



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

13.06.2023

Version:

4.0

4028-HYALURONIC FILLING SPHERES

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Hyaluronic Filling Spheres

Bulk code: 4028

Internal code: 47729

1.2 Synonyms.

No information available.

2. DESCRIPTION

Look: Translucent, viscous liquid.

Colour: White to off-white.

Odour: Characteristic.

Origin of components:

US INCI	SOURCE	DETAILS
Ethylhexyl Palmitate	Plant Petrochemical	Plant source: Palm country of origin: Malaysia/Indonesia Non-genetically modified product (supplier information).
Silica Dimethyl Silylate	Mineral	Manufactured in Germany
Butylene Glycol	Petrochemical	Manufactured in Japan
Sodium Hyaluronate	Biotechnological process	Obtained from the walls of the Streptococcus strain, using a culture medium not derived from animal sources (plant origin), with no genetically modified sequences (PCR testing)
Caprylyl Glycol	Petrochemical	Product manufactured in USA
Phenoxyethanol	Petrochemical	Product manufactured in USA
Hexylene Glycol	Petrochemical	Product manufactured in USA

Geographical origin of manufacture: France.

3. COMPOSITION/INFORMATION ON COMPONENTS.

CAS: 29806-73-3, 68611-44-9, 107-88-0, 9067-32-7, 1117-86-8, 122-99-6, 107-41-5.

INCI: Ethylhexyl Palmitate, Silica Dimethyl Silylate, Butylene Glycol, Sodium Hyaluronate, Caprylyl Glycol, Phenoxyethanol, Hexylene Glycol.

4028-HYALURONIC FILLING SPHERES**Composition:****Identity of Components**

US INCI	EU INCI	CAS No.	EINECS No.	Content
Ethylhexyl Palmitate	Ethylhexyl Palmitate	29806-73-3	249-862-1	95.3%
Silica Dimethyl Silylate	Silica Dimethyl Silylate	68611-44-9	271-893-4	2.5%
Butylene Glycol	Butylene Glycol	107-88-0	203-529-7	1.0%
Sodium Hyaluronate	Sodium Hyaluronate	9067-32-7	232-678-0	0.2%

Additives

US INCI	EU INCI	CAS No.	EINECS No.	Content
Caprylyl Glycol	Caprylyl Glycol	1117-86-8	214-254-7	0.5%
Phenoxyethanol	Phenoxyethanol	122-99-6	204-589-7	0.4%
Hexylene Glycol	Hexylene Glycol	107-41-5	203-489-0	0.1%

Method of production: Encapsulation.

4. PHYSICO-CHEMICAL DATA.

For more information, see the analysis report.

Solubility: The product does not disperse in water.

5. PROPERTIES/USES

Cosmetic use.

The product complies with cosmetic Regulation (EC) 1223/2009 and its amendments under typical conditions of use.

6. DOSAGE

Recommended dose: 0.5-3%

It is recommended that it be added to the oily phase of the emulsion at 80°C using moderate shaking. After obtaining a homogeneous phase, make the emulsion in the usual way.

Optimal temperature for use: 20-80°C.

Optimal pH: 4-8.

Not compatible with aqueous lotions, hydroalcoholic lotions, gels or foams.

Compatible with any kind of emulsion.



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7. REMARKS.

STORAGE:

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

The product should be shaken gently before use.

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

BSE/TSE:

Given the origins of the raw materials, the product is considered free of BSE/TSE.

GMOs:

Given the origins of the raw materials, the product is considered free of GMOs.

The product does not come from genetically modified plants, nor does it contain genetically modified DNA.

CMR:

Based on the starting raw materials and the manufacturing method, none of the CMR substances listed in Appendix VI of the CLP Regulation (EC) 1272/2008 are expected to be present. The product has not been tested.

SVHC:

Any substance that appears on the list of candidates for authorisation and whose content is greater than 0.1% will be described in section 3.2 of the updated version of the safety data sheet. If new substances should appear on the updated ECHA list, changes will be assessed and included in the aforementioned section of the safety data sheet.

NANOMATERIALS:

The product is not a nanomaterial according to the definition provided in Article 2 of Regulation (EC) No. 1223/2009 on cosmetic products.

Based on information concerning raw materials, the production process and the equipment used, no polymers (microplastics) are expected to be present and they are not added intentionally to the product either. Consequently, the product is not considered a microplastic in accordance with the ECHA's restrictions on the presence of microplastics.

VOCs:

None of the solvents listed in Appendix 1 (Article 2a) of the Swiss Ordinance on the Incentive Tax on Volatile Organic Compounds, RS 814.018, are expected to be present in



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the product at concentrations above the limit of 3% (limit set out in Article 8 on tax exemptions).

IRRADIATION:

Based on information concerning raw materials, the production process and the equipment used, no radioactive materials are expected to be present.

PESTICIDES:

Based on the results of random testing on the starting raw material or a representative sample, the presence of pesticides is compliant with the concentration limits set out in the Ph. Eur. table 2.8.13 of the latest version. (Pesticide residues).

PRESERVATIVES:

To stabilise the product, it contains the following preservatives:

1.0 Diocide (0.5% Caprylyl glycol, 0.4% Phenoxyethanol, 0.1% Hexylene glycol).

RESIDUAL SOLVENTS:

The product meets the ICH Guideline on Impurities: Residual Solvents (CPMP/ICH/283/95).

It may contain methanol (max. 20 ppm).

IMPURITIES/CONTAMINANTS:

Based on the starting raw material and the manufacturing method used, although they have not been tested, none of the following products are expected to be present:

- Glycol ethers (Butyl diglycol, Ethyl diglycol, 2-Butoxyethanol)
- Phthalates
- PAH (Benzo[a]pyrene, Fluoranthene, Benzo[b]fluoranthene, Benzo[k]fluoranthene, Benzo[ghi]perylene, Indeno[1,2,3,cd]pyrene).

The product may contain:

2-Ethylhexyl Alcohol: max. 2400 ppm (calculated)

2-Ethylhexyl Acid: max. 6700 ppm (calculated)

HEAVY METALS:

Based on the starting raw material and the manufacturing method used, none of these are expected to be present above 10 ppm, in accordance with the Ph. Eur. 2.4.8. (antimony, arsenic, lead, bismuth, cadmium, copper, mercury and tin).

CONFLICT MINERALS:

Based on the manufacturer's knowledge, no conflict minerals have been used in the manufacturing process.



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CALIFORNIA PROPOSITION 65:

Based on the information available on the starting raw material, the production process and the equipment used, the product may contain the substances indicated below as substances listed by the State of California in the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):

Methanol (CAS 67-56-1): 20 ppm (calculated).

NAGOYA PROTOCOL:

The product is outside the benefits/obligations of the Nagoya Protocol.

ALLERGENS:

- **Food allergens:** Based on the starting raw material and the manufacturing method used, gluten is not expected to be present in the product.
- **Cosmetic allergens:** Based on the starting raw material and the manufacturing method, none of the allergens listed in Appendix III of the Regulation 1223/2009 are expected to be present.

HALAL:

The product does not contain any ingredients of animal origin and/or ethanol.

- Ethanol is not used in our manufacturing process.
- No enzymes are used in the production process.
- The product does not come into contact with material of pig origin and/or ethanol during processing, transport and/or storage where the product is still correctly packaged.
- The facilities used for this product are not shared with pig products or by-products.

Furthermore, contamination risks are controlled on an ongoing basis and cleaning programmes are defined and set. All listed products have a renewable or synthetic base. The product is Halal certified.

VEGAN/VEGETARIAN:

The information in this document is provided for the "vegan" suitability assessment:

1. For manufacturing purposes, the definition of "animal" is given to all multicellular vertebrates and invertebrates.
2. Manufacturing does not involve, and has not involved, the use of any product, by-product or ingredient of animal origin.
3. Cross-contamination with animal substances is excluded/minimised as far as reasonably possible.
4. Where applicable, the use of genetically modified organisms (GMOs) has not included animal genes or substances of animal origin.
5. Unlike the EU's food regulation, cosmetic ingredient suppliers must generate toxicology data in order to be legally compatible.



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6. For the purposes of the chemical and cosmetic regulation, the definition of “animal” is that given in Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.
7. Tests on animals have not been carried out by the manufacturer, or on their behalf, in relation to the product's ingredients after 11 March 2009 and/or after the extension to the deadline of 11 March 2013 for the purpose of the Cosmetics Regulation (EU) 1223/2009.

The manufacturer of the end product is responsible for vegan labelling.

TESTED ON ANIMALS:

The product has not been tested on animals since March 2009 and after March 2013 (extended deadline for testing on animals for repeat doses and reproductive toxicity or toxicokinetics), respectively, for the purposes of the European Cosmetics Regulation (EC) 1223/2009.

CITES:

The product does not come from any of the species listed in CITES.

RSPO:

This product is RSPO-Mass Balance certified (INTERTEK 0100208).

The maximum percentage of parts derived from palm oil (PKO) in the product is 66.7%.

ISO 16128:

The natural origin percentage is calculated according to section 5 of the ISO 16128-2 Standard. As a product that does not contain water, it can be defined as:

Natural content in the formula: 0.0%

Content of natural origin in the formula: 66.8%

REACH:

2-Phenoxyethanol: REACH record number: 01-2119488943-21



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CHEMICAL INVENTORIES:

CHEMICAL INVENTORY	LISTED	REMARKS
Australia (AICS)	YES	
Canada (DSL)	YES	
China (IECSC)	YES	
Japan (ISHL)	YES	
Japan (ENCs/ISHL)	NO	
Korea (ECL) ***		Only for cosmetic use
New Zealand (NZIOC)	YES	
Philippines (PICCS)	YES	
Switzerland (CHEMINV)	YES	
Taiwan (TCSI)	YES	See ** for further explanations
USA (TSCA)		Only for cosmetic use

**) All of the aforementioned product ingredients have been pre-registered and/or registered (as a substance) by the manufacturer and/or are exempt. Thus, manufacture and/or import of the product named above may continue.

***) From 1 July 2019, each importer will require their own prior notification or a prior notification from the manufacturer as "only representative" for the import. According to the latest information (April 2019 statement), "cosmetic use" is exempt.

NMPA:

Not necessary. As the IECIC 2021 and the Positive List for Cosmetic Safety and Technical Standards (version 2015) can be used as references to identify if the product is present as a cosmetic product in China, a new cosmetic registration is not required.

However, NMPA has not carried out a safety assessment on all the cosmetic ingredients listed. In order to guarantee cosmetic product compliance, manufacturers must ensure they observe all regulations, standards and requirements, and perform a safety analysis on the final cosmetic product.