

RAW MATERIAL DATA SHEET

Sodium Hyaluronate MW 1%

PRODUCT IDENTIFICATION

(I) Supplier name	ROELMI HPC SRL Legal office: Corso Europa, 60 - 20020 Solaro (MI) Italy T. +39 02 3351 0150 F. +39 02 3354 9210		
(II) EU/US INCI name	EU INCI name	US INCI name	
	Sodium Hyaluronate	Sodium Hyaluronate	
	Aqua	Water	
	Pentylene glycol	Pentylene glycol	
	Sodium benzoate	Sodium benzoate	
(III) Regulatory information	Empirical Formula: (C ₁₄ H ₂₀ NO ₁₁ Na) _n ; H ₂ O; C ₅ H ₁₂ O ₂ ; C ₇ H ₅ NaO ₂ Chemical name: Sodium Hyaluronate; Water; 1,5-Pentanediol; Sodium benzoate		
	Common name	CAS n.	EC n.
	Sodium Hyaluronate	9067-32-7	---- (polymer)
	Aqua	7732-18-5	231-791-2
	Pentylene glycol	5343-92-0	226-285-3
	Sodium benzoate	532-32-1	208-534-8
	US and European Pharmacopoeia: Not applicable		
	Classification & labelling according to EU Chemical regulation 1272/2008 (CLP) Transport: not regulated		
	Tariff code: 39139000		
(IV) Functions	Active ingredient for cosmetic products.		
(V) Geographical origin	Produced in Italy		

REGULATORY STATUS

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(VI) Chemical Inventory position	<p>Components listed in IECICS (China): yes (Aqua, Pentylene Glycol, Sodium Hyaluronate, Sodium benzoate)</p> <p>Components listed in TSCA (USA): yes (Aqua, Pentylene Glycol, Sodium benzoate)</p> <p>Components listed in NZIoC (New Zeland): yes (Aqua, Pentylene Glycol, Sodium Hyaluronate, Sodium benzoate)</p> <p>Components listed in TCSI (Taiwan): yes (Aqua, Pentylene Glycol, Sodium benzoate)</p> <p>Components listed in ECNS (Japan): yes (Pentylene Glycol, Sodium benzoate)</p> <p>Components listed in KECI (Korea): yes (Aqua, Pentylene Glycol, Sodium benzoate)</p> <p>Components listed in PICCS (Philippines): yes (Aqua, Pentylene Glycol, Sodium benzoate)</p> <p>Components listed in AICS (Australia): yes (Aqua, Pentylene Glycol, Sodium Hyaluronate, Sodium benzoate)</p> <p>Components listed in DSL (Canada): yes (Aqua, Pentylene Glycol, Sodium Hyaluronate, Sodium benzoate)</p> <p>Preposition 65 (California): no</p>
(VII) Cosmetic Regulatory Status	<p>Restriction or limitation for personal care applications: no</p> <p>Canadian cosmetic ingredient hotlist: no</p> <p>Component listed in Cosmetic China IECIC: yes</p>
(VIII) Cosmetic Regulatory Conformity	<p><u>CMR</u>: Sodium Hyaluronate MW 1% does not contain any substances intentionally added and classified as Carcinogenic, Mutagenic or Reprotoxic substances</p> <p><u>Allergens</u>: We certify that Sodium Hyaluronate MW 1% 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.</p> <p><u>TSE/BSE</u>: We confirm that Sodium Hyaluronate MW 1% does not contain any animal raw material, therefore it is free from BSE/TSE transmitting agents</p> <p><u>Animal testing</u>: We declare that no animal testing was made by Roelmi HPC & C. srl for cosmetic use accordingly to Regulation (EC) 1223/2009.</p> <p><u>Ionization</u>: the product is not subjected to ionization process</p> <p><u>REACH</u>:</p> <p>Sodium Hyaluronate: 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).</p> <p>Pentylene glycol: Registred (01-2119456809-23-XXXX)</p> <p>Sodium Benzoate: Registred (01-2119460683-35-XXXX)</p>
X) Toxicology Ecotoxicity Biodegradability information	<p><u>Toxicological information</u></p> <p>Tests for cosmetic safety evaluation (sponsored by the company) for Sodium Hyaluronate</p> <p><u>Skin irritation test</u>: NOT IRRITANT (method: MTT/ %Tested: 0.5% & 0.1% / Date: April 2009)</p> <p><u>Ocular irritation test</u>: NOT IRRITANT (method: Red Blood Cell Test/ %Tested: 1% & 10% / Date: April 2009)</p>

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	<p><u>Skin sensitization test</u>: NON SENSITIZING (method: Repeated Patch test / %Tested: Pure 100% / Date: April 2009) Mutagenicity test: Not available Photo toxicity test/ Photo allergency: test Not available</p> <p><i>Bibliographic data</i> 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 lead us to assume it is not toxic when used at normal dose.</p> <p><u>NOAEL</u>: Not available</p>
(X) Unavoidable impurities and possible traces of contaminants	<p>SVHC: absence Heavy metals (Pb): see SDS Pesticides: absence GMO: absence Food allergens (as per Directive 2007/68/C): absence Latex: absence Residual solvents: yes (maximum content < 50 ppm Ethanol) Polycyclic Aromatic Hydrocarbons: absence Free amines: absence Phthalates: absence Glycol ethers: absence Formaldehyde: absence Ethylene oxide: absence Nanomaterials: absence Monomers: absence Proteins: see SDS VOC (volatile organic components as per European and Swiss laws): absence Gluten: absence Other impurities or residues : absence <u>Absence</u>: 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.</p>
(XI) Additives	<p>Neutralisers: no. Preservatives: yes (Sodium Benzoate) Antioxidants: no. Stabilisers: no. Catalysts: no. Bleaching agents: no. Chelating agents: no. Ethanol: yes (maximum content < 50 ppm Ethanol)</p>
(XII) Ingredients origin	<p><u>Synthetic</u>: Yes</p> <p>Component name: Pentylene glycol Component name: Sodium Benzoate</p> <p><u>Animal</u>: No</p>

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	<p>Animal Protection (Cites): NA (not applicable)</p> <p><u>Vegetable</u>: No</p> <p><u>Mineral</u>: No</p> <p><u>Polymer</u>: yes (Sodium Hyaluronate)</p> <p><u>Biotechnological processing</u>: Yes</p> <p>Component name: Sodium Hyaluronate Strain used for biotechnological fermentation: <i>Streptococcus equi subsp. Zooepidemicus</i> Components of the fermentation broth:</p> <table border="1"> <thead> <tr> <th>Substrate/Organism</th> <th>Origin</th> </tr> </thead> <tbody> <tr> <td>Peptones</td> <td>Wheat</td> </tr> <tr> <td>Glucose</td> <td>Corn starch</td> </tr> <tr> <td>Yeast extract</td> <td>Yeast</td> </tr> </tbody> </table> <p><u>Monomers</u>: No</p>	Substrate/Organism	Origin	Peptones	Wheat	Glucose	Corn starch	Yeast extract	Yeast
Substrate/Organism	Origin								
Peptones	Wheat								
Glucose	Corn starch								
Yeast extract	Yeast								
(XIII) Halal/Kosher	<p>Sodium Hyaluronate MW 1% is not certified Halal/Kosher. We confirm that the product:</p> <ul style="list-style-type: none"> - Does not contain any substance of animal origin neither these substances are used during manufacturing process. 								
(XIV) Vegan/vegetarian	<p>Sodium Hyaluronate MW 1% is suitable for vegan and vegetarian use</p>								

PRODUCT INFORMATION

(XV) Properties	<p><u>MICROBIOLOGICAL STABILITY</u></p> <p>CHALLENGE TEST (2016) - Evaluation of the antimicrobial protection of a cosmetic product (CT CTFA M-3-2007)</p> <p>The results from the present study show that Sodium Hyaluronate MW 1% fulfills the <i>Acceptance Criteria reported in the method M3 - CTFA Microbiology Guidelines 2007.</i></p>
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<p>(XVI) Manufacturing flow chart</p>	<div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>PROCEDURES</p> <pre> graph TD A[Loading of raw materials] --> B[Dissolution of powders in water] B --> C[Mixing under controlled conditions] C --> D[IPC (Homogeneity)] D --> E[CQ release] E --> F[Packaging and labelling] F --> G[Sodium Hyaluronate MW 1%] </pre> </div>
<p>(XVII) Specification</p>	<p>SDS available</p>
<p>XVIII) Material safety data sheet</p>	<p>MSDS available</p>
<p>(XIX) Personal Care Applications and formulation</p>	<p>Formula information</p> <p>Solubility: Soluble in water.</p> <p>Application: 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</p> <p>Usual finished product applications are diverse: - Anti-aging formulas - Lifting & boosting solutions - Multi-function formulas</p>

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	<ul style="list-style-type: none"> - Short-term hydration - Sagging or inelastic skins - Mature & young skins
(XX) Efficacy test	No test for efficacy
(XXI) Storage and handling	Keep the product in the original container well closed in fresh and dry place, repaired from humidity, light or heat sources.
(XXII) Shelf Life	24 months from the production date

THE INFORMATION CONTAINED IN THIS RAW MATERIAL DATA SHEET ARE BASED ON OUR CURRENT SCIENTIFIC KNOWLEDGE. THE INFORMATION ARE CAREFUL AND RELIABLE BUT IT SHOULD NOT BE TAKEN AS EXPRESSING OR IMPLYING ANY WARRANTY CONCERNING THE PRODUCT CHARACTERISTICS. THE RULES AND LAWS IN ACT MUST BE RESPECTED BY PRODUCT USER, UNDER HIS OWN RESPONSIBILITY. ROELMI HPC SRL DECLINES ANY RESPONSABILITY IN CASE THE USE OF THIS PRODUCT INFORMATION MIGHT TAKE TO PATENT INFRINGEMENT.

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