

RAW MATERIAL DATA SHEET

# CELUS BI SPHERA 12

**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	Glycol/Sebacic Acid Copolymer								
(III) Regulatory information	Empirical Formula: - Chemical name: Ethylene Glycol Sebacate <table border="1" data-bbox="411 725 1396 880"> <thead> <tr> <th>EU INCI</th> <th>US INCI</th> <th>EC n.</th> <th>CAS n.</th> </tr> </thead> <tbody> <tr> <td>Glycol/Sebacic Acid Copolymer</td> <td>Glycol/Sebacic Acid Copolymer</td> <td>N.A. (polymer)</td> <td>25037-32-5</td> </tr> </tbody> </table> <p>US and European Pharmacopoeia: Not applicable. Classification &amp; 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: 39079980</p>	EU INCI	US INCI	EC n.	CAS n.	Glycol/Sebacic Acid Copolymer	Glycol/Sebacic Acid Copolymer	N.A. (polymer)	25037-32-5
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Glycol/Sebacic Acid Copolymer	Glycol/Sebacic Acid Copolymer	N.A. (polymer)	25037-32-5						
(IV) Functions	Abrasive, film formers, controlling agents, exfoliating agents								
(V) Geographical origin	Produced in Italy								

**REGULATORY STATUS**

(VI) Chemical Inventory position	Component(s) listed in IECSC (China): yes Component(s) listed in TSCA (USA): yes Component(s) listed in ENCS (Japan): yes Component(s) listed in KECI (Korea): yes Component(s) listed in NDSL (Canada): 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: not listed (submission in process).
(VIII) Cosmetic Regulatory Conformity	<u>CMR</u> : CELUS BI SPHERA 12 does not contain any substances intentionally added and classified as Carcinogenic, Mutagenic or Reprotoxic.  <u>Allergens</u> : We certify that CELUS BI SPHERA 12 complies with Regulation (EC) 1223/2009 regarding the presence of the 26 substances identified as allergenic in cosmetics.  <u>TSE/BSE</u> : We confirm that CELUS BI SPHERA 12 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 SRL for cosmetic use accordingly to Regulation (EC) 1223/2009.

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	<p><u>Ionization</u>: the product is not subjected to ionization process</p> <p><u>REACH</u>: exempted as polymer</p>
(IX) Toxicology Ecotoxicity Biodegradability information	<p><u>Toxicological information</u>:</p> <p><u>-Evaluation of the cytotoxic potential of a cosmetic raw material (in vitro product safety study)</u></p> <p>The study concerns with the in vitro evaluation of the cytotoxic/irritating potential of tested product on skin derived cells. The cytotoxicity of the tested product was measured by means of cell viability determination on skin-derived human fibroblasts. Cell viability was evaluated by a MTT measurement. MTT is a yellow coloured tetrazolium salt, which is reduced into a blue formazan precipitate by succinate dehydrogenase, in the mitochondria of living cells. The precipitated formazan is used as an indicator of cell viability.</p> <p>Tested product was emulsified in corn oil, diluted in culture medium at scalar concentrations from 2 mg/ml to 0.016 mg/ml and added to the wells containing fibroblasts.</p> <p>CELUS BI SPHERA 12 does not show cytotoxic effects on the experimental model. It does not show a predictive cytotoxic/irritating potential.</p> <p><u>-HET CAM TEST – in vitro evaluation of the irritating potential of a cosmetic raw material</u></p> <p>Het Cam Test is a useful in vitro assay for assessing the irritation properties of finished products or ingredients. The Het Cam Test has been shown to be a qualitative method of assessing the irritancy potential of chemicals. The CAM is a tissue containing arteries, veins and capillaries. It responds to injury with an inflammatory process.</p> <p>Concentration of tested product: 5% diluted in corn oil.</p> <p>Summary of the data and evaluation of the possible irritating potency of the tested product: CELUS BI SPHERA 12 is practically not irritant (IS- Irritant Score: 0.24±0.46).</p> <p><u>-HUMAN DERMATOLOGICAL INVESTIGATION – Repeated patch test to detect the skin sensitization potency of a cosmetic raw material by using the protocol of Marzulli-Maibach</u></p> <p>On the basis of the data obtained, we assess that the application on the skin of tested product do not cause any skin irritation or sensitization. It is concluded that this product should be well tolerated and that the risk of sensitization is exceedingly small. The product has been tested as it.</p> <p><u>Ecological &amp; Biodegradability information</u></p> <p>The product is to be considered as inherent biodegradable.</p>
(X) Unavoidable impurities and possible traces of contaminants	<p>SVHC: absence</p> <p>Heavy metals ( randomly analysed with atomic absorption spectrophotometer): Lead-Arsenic-Cobalt-Mercury, Antimony, Cadmium, Nichel and Chromium &lt; 1 ppm.</p> <p>Total amount below 10 ppm</p> <p>Pesticides: absence</p>

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	<p>GMO: absence</p> <p>Fruits and nuts traces: absent</p> <p>Food allergens (as per Regulation EU No 1169/2011): absence</p> <p>Latex: absent</p> <p>Residual solvents: absence</p> <p>Polycyclic Aromatic Hydrocarbons: absence</p> <p>Free amines: absence</p> <p>Phthalates: absence</p> <p>Glycol ethers: absence</p> <p>Gluten: absence</p> <p>Formaldehyde: absence</p> <p>Ethylene oxide: absence</p> <p>Monomers: absence</p> <p>Proteins: absence</p> <p>Nanomaterials: absence</p> <p>VOC (volatile organic components as per European and Swiss laws): 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: 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: No.</p>
(XII) Ingredients origin	<p>Synthetic: No.</p> <p>Animal: No.</p> <p>Animal Protection (Cites): NA</p> <p>Vegetable: No.</p> <p>Plant name: N.A.</p> <p>Palm oil and derivate: absence</p> <p>GMO: We herewith declare that the raw materials and processing aids used in the production of CELUS BI SPHERA 12 do not contain or consist of GMO's and they are not produced from GMO's.</p>

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	<p>Mineral: No.</p> <p>Biotechnological processing: No.</p> <p>Polymer: Yes (Copolymer constituted by Sebacic acid (&gt; 75%), from vegetable origin mainly <i>Ricinus communis</i> and Ethane-1.2-diol (&gt;10% ≤ 25%) from synthetic origin).</p> <p>Monomers CMR or vPvB: No.</p>
(XIII) Halal/Kosher	<p>CELUS BI SPHERA 12 is not certified Halal/Kosher.</p> <p>We confirm that the product:</p> <ul style="list-style-type: none"> <li>- does not contain any substance of animal origin neither these substances are used during manufacturing process.</li> <li>- does not contain alcohol neither the alcohol is used during the manufacturing process.</li> <li>- Is completely separated from any substance of animal origin and/or containing alcohol during the manufacturing process, as well as in the warehouse.</li> </ul>
(XIV) Vegan/vegetarian	<p>CELUS BI SPHERA 12 is suitable for vegan/vegetarian use</p>
<b>PRODUCT INFORMATION</b>	
(XV) Properties	<p>Applied in several types of products: skin &amp; body care (exfoliating products, cleanser, scrub) and toiletries (body wash, show gel, shampoo) reveals to be a great cleansing agent leaving a pleasant skin-feel.</p> <p>Application: soft cleansing;</p> <p>Results: silky effect – skin smoother</p> <p><b>MICROBIOLOGICAL STABILITY</b></p> <p>The product is stable with a reduced water content (practically absent). Anhydrous product. In order to guarantee the micronized product, for all batches are performed microbiological analysis with release specification indicated in the SDS.</p>
(XVI) Manufacturing flow chart	<p>Polyesters are produced in two process steps:</p> <p>Step 1=Poly-esterification: reaction between reactants (diols and diacids) with removal of water, at temperature 190-245°C and pressure 1 bar;</p> <p>Step 2=Poly-condensation (or transesterification): reaction between the low molecular weight esters formed in step 1 with removal of excess diol at temperature 225-250°C and pressure gradually reduced to values lower than 3 mbar</p> <p>Step 3= Micronization: controlled micronization process.</p>
(XVII) Specification	<p>SDS available.</p>
(XVIII) Material safety data sheet	<p>MSDS available.</p>

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(XIX) Personal Care Applications and formulation	See marketing brochure
(XX) Efficacy test	None
(XXI) Storage and handling	As the product is moisture sensitive and tends to absorb it when exposed to humid environments, the original packaging must be opened just before use. When production is finished, reseal hermetically remaining quantities of product in its original packaging or other barrier containers. It is recommended to convert all the material, once the original has been opened.
(XXII) Shelf Life	24 months from production date if stored as described above.

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