

RAW MATERIAL DATA SHEET

# NIPEst® 65

## 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	CARBOMER							
(III) Regulatory information	Empirical Formula: Not applicable. Chemical name: 2-Propenoic acid, homopolymer							
	<table border="1"> <thead> <tr> <th>Common name</th> <th>CAS</th> <th>EC number</th> </tr> </thead> <tbody> <tr> <td>CARBOMER (2-Propenoic acid, homopolymer)</td> <td>9003-01-4</td> <td>-</td> </tr> </tbody> </table>			Common name	CAS	EC number	CARBOMER (2-Propenoic acid, homopolymer)	9003-01-4
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CARBOMER (2-Propenoic acid, homopolymer)	9003-01-4	-						
	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.							
(IV) Functions	Thickener gelling agent for product containing aqueous phase. Stabilizer for emulsions.							
(V) Geographical origin	Europe							

## REGULATORY STATUS

(VI) Chemical Inventory position	Component(s) listed in TSCA (US): yes. Component(s) listed in European Union: No (polymer) Component(s) listed in DSL/NDSL (Canada): yes (DSL) Component(s) listed in AICS (Australia): yes. Component(s) listed in IECICS (China): No Component(s) listed in ENCS (Japan): yes. Component(s) listed in KECL (Korea): yes. Component(s) listed in PICCS (Philippines): 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: yes.
(VIII) Cosmetic Regulatory Conformity	<u>CMR</u> : NIPEST® 65 does not contain any substances intentionally added and classified as Carcinogenic, Mutagenic or Reprotoxic substances apart from traces which are technically unavoidable and expected regarding the process : - Dichloromethane (CAS 75-09-2), Carc. Cat. 3, < 2000 ppm <u>Allergens</u> : We certify that NIPEST® 65 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.

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	<p><u>TSE/BSE</u>: We confirm that NIPEST® 65 does not contain any animal raw material, therefore it is free from any BSE/TSE transmitting agents</p> <p><u>Animal testing</u>: We declare that no animal testing was made by Roelmi HPC &amp; 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>: NIPEST® 65 is a polymer exempted from REACH</p>
<p>(IX) Toxicology Ecotoxicity Biodegradability information</p>	<p><u>Toxicological information (bibliographic data where not specified)</u></p> <ul style="list-style-type: none"> <li>▪ Acute LD50 (oral, rat) &gt; 2500 mg/kg</li> <li>▪ Skin irritation: Not irritating as is. The direct contact of the product with injured skin can be irritant for physical action.</li> <li>▪ Skin sensitization: Not sensitizing (low potential)</li> <li>▪ Eye irritation: Not irritating as is. Mildly irritant for physical action</li> <li>▪ Mutagenic/carcinogenic: Non mutagenic/carcinogenic</li> <li>▪ Photo-sensitizing: Not sensitizing (low potential)</li> <li>▪ MTT assay for the in vitro evaluation of the cytotoxicity potential (test sponsored by our company): Not irritant</li> <li>▪ The product has been selling for more than 10 years with no reported adverse cases for human health.</li> <li>▪ The safety of carbomer has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that carbomer polymers were safe as ingredients in cosmetics and personal care products. In 2001, as part of the scheduled re-evaluation of ingredients, the CIR Expert Panel considered available new data on carbomer polymers and reaffirmed the above conclusion.</li> </ul> <p><u>Ecological &amp; Biodegradability information (based on data of similar products):</u></p> <ul style="list-style-type: none"> <li>▪ Test: LC50 Species: Daphnia Duration h: 48 mg/l: 210 (UNI EN ISO 6341);</li> <li>▪ Test: LC50 Species: Daphnia Duration h: 96 mg/l: 174 (UNI EN ISO 6341);</li> <li>▪ Test: LC50 Species: Fish Duration h: 48 mg/l: 660</li> <li>▪ Test: LC50 Species: Fish Duration h: 96 mg/l: 580</li> <li>▪ As high molecular weight product is considered as flocculating agent and does not significantly improve the BOD value. It is not to be considered as biodegradable. Do not inhibit waste treatment bacteria. Do not pass through typical wastewater treatment to the environment, but are instead removed with the biomass.</li> </ul>
<p>(X) Unavoidable impurities and possible traces of contaminants</p>	<p>SVHC: absence.</p> <p>Heavy metals: below 10 ppm (as sum of Hg, Pb, As, Sb)</p> <p>Pesticides : absence.</p> <p>GMO: absence.</p> <p>Food allergens (as per Directive 2007/68/C): absence</p> <p>Latex: allergens</p>

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	<p>Residual solvents: methylene chloride below 2000 ppm          Polycyclic Aromatic Hydrocarbons : absence.          Free amines : absence.          Phthalates: absence.          Glycol ethers: absence.          Formaldehyde: absence.          Ethylene oxide: absence.          Nanomaterials: absence.          Monomers: below 0,25% as free acrylic acid          Proteins: absence          VOC (volatile organic components as per European and Swiss laws ): NIPEST<sup>®</sup> 65 does not contain any volatile organic compounds except for traces (methylene chloride below 2000 ppm).          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: no.          Antioxidants: no.          Stabilisers: no.          Catalysts: no.          Bleaching agents: no.          Chelating agents: no.          Ethanol: no</p>
(XII) Ingredients origin	<p><u>Synthetic</u>: Yes  <u>Animal</u>: no          Animal Protection (Cites): NA  <u>Vegetable</u>: no          Plant name: NA          Plant Protection (Cites): NA          Palm oil and derivatives: no  <u>Mineral</u>: no.  <u>Biotechnological processing</u>: no.  <u>Polymer</u>: Yes  <u>Monomers</u>: acrylic acid</p>
(XIII) Halal/Kosher	<p>NIPEST<sup>®</sup> 65 is not certified Halal/Kosher.          We confirm that the product:          - 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</p>

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	<p>manufacturing process.</p> <p>- Is completely separated from any substance of animal origin and/or containing alcohol during the manufacturing process, as well as in the warehouse.</p>
(XIV) Vegan/vegetarian	NIPEST® 65 is suitable for vegan/vegetarian use

**PRODUCT INFORMATION**

(XV) Properties	<ul style="list-style-type: none"> <li>• Gelling agent for cosmetic products</li> <li>• Formation of transparent aqueous or organic solvent-based gels with excellent filming and protective properties</li> <li>• NIPEST® 65 reaches a viscosity range at pH values between 5 to 9 (maximum at 7 - 8).</li> <li>• Very good stability of the gels in the time and to the temperature variations</li> <li>• Formation of thick gels at low concentrations</li> <li>• Compatible with most cosmetic raw materials</li> <li>• Safe widely known and versatile raw material - absence of irritant and allergenic substances of the gels</li> <li>• Different methods of dispersion can be used without affecting the properties of the final product: dispersion into rapidly agitating water with a suitable stirrer (around 4 hours), self-dispersion of the powder in water overnight without any stirring, dispersion in water by using a mixer equipped with a turbine (few minutes)</li> </ul> <p><u>Microbial stability:</u> Due to its nature, absence of free water and very low pH in aqueous solution (approx. 3 at 0,5 %) NIPEST® 65 has to be considered at very low risk of microbial contamination with substantially no possibility of growth for the most common pathogens in the powder as is</p>
(XVI) Manufacturing flow chart	Reflux polymerization of acrylic acid in presence of solvents and crosslinking agent with further removal of solvents.
(XVII) Specification	SDS available.
(XVIII) Material safety data sheet	MSDS available.
(XIX) Personal Care Applications and formulation	See marketing brochure
(XX) Efficacy test	Not tested for efficacy
(XXI) Storage and handling	<p>Keep the product in well-closed original packaging, in a fresh (below 30° C) place, protected from light, heat sources. Material do not need homogenisation before use.</p> <p>Stability: stable material.</p>

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(XXII) Shelf Life | 24 months from the production date, in the original sealed containers.

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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