



RAW MATERIAL DATA SHEET

PrincipHYAL Line

PRODUCT IDENTIFICATION

(I) Supplier name	ROELMI HPC SRL Legal office: Via Celeste Milani, 24/26 – 21040 Origgio (VA) - Italy T. +39 02 3351 0150 F. +39 02 3354 9210 This RMDS refers to all the PrincipHYAL products, except to the “full spectrum” line (Cube ³ , Difference, Aurora, Signal 10)								
(II) EU/US INCI name	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th style="width: 50%;">EU INCI name</th> <th style="width: 50%;">US INCI name</th> </tr> </thead> <tbody> <tr> <td>Sodium Hyaluronate</td> <td>Sodium Hyaluronate</td> </tr> </tbody> </table>	EU INCI name	US INCI name	Sodium Hyaluronate	Sodium Hyaluronate				
EU INCI name	US INCI name								
Sodium Hyaluronate	Sodium Hyaluronate								
(III) Regulatory information	Empirical Formula: (C ₁₄ H ₂₀ NO ₁₁ Na) _n Chemical name: Sodium Hyaluronate <table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th style="width: 25%;">Common name</th> <th style="width: 25%;">CAS n.</th> <th style="width: 25%;">EC n.</th> <th style="width: 25%;">Composition</th> </tr> </thead> <tbody> <tr> <td>Sodium Hyaluronate</td> <td>9067-32-7</td> <td>---- (polymer)</td> <td>100%</td> </tr> </tbody> </table> <p>US and European Pharmacopoeia: Not applicable</p> <p>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</p> <p>Tariff code: 39139000</p>	Common name	CAS n.	EC n.	Composition	Sodium Hyaluronate	9067-32-7	---- (polymer)	100%
Common name	CAS n.	EC n.	Composition						
Sodium Hyaluronate	9067-32-7	---- (polymer)	100%						
(IV) Functions	Humectant Skin conditioning								
(V) Geographical origin	PrincipHYAL Line is produced in our production plant located in China								

REGULATORY STATUS

ROELMI HPC srl

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 21040 Origgio (VA) Italia
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(VI) Chemical Inventory position	<p>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) Component(s) listed in DSL (Canada): yes (Sodium Hyaluronate) Preposition 65 (California): not listed</p>
(VII) Cosmetic Regulatory Status	<p>No restrictions in Europe. Other countries: PrincipHYAL Line 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</p>
(VIII) Cosmetic Regulatory Conformity	<p>Regulatory Conformity: PrincipHYAL Line 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: PrincipHYAL Line does not contain any substances intentionally added and classified as Carcinogenic, Mutagenic or Reprotoxic substances, based on the classification criteria of the Regulation (EC) 1272/2008 (CLP). Allergens: We certify that PrincipHYAL Line 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 PrincipHYAL Line 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 Roelmi HPC & C. srl for cosmetic use accordingly 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. PrincipHYAL Line 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>

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(IX) Toxicology Ecotoxicity Biodegradability information	<p><u>Toxicological information</u></p> <p>Tests for cosmetic safety evaluation (sponsored by the company)</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> <p><u>Skin sensitization test</u>: NON SENSITIZING (method: Repeated Patch test / %Tested: Pure 100% / Date: April 2009)</p> <p>Mutagenicity test: Not available</p> <p>Photo toxicity test/ Photo allergency: test Not available</p> <p><i>Bibliographic data*</i></p> <p><u>Eye irritation (Draize test)</u>: non irritant</p> <p><u>Skin irritation</u>: non irritant (Japanese rabbits and Hartley guinea pig)</p> <p><u>Skin sensitization</u>: non sensitizing (Guinea Pigs - Comparison between Sensitization of Non-crosslinked (SupArtz tes) and Crosslinked (Synvisc test) Hyaluronic Acid)</p> <p><u>Reproductive and Developmental Toxicity</u>:</p> <p>NOAEL (Rats): 60 mg/Kg (Source: Rooster combs/ Treatment: subcutaneous injection from day 17 of pregnancy to day 20 after parturition)</p> <p>NOAEL (Female rats): 64 mg/kg (Source: Bacteria/Treatment: subcutaneous injection from day 7 today 17 of pregnancy)</p> <p>*CIR- Final Report of the Safety Assessment of Hyaluronic Acid, Potassium Hyaluronate, and Sodium Hyaluronate. (July/August 2009)</p> <p>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>Ecological & Biodegradability information</u></p> <p>Biodegradability: expected to be biodegradable</p>
(X) Unavoidable impurities and possible traces of contaminants	<p>SVHC (as per REACH regulation): absence</p> <p>Heavy metals: see SDS</p> <p>Pesticides: absence</p> <p>GMO/GMM: absence</p> <p>Food allergens (as per Regulation (EC) no. 1169/2011) and gluten: absence (no starting materials containing food allergens or gluten are used in the product).</p> <p>Latex: absence</p> <p>Residual solvents: yes (maximum content < 0,5% Ethanol)</p> <p>Polycyclic Aromatic Hydrocarbons: absence</p> <p>Free amines: absence</p>



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	<p>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): maximum content < 0.5% Ethanol 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 (following annex V of Regulation (EC) NO. 1223/2009): no. Antioxidants: no. Stabilisers: no. Catalysts: no. Bleaching agents: no. Chelating agents: no. Ethanol: yes (maximum content < 0,5% Ethanol*) *Vegetal origin, main sources: corn, potatoes.</p>
(XII) Ingredients origin	<p><u>Synthetic</u>: No <u>Animal</u>: No Animal Protection (Cites): NA (not applicable) <u>Vegetable</u>: No Plant name: NA (not applicable) Plant Protection (Cites): NA (not applicable) Palm oil and derivates: No GMM/GMO: We herewith declare that the raw materials and processing aids used in the production of PrincipHYAL Line do not contain or consist of GMM/GMO's and they are not produced from GMM/GMO's. <u>Nagoya protocol</u>: NA (not applicable) <u>Mineral</u>: No</p>





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	<p><u>Biotechnological processing:</u> Yes 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>Polymer:</u> yes (Sodium Hyaluronate) <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	We confirm that the product does not contain any substance of animal origin neither these substances are used during manufacturing process. Roelmi HPC will communicate any Certifications obtained.								
(XIV) Vegan/vegetarian	PrincipHYAL Line does not contain any animal origin ingredients or animal derivatives.								

PRODUCT INFORMATION

(XV) Properties	<p>Please refer to marketing brochure <u>MICROBIOLOGICAL STABILITY</u> 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).</p>
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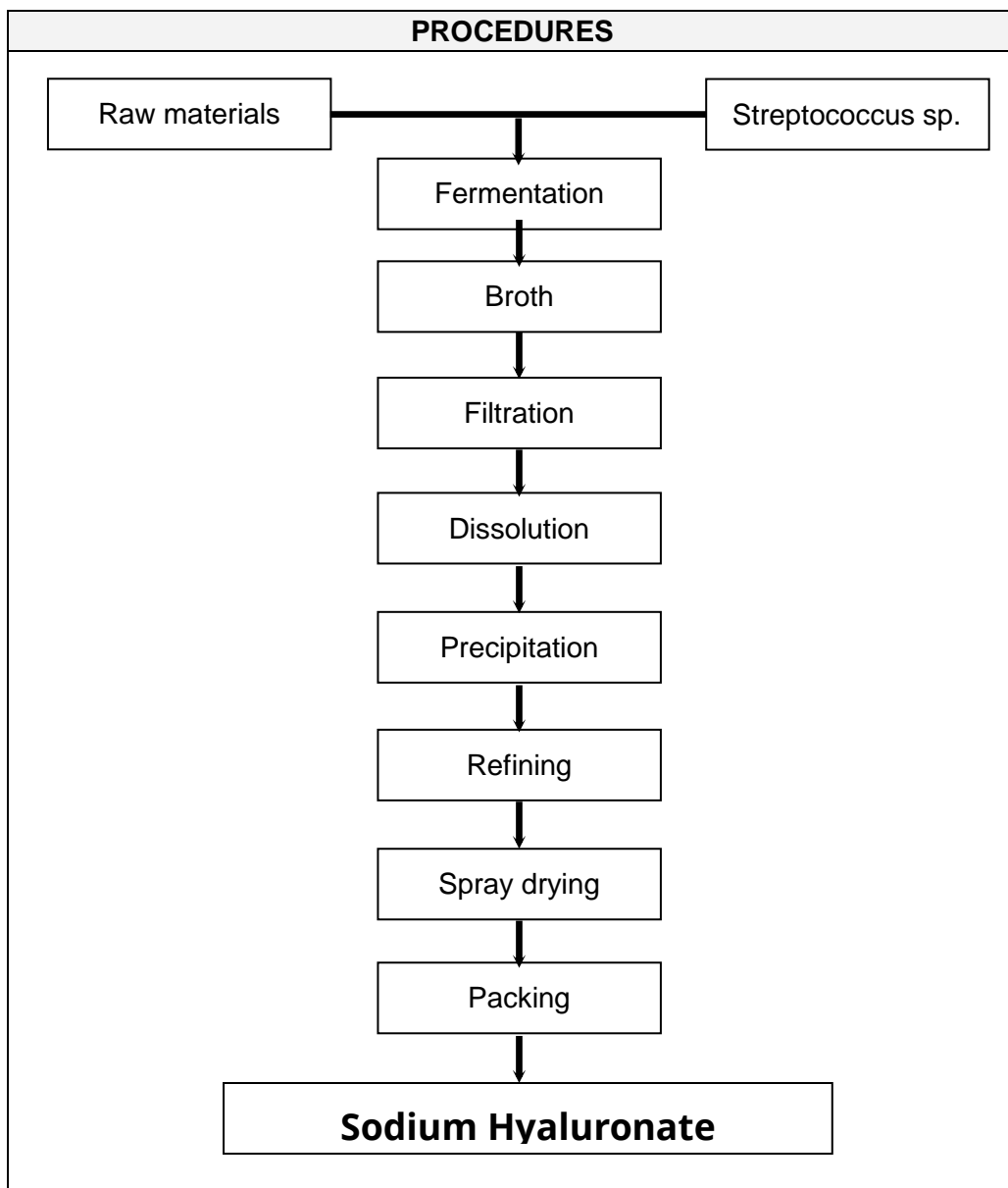




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(XVI) Manufacturing flow chart



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(XVII) Specification	SDS available
(XVIII) Material safety data sheet	MSDS or equivalent statement available
(XIX) Personal Care Applications and formulation	<p>Particular instructions for the use of PrincipHYAL Line in cosmetic applications:</p> <p>Solubility: Slowly but fully dissolves in water to give viscous, clear to slightly opalescent and colourless solutions.</p> <p>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.</p> <p>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</p> <p>Compatibility: Sodium Hyaluronate is a large molecule polyanion polysaccharide. During dissolution, avoid cation emulsifiers or cation preservatives to keep a stable and transparent formula.</p> <p>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 behaviour 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.</p> <p>Other: This ingredient is very hygroscopic, and should be maintained in closed packaging away from humidity. It is preferable to avoid turbo mixer.</p> <p>Formulation information: The typical dosage is: 0.1 – 2.0 %</p> <p>Its use is recommendable for the following cosmetic products: - Emulsion, cream, gel, lotion, serum, mask - Skin care, body-care, make-up - Face, eye-contour, baby % specific</p>

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	<p>Usual finished product applications are diverse:</p> <ul style="list-style-type: none"> - Anti-aging formulas - Lifting & boosting solutions - Multi-function formulas - Short-term hydration - Sagging or inelastic skins - Mature & young skins
(XX) Efficacy test	No test for efficacy
(XXI) Storage, packaging and handling	<p>Keep the product in the original container well closed in fresh and dry place, repaired from humidity, light or heat sources.</p> <p>ROELMI HPC Srl declares that the primary packaging used for the product is suitable for food contact and it complies with the European Regulations or comparable legislations.</p>
(XXII) Shelf Life	<p>36 months from the production date**</p> <p>**24 months from production date if the molecular weight is greater than 1800kDa.</p>

THE INFORMATION CONTAINED IN THIS DOCUMENT ARE BASED ON OUR CURRENT SCIENTIFIC KNOWLEDGE AND DOES NOT DISCHARGE THE USER FROM THE CONTROL OF THE PRODUCT BEFORE THE USE. THE INFORMATION ARE CAREFUL AND RELIABLE BUT IT SHOULD NOT BE TAKEN AS EXPRESSING OR IMPLYING ANY WARRANTY CONCERNING THE PRODUCT CHARACTERISTICS. THE USER, UNDER HIS OWN RESPONSIBILITY, MUST RESPECT THE RULES AND LAWS IN FORCE. ROELMI HPC SRL DOES NOT TAKE LIABILITY FOR ANY DAMAGE TO PEOPLE OR PROPERTY FOR IMPROPER USE AND DECLINES ANY RESPONSABILITY IN CASE THE USE OF THE PRODUCT INFORMATION MIGHT TAKE TO PATENT INFRINGEMENT OF THIRD PARTIES.

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