regulation 999/2001.

GMO:

The product is GMO free and is not manufactured from GMO raw materials.

CMR:

The product does not contain carcinogenic, mutagenic or reprotoxic substances.

SVHC:

In accordance with Regulation 1223/2009, the product does not contain SVHC substances.

NANOTECHNOLOGY:

According to the definition of "nanomaterials" in EU Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of information to consumers, during the manufacturing process no nanomaterials are used in the formulation or packaging material of the product.

VOCs:

The product does not contain volatile organic compounds according to Directive 2004/42/EC -April 2004 and its amendments Dir. 1999/13/EC.

RADIATION:

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The product has not undergone irradiation or been treated with ionising radiation (1169/2011/EC).

ETHYLENE OXIDE:

The product has not been treated with ethylene oxide (ETO), 2-chloroethanol or any other sterilising chemical during the manufacturing, storage or transportation process, and neither is the use thereof allowed in the subcontracted manufacturing processes.

PESTICIDES:

The product is compliant with Regulation (EC) No 396/2005.

DYES/ PRESERVATIVES:

The product does not contain dyes or preservatives.

RESIDUAL SOLVENTS:

The product is compliant with Directive E 2010/59/EU of 26 August 2010 and its amendments Directive 2009/32/EC of the European Parliament and of the Council.

CONTAMINANTS:

The product is compliant with:

- Regulation (EC) No 1881/2006 and subsequent amendments as regards the maximum permitted level of the following contaminants:
 - o Aflatoxin B1
 - o Aflatoxins B1 + B2 + G1 + G2
 - o Ochratoxin
 - o Melamine
- Regulation (EC) No 2015/1933 amending Regulation (EC) No 1881/2006 as regards the maximum levels for polycyclic aromatic hydrocarbons, in particular:
 - o Benzo(a)pyrene, maximum level of 10 µg/kg.
 - o 50 µg/kg for the total combined amount of PAH4 (benzo[a]pyrene, chrysene, benzo[a]anthracene and benzo[b]fluoranthene) in food supplements.
- Regulation (EU) No. 594 / 2012 and its amendments present in Regulation (CE) No. 1881/2006):
 - o The product complies with the established limits of ochratoxin a contaminants, PCBS not analogous to dioxins and melamine in food products.
- The product does not contain:
 - o Dioxines
 - o Aflatoxines
 - o Latex
 - o Silicone

ELEMENTAL IMPURITIES:

The product complies with the limits of elemental impurities established in the legislation EMA/CHPM/ICH/323369/2013 "ICH Guideline Q3D on elemental impurities.

PROPOSITION CALIFORNIA 65:

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The product does not contain any of the substances listed in California Proposition 65 above the OEHHA allowable safe limits at the recommended dose level.

ALLERGENS:

- **Food allergens:** The product does not contain allergens referred to in Annex II to Regulation (EU) No 1169/2011.
- **Cosmetic allergens:** The product does not contain any of the substances listed in Annex II (prohibited substances), Annex III (substances subject to restrictions and conditions, including allergens), Annex IV (Colors subject to restrictions and conditions) and Annex V (Preservatives subject to restrictions and conditions) of the Cosmetic Regulation (EC) No. 1223/2009.

HALAL:

The product is Halal certified.

KOSHER:

The product is Kosher certified.

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian use.

The product does not come from animal origin, does not contain a (some) component(s) from animal origin and does not come into contact with any animal derived products during the process.

As a consequence, this product is suitable for vegetarians and vegans.

ANTI-DOPING STATEMENT:

According to the current World Anti-Doping Agency list, the ingredient is not a doping substance, nor a combination of doping substances. The ingredient does not contain any doping substances. The ingredient is not derived from a doping substance.

NUTRITIONAL INFORMATION:

ENERGY	UNITS	TYPICAL VALUES PER 100 G OF PRODUCT
Energy (total calories)	Kcal or kJ	0

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- Fat energy	Kcal or kJ	0
Protein	g	≤0.1
Carbohydrates (total), of which:	G	90.7
- Sugars	G	0
- Polyols	G	0
- Starch	G	0
Fat (total), of which:	G	0
- Saturated	G	0
- Monounsaturated	G	0
- Polyunsaturated	G	0
- Trans fat	G	0
- Cholesterol	mg	0
Dietary fibre	g	0
Sodium	mg	5.7
Potassium	mg	0
Calcium	mg	≤0.3%
Ash	g	≤13%
Moisture	g	≤10%
Vitamin A	ug	0
Vitamin B	mg	0
Vitamin C	mg	0
Vitamin D	IU	0
Vitamin E	IU	0

TESTED ON ANIMALS:

The product has not been tested on animals.

CITES:

The product does not contain ingredients listed in Annexes I, II and III of CITES

ECOCERT:

Have.

COSMOS:

Have.

RSPO:

The product does not contain palm oil or derivatives and it has not been used during the manufacturing process.

REACH:

Exempt from registration according to Article 2.5 of REACH.