

## RAW MATERIAL DATA SHEET

# FaraHyal (cosmetic grade)

**PRODUCT IDENTIFICATION****Supplier name**

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**EU/US INCI name**

EU INCI name	US INCI name
Sodium Hyaluronate	Sodium Hyaluronate

**Regulatory information**

Empirical Formula: (C<sub>14</sub>H<sub>20</sub>NO<sub>11</sub>Na)

Chemical name: Sodium Hyaluronate

Common name	CAS n.	EC n.	Composition
Sodium Hyaluronate	9067-32-7	--- (polymer)	100%

- US and European Pharmacopoeia: Not applicable
- Classification & labelling according to EU Chemical regulation: this product is not subjected to labelling as it is not a dangerous substance (regulation 1272/2008).
- Transport: not regulated
- Tariff code: 3913900090

**Functions**

Humectant; Skin conditioning

**Geographical Origin**

Produced in China

**REGULATORY STATUS****Chemical Inventory position**

- Component(s) listed in EU Inventory: yes (Sodium Hyaluronate)
- Component(s) listed in IECSC (China): yes (Sodium Hyaluronate)
- Component(s) listed in TSCA (USA): no
- Component(s) listed in NZIoC (New Zeland): yes (Sodium Hyaluronate)
- Component(s) listed in TCSI (Taiwan): no
- Component(s) listed in ECNS (Japan): no
- Component(s) listed in KECI (Korea): no
- Component(s) listed in PICCS (Philippines): no
- Component(s) listed in AICS (Australia): yes (Sodium Hyaluronate)

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- Component(s) listed in DSL (Canada): yes (Sodium Hyaluronate)
- Component(s) listed in Proposition 65 (California): not listed

## Cosmetic Regulatory Status

- No restrictions in Europe.
- Other countries: Sodium Hyaluronate is accepted in most other legislative areas. Please refer to your local legislation of interest.
- Restriction or limitation for personal care applications: no
- Canadian cosmetic ingredient hotlist: no
- Component listed in Cosmetic China IECIC: yes

## Cosmetic Regulatory Conformity

- Regulatory Conformity: Sodium Hyaluronate is in line with Cosmetics Regulation 1223/2009 and further amendments. It does not contain any of restricted or prohibited substances listed in Annex II and Annex III of cosmetics regulation.
- CMR: Sodium Hyaluronate does not contain any substances intentionally added and classified as Carcinogenic, Mutagenic or Reprotoxic substances.
- Allergens: We certify that Sodium Hyaluronate complies with Regulation (EC) 1223/2009 regarding the presence of the 26 substances identified as allergenic in cosmetics. Due to the nature of the materials used for our productions and to bibliographic data, it can be stated that these allergens are absent.
- TSE/BSE: We confirm that Sodium Hyaluronate does not contain any animal raw material, therefore it is free from BSE/TSE transmitting agents.
- Animal testing: we declare that no animal testing was made by Farachem and the product manufacturer for cosmetic use according to Regulation (EC) 1223/2009.
- Ionization: the product is not subjected to ionization process.
- REACH: According to Article 2(9), polymers are exempted from the provisions on regulation of Title II of REACH.
- Sodium Hyaluronate meets the criteria set for a polymer defined in Article 3(5). Its monomers can be considered as non-isolated intermediates, for which REACH regulation is not applicable according to Article 2(1).
- Based on the available data, the criteria for exemption from REACH registration are fulfilled for Sodium Hyaluronate (CAS: 9067-32-7).

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## TOXICOLOGY ECOTOXICITY & BIODEGRADABILITY INFORMATION

### Toxicological information

#### **Tests for cosmetic safety evaluation (sponsored by the company)**

- Skin irritation test: NOT IRRITANT (method: MTT/ %Tested: 0.5% & 0.1% / Date: April 2009)
- Ocular irritation test: NOT IRRITANT (method: Red Blood Cell Test/ %Tested: 1% & 10% / Date: April 2009)
- Skin sensitization test: NON SENSITIZING (method: Repeated Patch test / %Tested: Pure 100% / Date: April 2009)
- Mutagenicity test: Not available
- Photo toxicity test/ Photo allergenicity: test Not available

#### **Bibliographic data\***

- Eye irritation (Draize test): non irritant
- Skin irritation: non-irritant
- Skin sensitization: non sensitizing
- NOAEL: Sodium Hyaluronate: 60 mg/Kg
- Following our bibliographic research on our raw material, to date no scientific data and/or reference has been found which could be interpreted as a sign of toxicity. This led us to assume it is not toxic when used at normal dose.

\*CIR- Final Report of the Safety Assessment of Hyaluronic Acid, Potassium Hyaluronate, and Sodium Hyaluronate. (July/August 2009)

### Ecological & Biodegradability information

Biodegradability: expected to be biodegradable

#### **Unavoidable impurities and possible traces of contaminants**

- SVHC: absence
- Heavy metals: see SDS
- Pesticides: absence GMO: absence
- Food allergens (as per Regulation (EC) no. 1169/2011): absence
- Latex: absence
- Residual solvents: yes (maximum content < 0,5% Ethanol)
- Polycyclic Aromatic Hydrocarbons: absence
- Free amines: absence
- Phthalates: absence Glycol ethers: absence
- Formaldehyde: absence
- Ethylene oxide: absence
- Nanomaterials: absence
- Monomers: absence

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- Proteins: see SDS
- VOC (volatile organic components as per European and Swiss laws): maximum content < 0.5% Ethanol
- Gluten: absence (no starting materials containing gluten are used in the product).
- Other impurities or residues: absence
- Absence: based upon data from our starting material suppliers and knowledge of the manufacturing process, we have no reason to believe that these substances are present.

**Additives**

- Neutralizers: no.
- Preservatives (following annex V of Regulation (EC) NO. 1223/2009): no.
- Antioxidants: no.
- Stabilizers: no.
- Catalysts: no.
- Bleaching agents: no.
- Chelating agents: no.
- Ethanol: yes (maximum content < 0,5% Ethanol)

**Ingredients origin**

- Synthetic: No
- Animal: No
- Animal Protection (Cites): NA (not applicable)
- Vegetable: No
- Plant name: NA (not applicable)
- Plant Protection (Cites): NA (not applicable)
- Palm oil and derivates: No
- GMO: No
- Mineral: No
- Polymer: yes (Sodium Hyaluronate)
- Biotechnological processing: Yes
- Component name: Sodium Hyaluronate
- Strain used for biotechnological fermentation: *Streptococcus equi* subsp. *Zooepidemicus*
- Components of the fermentation broth:

Substrate/Organism	Origin
Peptones	Wheat
Glucose	Corn starch
Yeast extract	Yeast

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- GMO: We herewith declare that the raw materials and processing aids used in the production of Sodium Hyaluronate do not contain or consist of GMO's and they are not produced from GMO's.
- Monomers: no

### Halal/Kosher

We confirm that the product does not contain any substance of animal origin neither these substances are used during manufacturing process.

### Vegan/vegetarian

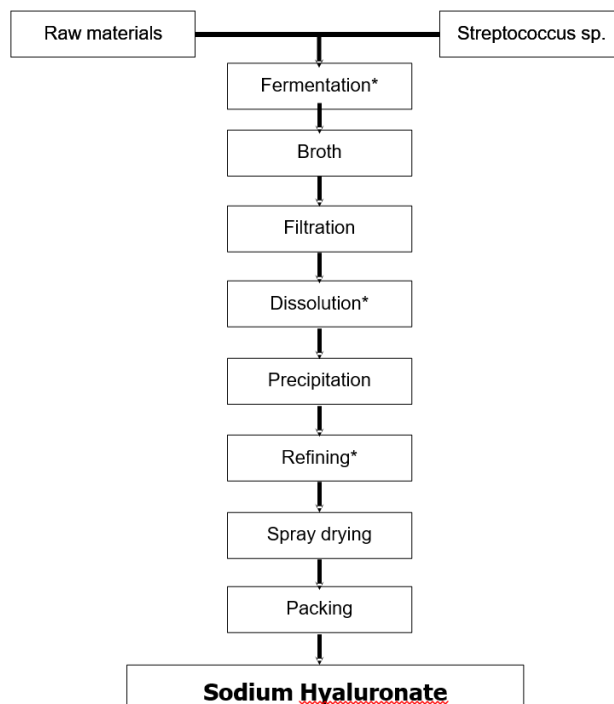
Sodium Hyaluronate is suitable for vegetarian use. Furthermore, to the best of our knowledge, we declare that Sodium Hyaluronate does not contain any animal origin ingredients or animal derivatives.

## PRODUCT INFORMATION

### Properties

Due to the refining steps included in the manufacturing process and to the low availability of water in the finished product we can guarantee the microbiological specifications of the SDS for any batch (absence of common pathogens).

### Manufacturing flow chart\*



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*\*Steps subjected to fine tuning process in order to obtain a specific molecular weight spectrum.*

Code	Trade name	Molecular weight
FH0003	FaraHyal® VL	(100-600) KDa
FH0005	FaraHyal® M	(1.000-1.600)KDa

**Specification:** SDS available

**Material safety data sheet:** MSDS or equivalent statement available

## PERSONAL CARE APPLICATIONS AND FORMULATION

Particular instructions for the use of Sodium Hyaluronate in cosmetic applications:

- **Solubility:** soluble in water.
- **Temperature:** The ingredient is not sensitive to usual temperature range. It can be heated up to 80° C for 1 to few hours before starting/accelerating degradation process.
- **Incorporation:** prepare a pre-solution of the powder (e.g.: at 1%) in water, at ambient temperature. Mix under mechanical agitation for approximately 40 minutes, until totally dispersed. Include then the solution:
  - either in aqueous phase before mixing
  - either in formed emulsion during cooling phase
- **Compatibility:** Sodium Hyaluronate is a large molecule polyanion polysaccharide. During dissolution, avoid cation emulsifiers or cation preservatives to keep a stable and transparent formula.
- **pH range:** the ingredient is stable at cosmetic pH: its rheological attitude is perfectly maintained in a pH range of 2.8 – 12.0. For further information, let's note that around pH 2.5, a thermo-reversible gel-like behavior can be registered, attributed to an interaction mechanism. At pH lower < 2.5, the polymer is re-solubilized again, and the solution-gel transition is pH-reversible. At higher pH (> 12.5), a transition to a random coil configuration can occur. This phenomenon is due to the –OH groups dissociation in alkaline conditions, and a consequent reduction of –OH bonds that control the physiological stiffness of the hyaluronan molecule.
- **Other:** this ingredient is very hygroscopic and should be maintained in closed packaging away from humidity. It is preferable to avoid turbo mixer.
- **Formulation information:** the typical dosage is 0.1 – 2.0 %

Its use is recommendable for the following cosmetic products:

- Emulsion, cream, gel, lotion, serum, compact powder, mask
- Skin care, body-care, make-up
- Face, eye-contour, baby % specific

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Usual finished product applications are diverse:

- Anti-aging formulas
- Lifting & boosting solutions
- Multi-function formulas
- Short-term hydration
- Sagging or inelastic skins
- Mature & young skins

**Efficacy test:** No test for efficacy

**Storage and handling:** Keep the product in the original container well closed in fresh and dry place, repaired from humidity, light or heat sources.

**Shelf Life:** 36 months from the production date\*\*

**\*\*24 months from production date if the molecular weight is greater than 1800kDa.**

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