



RAW MATERIAL DATA SHEET

TechnoHYAL HyaPearl

PRODUCT IDENTIFICATION

(I) Supplier name	ROELMI HPC SRL Operative & Legal Office: Via Celeste Milani, 24/26 - 21040 Origgio (VA) Italy T. +39 02 3351 0150 F. +39 02 3354 9210			
(II) EU/US INCI name	EU INCI name	US INCI name		
	C10-18 TRIGLYCERIDES	C10-18 TRIGLYCERIDES		
	SODIUM HYALURONATE	SODIUM HYALURONATE		
	TRIOLEIN	TRIOLEIN		
	GLYCERYL DIOLEATE	GLYCERYL DIOLEATE		
(III) Regulatory information	Empirical Formula: NA Chemical name: NA			
	Common name	CAS n.	EC n.	Composition
	C10-18 TRIGLYCERIDES	85665-33-4	288-123-8	≥50 ≤ 75
	SODIUM HYALURONATE	9067-32-7	N.A	≥25 ≤ 50
	TRIOLEIN	122-32-7	204-534-7	≥10 ≤ 25
	GLYCERYL DIOLEATE	25637-84-7	247-144-2	≤ 5
	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: 15162098			
	(IV) Functions	Active ingredient for cosmetic products.		
(V) Geographical origin	Produced in Italy			

REGULATORY STATUS

(VI) Chemical Inventory position	Components listed in IECICS (China): yes (Sodium Hyaluronate, Triolein; C10-18 triglycerides, glyceryl dioleate) Components listed in TSCA (USA): yes (Triolein, C10-18 triglycerides, glyceryl dioleate)
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	<p>Components listed in NZIoC (New Zeland): yes (Sodium Hyaluronate, Triolein, glyceryl dioleate)</p> <p>Components listed in TCSI (Taiwan): yes (Triolein, glyceryl dioleate)</p> <p>Components listed in ENCS (Japan): yes (Triolein, glyceryl dioleate , C10-18 triglycerides)</p> <p>Components listed in KECI (Korea): yes (Triolein, C10-18 triglycerides, glyceryl dioleate)</p> <p>Components listed in PICCS (Philippines): yes (Triolein, C10-18 triglycerides, glyceryl dioleate)</p> <p>Components listed in AICS (Australia): yes (Sodium Hyaluronate, Triolein, C10-18 triglycerides, glyceryl dioleate)</p> <p>Components listed in DSL (Canada): yes (Sodium Hyaluronate, Triolein, C10-18 triglycerides, glyceryl dioleate)</p> <p>Preposition 65 (California): no</p>
(VII) Cosmetic Regulatory Status	<p>No restrictions in Europe.</p> <p>Other countries: TechnoHyal HyaPearl is accepted in most other legislative areas. Please refer to your local legislation of interest.</p> <p>Restriction or limitation for personal care applications: no</p> <p>Canadian cosmetic ingredient hotlist: no</p> <p>Component(s) listed in Cosmetic China IECIC: yes (Sodium Hyaluronate, Triolein, C10-18 triglycerides, glyceryl dioleate)</p>
(VIII) Cosmetic Regulatory Conformity	<p><u>Regulatory Conformity:</u> TechnoHyal HyaPearl 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.</p> <p><u>CMR:</u> TechnoHyal HyaPearl does not contain any substances intentionally added and classified as Carcinogenic, Mutagenic or Reprotoxic substances</p> <p><u>Allergens:</u> We certify that TechnoHyal HyaPearl 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 TechnoHyal HyaPearl does not contain any animal raw material, therefore it is free 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>IFRA:</u> TechnoHyal HyaPearl does not contain any substances mentioned in the IFRA-RIFM Code Practice.</p> <p><u>REACH:</u> TechnoHyal HyaPearl is a mixture not subjected to REACH obligations. Its components:</p>

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	<ul style="list-style-type: none"> 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). Triolein and glyceryl dioleate come from a unique product exempted as per Annex IV of REACH (now Annex I of Regulation 987/2008). The product is obtained in such a way that "Glycerides, C16-18 and unsaturated C18 (CAS 67701-30-8)" and "Glycerides, C16-18 and unsaturated C18, mono- and di- (CAS 68424-61-3)" are obtained. The components are included in the above mentioned annex. C10-18 triglycerides: Registered with registration number 01-2119485968-12-xxxx (under CAS number 68002-71-1)
(IX) Toxicology Ecotoxicity Biodegradability information	<p><u>Toxicological information</u></p> <p>Tests for cosmetic safety evaluation (performed on raw materials)</p> <p><u>Skin irritation test</u>: NOT IRRITANT (method: MTT/ %Tested: Scalar concentration)</p> <p><u>Ocular irritation test</u>: NOT IRRITANT (method: Red Blood Cell Test/ %Tested: 100% pure)</p> <p><u>Skin sensitization test</u>: NOT SENSITIZING (method: Insulted Repeated Patch test / %Tested: Pure 100%)</p> <p>Mutagenicity test: Not available</p> <p>Photo toxicity test/ Photo allergenicity: test Not available</p> <p>Bibliographic data</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> No data available on the mixture.</p> <p>Data found for raw materials:</p> <p><i>C10-18 triglycerides (registration data, available on ECHA website (Glycerides, C16-18)):</i></p> <ul style="list-style-type: none"> Acute toxicity fish: LC0 > 1000 mg/kg (OECD 203) Acute toxicity algae: 72 h EbL50 and ErL50 of the test material were determined to be 10 - 100 and 100 - 1,000 mg/L (ISO 10253) Biodegradability: readily Biodegradable (Method published by the Coordinating European Council, now listed as CEC L-33-A-934)





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	<ul style="list-style-type: none"> Bioaccumulation: when ingested, the constituent triglycerides are well known to be broken down into glycerol and fatty acids. As such, the substance is not expected to bioaccumulate in aquatic or terrestrial organisms PBT/vPvB: No, Glycerides, C16-18 are readily biodegradable (not 'P' and not 'vP') and have low potential for bioaccumulation (not 'B' and not 'vB'). Furthermore, the substance does not fulfills the criteria for 'T' as defined by the REACH legislation. In conclusion, it is not considered to be PBT or vPvB. <p><i>Triolein and glyceryl dioleate (based on data of similar products classified from ECHA: i.e. Glycerides, C14-18 and C16-18-unsatd. mono-, di- and tri-):</i></p> <ul style="list-style-type: none"> Short term toxicity to fish: LC50 (48h) 1 - 10 g/L Short term toxicity to aquatic invertebrates: EL50 (48h) 100 mg/L Long term toxicity to aquatic invertebrates: NOELR (21 days) 10 mg/L LOELR (21 days) 10 mg/L Toxicity to aquatic algae and cyanobacteria: EL50 (72 h) 296 - 320 mg/L Toxicity to microorganism: EC50 (18 h) > 0,8 mg/L. The product has been tested until 0,8 mg/L and no inhibitory effects on cell multiplication of <i>Pseudomonas putida</i> could be observed up to this concentration. Based on the characteristic of the product it is possible to predict that also to higher concentration (i.e 1 mg/L) no toxicity to microorganisms should be generated. Biodegradability: Ready Biodegradability (OECD Guideline 301 B - CO2 Evolution Test)
(X) Unavoidable impurities and possible traces of contaminants	<p>SVHC (as per REACH regulation): absence</p> <p>Heavy metals: total ≤ 20 ppm</p> <p>Pesticides: absence</p> <p>GMO: 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 (in sodium hyaluronate: maximum content 0.5% Ethanol)</p> <p>Polycyclic Aromatic Hydrocarbons: absence</p> <p>Free amines: absence</p> <p>Phthalates: absence</p> <p>Glycol ethers: absence</p> <p>Formaldehyde: absence</p> <p>Ethylene oxide: absence</p> <p>Nanomaterials: absence</p> <p>Monomers: absence</p>

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	<p>Proteins: see sds</p> <p>VOC (volatile organic components as per European and Swiss laws): in sodium hyaluronate maximum content 0.5% Ethanol</p> <p>Gluten: absence</p> <p>Formalin: absence</p> <p>Other impurities or residues : absence</p> <p><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.</p> <p>Preservatives (following annex V of Regulation (EC) NO. 1223/2009): no.</p> <p>Antioxidants: no.</p> <p>Stabilisers: no.</p> <p>Catalysts: no.</p> <p>Bleaching agents: no.</p> <p>Chelating agents: no.</p> <p>Ethanol: yes (in sodium hyaluronate: maximum content 0.5% Ethanol)</p>
(XII) Ingredients origin	<p><u>Synthetic</u>: no</p> <p><u>Animal</u>: No</p> <p>Animal Protection (Cites): NA</p> <p><u>Vegetable</u>: yes</p> <p>Component name: Triolein, glyceryl dioleate, C10-18 triglycerides</p> <p>Plant name: <i>Olea Europaea</i></p> <p>Plant protection (CITES): no</p> <p>Palm oil and derivatives: no</p> <p>GMO: We herewith declare that the raw materials and processing aids used in the production of TechnoHyal HyaPearl do not contain or consist of GMO's and they are not produced from GMO's.</p> <p><u>Nagoya Protocol</u>: Not applicable</p> <p><u>Mineral</u>: No</p> <p><u>Biotechnological processing</u>: Yes</p> <p>Component name: Sodium Hyaluronate</p> <p>Strain used for biotechnological fermentation: <i>Streptococcus equi subsp. Zooepidemicus</i></p>



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	<p>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>Polymer: yes (Sodium Hyaluronate) Monomers: 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>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.</p>								
(XIV) Vegan/vegetarian	<p>We declare that TechnoHyal HyaPearl does not contain any animal origin ingredients or animal derivatives.</p>								

PRODUCT INFORMATION

(XV) Properties	<p><u>PHISICO-CHEMICAL CHARACTERISTICS</u></p> <p>The following parameters are found with the typical values indicated in several substances with the same chemical nature. The deviation from the typical values indicated has no effect on the stability, quality or efficacy of the product TechnoHYAL HyaPearl</p> <p>Acid value: ≤ 5 mg KOH/g Saponification value: 120 – 145 mg KOH/g Iodine value: 12 – 15 gI₂/100g Drop point: 45 – 55 °C</p> <p>Please refer to the corresponding marketing brochure for further information.</p> <p><u>MICROBIOLOGICAL STABILITY</u></p> <p>Due to the knowledge of the manufacturing process and of the chemical characterization of the product (low availability of free water), TechnoHyal HyaPearl can be considered at low risk of microbiological contamination and possibility of microbial growth during the time.</p>
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(XVI) Manufacturing flow chart	<pre> graph TD A[Olive fruit oil] --> B[Distillation] B --> C[Pure fatty acids] C --> D[Esterification] D --> E["- Triolein
- C10-18 triglycerides
- Glyceryl dioleate"] F[Raw material with Streptococcus spp] --> G[Fermentation] G --> H[Crude H.A.] H --> I[filtration & Dissolution] I --> J[Precipitation & refining] J --> K[Spray drying] K --> L[Sodium hyaluronate] E --> M[Dispersion through a dedicated system] L --> M M --> N[Pearls making & packaging] N --> O[TechnoHyal Hyapearl] </pre>
(XVII) Specification	SDS available
(XVIII) Material safety data sheet	MSDS or equivalent statement available



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<p>(XIX) Personal Care Applications and formulation</p>	<p>Formulation information</p> <p>The typical dosage is: 0.5 – 1.5 %</p> <p>Its use is recommendable for the following cosmetic products:</p> <ul style="list-style-type: none"> - poured make-up; - hydrating lipbalm, moisturizing lipstick. <p>Instruction to formulate by using TechnoHyal HyaPearl in a lipstick:</p> <ol style="list-style-type: none"> 1. Melt all the oils and waxes of the finished product; 2. When the last high fusion wax is added and its drop point is reached, heat until 10°C more than the melting point, so everything will be perfectly melted and start cooling down; 3. Before reaching the dropping point, insert the TechnoHyal HyaPearl and let it completely dispersed by stirring; 4. Cool down until 10°C more than the melting point of the lipstick (mix of all) and start casting in the mold. <p>By this way, the mix will become solid in the mold and the TechnoHyal HyaPearl will be homogeneously dispersed.</p> <p>The step of inserting the TechnoHyal HyaPearl has to be done while cooling down, so the solidifying process will trap the HA in its net, with a homogenous dispersion and not different layers.</p> <p>Formula indications</p> <p>Particular instructions for the use of TechnoHyal HyaPearl in cosmetic applications:</p> <p><u>Solubility:</u> Soluble in lipid phase.</p> <p><u>Temperature:</u> 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><u>Incorporation:</u> Add TechnoHyal HyaPearl under mechanical agitation in the lipid phase and heat it until approx. 55-60 °C till totally dispersed.</p> <p><u>Compatibility:</u> TechnoHyal HyaPearl is compatible with the majority of the cosmetic ingredients</p> <p><u>pH range:</u> Not applicable</p> <p><u>Other:</u> This ingredient is not highly hygroscopic, anyway we advise to maintain in closed packaging away from humidity.</p>
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(XX) Efficacy test	Please refer to the corresponding marketing brochure
(XXI) Storage, packaging and handling	Storage: keep the product in the original container well closed in fresh and dry place (15°C - 30°C), repaired from humidity, light or heat sources. 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.
(XXII) Shelf Life	24 months from the production date

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.

THE PRESENT DOCUMENT SUBSTITUTES AND CANCELS THE PREVIOUS VERSION.

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