

RAW MATERIAL DATA SHEET

Celus Bi Light Ester

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	INCI	EC n.	CAS n.
	TRIPELARGONIN	126-53-4*	204-791-5*
	C8-C12 ACID TRIGLYCERIDE		
	<p>EU (CosIng): yes US (PCPC): yes China: registration CFDA in process</p> <p>EU (CosIng): yes US (PCPC): yes China: yes</p>		
	<p>* CAS and EC number refer to identifiers used for the preregistration and future REACH registration of the product as Propane-1,2,3- triyl trinonan-1-oate (tripelargonin, Glycerol tripelargonate / Trinonanoin)</p>		
(III) Regulatory information	<p>Empirical Formula: C₃₀H₅₆O₆ (512,76 g/mol molecular weight) Chemical name: Glycerol tripelargonate, Trinonanoin US and European Pharmacopoeia: Not applicable. Classification & labelling according to EU Chemical regulation: this product is not subject to labelling, it does not contain any dangerous compound (regulation 1272/2008). Transport: not regulated Tariff code: 2915 90 70 90</p>		
(IV) Functions	Emollient/Skin conditioning		
(V) Geographical origin	Italy		

REGULATORY STATUS

(VI) Chemical Inventory position	Component(s) listed in EU inventory: yes Component(s) listed in IECSC (China): yes Component(s) listed in KECI (Korea): yes Preposition 65 (California): not listed
(VII) Cosmetic Regulatory Status	No restriction or limitation for personal care applications. Canadian cosmetic ingredient hotlist: not listed Component(s) listed in Cosmetic China IECIC:

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	<p>C8-C12 Acid Triglycerides: yes Tripelargonin: in process</p>
(VIII) Cosmetic Regulatory Conformity	<p><u>CMR</u>: CELUS BI LIGHT ESTER does not contain any substances intentionally added and classified as Carcinogenic, Mutagenic or Reprotoxic substances. <u>Allergens</u>: We certify that CELUS BI LIGHT ESTER complies with Regulation (EC) 1223/2009 regarding the presence of the 26 substances identified as allergenic in cosmetics. Analytical tests performed with GC-MS did not detect the presence of these substances (below detection limit equal to 10 ppm). <u>TSE/BSE</u>: We confirm that CELUS BI LIGHT ESTER does not contain any animal raw material, therefore it is free from any BSE/TSE transmitting agents. <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. <u>Ionization</u>: the product is not subjected to ionization process. <u>REACH</u>: CELUS BI LIGHT ESTER has been pre-registered, deadline 2018.</p>
(IX) Toxicology Ecotoxicity Biodegradability information	<p><u>Toxicological information</u> Based on read across approach on data published for a similar product (trimethylolpropane tripelargonate (CAS 126-57-8)) <i>Acute toxicity</i>: LD50 (oral, rat) > 2000 mg/kg (OECD 423, read across) <i>Skin irritation</i>: not irritating following OECD 431 (read across) <i>Eye irritation</i>: not irritating following OECD 437 (read across) and OECD 405 (rabbit, read across) <i>Respiratory Sensitization</i>: N.A. <i>Skin Sensitization</i>: based on sperimental data on similar the product is not sensitizing (Guinea pig, OECD 406) <i>Mutagenicity</i>: based on sperimental data on similar the product is not mutagenic (Ames test, OECD 471, "In vitro cytogenicity study in mammalian cells OECD 487) <i>Repeteaed doses toxicity (5 weeks)</i>: NOAEL (oral, rat) = 1000 mg/kg/die (OECD 422, read across) <i>Reproduction toxicity</i>: NOAEL (oral, rat) = 1000 mg/kg/die (OECD 422, read across)</p> <p>Tests for cosmetic safety evaluation <i>In vitro MTT assay for the evaluation of the cytotoxic potential</i>: the product does not show a predictive cytotoxic / irritating potential <i>In vitro Het cam Test for the eye irritating potential cytotoxic potential</i>: the product is pratically not irritating</p> <p><u>Biodegradability</u>: CELUS-BI LIGHT ESTER has been not tested in terms of biodegradability, however an experimental test according to OECD 301B (modified sturm test) is available on the analogue trimethylolpropane tripelargonate. Reading across from the source substance, we can attest that CELUS-BI LIGHT ESTER is readily biodegradable, with a biodegradability (after 28 days) not lower than 76 % by weight. In particular, the test was conducted according to OECD 301B (Ready Biodegradability: CO2 Evolution Test). The</p>

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	<p>inoculum was collected from a waste water treatment plant in Novara, Italy. Cellulose was used as reference substance. Degradation of the reference compound was 82.0% + 14.0% and of the test compound 76.0% + 2.4%.</p> <p>The biodegradability of CELUS-BI LIGHT ESTER was also calculated using EPYSUITE - BioWin v 4.10. The following line appears at the end of the Biowin (Biowin1 and 2) prediction results: Ready Biodegradability Prediction. This method is based on the application of Bayesian analysis to ready biodegradation data for US Premanufacture Notification (PMN) chemicals, derived collectively from all six OECD301 test methods plus OECD310. The approach is fully described in Boethling et al. (2004). The linear and nonlinear MITI models (Biowin5 and 6) also predicted ready biodegradability. These methods are based exclusively on data from the Chemicals Evaluation and Research Institute Japan (CERIJ) database.</p> <p><u>Disposal indications:</u></p> <p><i>Accumulation:</i> The substance is predicted to be not accumulative (BCF: 53,24 estimated)</p> <p>Environmental impact: not toxic for environment.</p>
(X) Unavoidable impurities and possible traces of contaminants	<p>SVHC: absence.</p> <p>Heavy metals (randomly analysed with atomic absorption spectrophotometer): As, Cd, Co, Cr, Hg, Ni, Pb, Sb below 1 ppm. Total below 10 ppm.</p> <p>Pesticides: absence.</p> <p>GMO: absence.</p> <p>Food allergens (as per Regulation (EC) No. 1169/2011): absence</p> <p>Latex: allergens</p> <p>Residual solvents: absence (not used)</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> <p>Proteins: absence</p> <p>VOC (volatile organic components as per European and Swiss laws): CELUS BI LIGHT ESTER does not contain any volatile organic compounds</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: no.</p> <p>Antioxidants: no.</p>

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	<p>Stabilisers: no. Catalysts: no. Bleaching agents: no. Chelating agents: no. Ethanol: no</p>
(XII) Ingredients origin	<p><u>Synthetic</u>: No</p> <p><u>Animal</u>: no Animal Protection (Cites): NA</p> <p><u>Vegetable</u>: yes Plant name: <i>Silybum marianum</i> Plant Protection (Cites): No Palm oil and derivates: Absence GMO: We herewith declare that the raw materials and processing aids used in the production of Celus Bi Light ester do not contain or consist of GMO's and they are not produced from GMO's.</p> <p><u>Mineral</u>: no.</p> <p><u>Biotechnological processing</u>: no.</p> <p><u>Polymer</u>: No <u>Monomers</u>: No</p>
(XIII) Halal/Kosher	<p>CELUS BI LIGHT ESTER 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. - does not contain alcohol neither the alcohol is used during the manufacturing process. - Is completely separated from any substance of animal origin and/or containing alcohol during the manufacturing process, as well as in the warehouse.
(XIV) Vegan/vegetarian	<p>CELUS BI LIGHT ESTER is suitable for vegan/vegetarian use</p>

PRODUCT INFORMATION

(XV) Properties	<p>Celus-Bi® Esters, the innovative and renewable natural esters from ROELMI's long-term experience in health & personal care ingredients. Focused on sustainability and eco-responsibility, Celus-Bi® Esters represents the new driver of innovation. They are high added-value products manufactured through low-impact processes</p> <p>_ <i>Pigments dispersion</i>: high flowability, film evenness and gloss effect. _ <i>UV filters dispersion</i>: fast dispersion of physical filters (Titanium Dioxide, Zinc Oxide) _ <i>Anhydrous formula</i>: high performances in body care, hair oil and lipstick</p>
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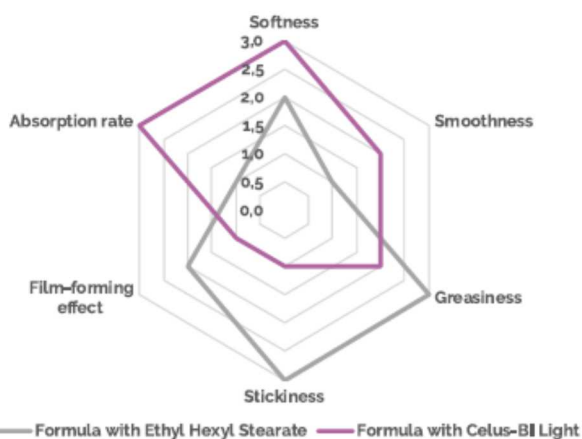
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Compact powders: Celus-BI® Light Ester showed a good binding capacity of Talc already at 2%. It gives to the powder a dry and pleasant touch on the skin.

Emulsions: sensorial performances of 7% Celus-BI® Light Ester were evaluated by a sensory in-vivo test about an Hydrating Cream and compared to the same formulation containing 7% Ethyl Hexyl Stearate

Sensorial evaluation of Hydrating Cream

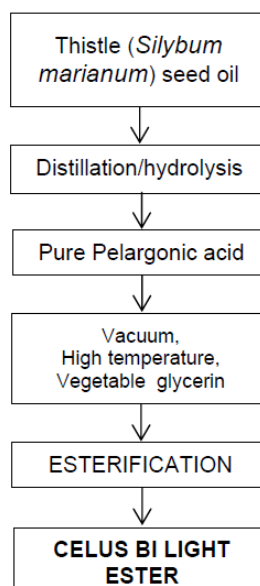


_ Higher softness, smoothness and absorption rate

MICROBIOLOGICAL STABILITY

Due to the knowledge of the manufacturing process (performed under high temperature) and of the chemical characterization of the product (absence of free water), Celus Bi Light ester can be considered exempted from microbiological contamination and possibility of microbial growth during the time. Literature studies carried out on similar products showed bacteriostatic properties of this kind of ester

(XVI) Manufacturing flow chart



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(XVII) Specification	SDS available.
(XVIII) Material safety data sheet	MSDS available.
(XIX) Personal Care Applications and formulation	See marketing brochure
(XX) Efficacy test	See chapter XV
(XXI) Storage and handling	Keep the product in the original container well closed in fresh and dry place (15 – 30 °C), repaired from humidity, light or heat sources. A prolonged storage at low temperature (below 10 °C) can cause the solidification of the product. The phenomenon is reversible by taking the product at room temperature.
(XXII) Shelf Life	24 months from the production date, in the original sealed containers.

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