

RAW MATERIAL DATA SHEET

**ABWAX PE 9394**

**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	<b>EU INCI name</b>	<b>US INCI name</b>	
	POLYETHYLENE	POLYETHYLENE	
(III) Regulatory information	Empirical Formula: N.A. Chemical name: N.A.		
	<b>Common name</b>	<b>CAS n.</b>	<b>EC n.</b>
	POLYETHYLENE	9002-88-4	--
	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). See MSDS Transport: not regulated.  Polyethylene is listed in: - Regulation (EU) 10/2011 amended by Regulation 2015/174 on plastic materials and articles intended to come into contact with food - Regulation 1935/2004 on materials intended to come into contact with food" Polyethylene complies with: - FDA Regulation 21 CFR 175.105 "Adhesives" - FDA Regulation 21 CFR 175.300 "Resinous and polymeric coatings" - FDA Regulation 21 CFR 175.170 "components of paper and paperboard in contact with aqueous and fatty foods" - FDA Regulation 21 CFR 176.180 "components of paper and paperboard in contact with dry food"  Tariff code: 39011010		
(IV) Functions	Abrasive, Film Forming and Viscosity Controlling		
(V) Geographical origin	Europe		

**REGULATORY STATUS**

(VI) Chemical Inventory position	Component(s) listed in TSCA (US): yes. Component(s) listed in DSL (Canada): yes. Component(s) listed in AICS (Australia): yes. Component(s) listed in IECICS (China): yes Component(s) listed in ENCS (Japan): yes. Component(s) listed in KECL (Korea): yes. Component(s) listed in PICCS (Philippines): yes Component(s) listed in NZIoC (New Zealand): yes Component(s) listed in EU inventory: yes Preposition 65 (California): not listed
(VII) Cosmetic Regulatory Status	No restriction or limitation for personal care applications. Canadian cosmetic ingredient hotlist: not listed

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	Component(s) listed in Cosmetic China IECIC: yes.
(VIII) Cosmetic Regulatory Conformity	<p><u>CMR</u>: ABWAX PE 9394 does not contain any substances intentionally added and classified as Carcinogenic, Mutagenic or Reprotoxic substances</p> <p><u>Allergens</u>: We certify that ABWAX PE 9394 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 ABWAX PE 9394 is free from any BSE/TSE transmitting agents as beeswax is excluded from the Regulation 999/2001.</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>: ABWAX PE 9394 complies with the definitions of polymer and is exempted from REACH obligation.</p>
(IX) Toxicology Ecotoxicity Biodegradability information	<p><u>Toxicological information</u></p> <p><b><i>Bibliographic data (SOURCES: CIR assessment)</i></b></p> <ul style="list-style-type: none"> <li>▪ Acute oral toxicity: LD50 &gt; 2000 mg/kg</li> <li>▪ Skin irritation: Non irritant (rabbits)</li> <li>▪ Skin sensitization: Non irritant (Guinea pigs)</li> <li>▪ Ocular irritation : not irritant</li> <li>▪ Genotoxicity : not genotoxic</li> <li>▪ carcinogenic: Non carcinogenic (IARC evaluaiton)</li> <li>▪ Polyethylene has been selling for more than 20 years with no reported adverse cases for human health.</li> <li>▪ CIR assessment evaluation: safe for cosmetic use</li> </ul> <p>Other: see chapter III for suitability</p> <p><u>Ecological &amp; Biodegradability information</u></p> <p>No data available, supposed to be not toxic for the environment</p>
(X) Unavoidable impurities and possible traces of contaminants	<p>SVHC: absence.</p> <p>Heavy metals: absence</p> <p>Pesticides: absence</p> <p>GMO: absence.</p> <p>Food allergens (as per Regulation (EU) 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>Formaldehyde: absence</p> <p>Glycol ethers: absence.</p> <p>Formaldehyde: absence.</p> <p>Ethylene oxide: absence.</p> <p>1-4 Dioxane: absence</p> <p>Nanomaterials: absence.</p>

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	<p>Monomers: absence.          Proteins: absence          VOC (volatile organic components as per European and Swiss laws ): ABWAX PE 9394 does not contain any volatile organic compounds          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 (see polymer)  <u>Animal</u>: No          Animal Protection (Cites): No  <u>Vegetable</u>: No  <u>Mineral</u>: no.  <u>Biotechnological processing</u>: no.  <u>Polymer</u>: Yes  <u>Monomers</u>: No</p>
(XIII) Halal/Kosher	<p>ABWAX PE 9394 is not certified Halal/Kosher.          We confirm that the product:</p> <ul style="list-style-type: none"> <li>- does not contain alcohol neither the alcohol is used during the manufacturing process.</li> <li>- does not contain any substance of animal origin neither these substances are used during 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>ABWAX PE 9394 is suitable for vegan/vegetarian use</p>

**PRODUCT INFORMATION**

(XV) Properties	<p>Abwax PE 9394 provides structure and melting point in many cosmetic applications  <u>MICROBIOLOGICAL STABILITY</u>          Due to the knowledge of the manufacturing process (performed under high temperature) and of the chemical characterization of the product (absence of free water), ABWAX PE 9394 can be considered exempted from microbiological contamination and possibility of pathogens growth during the time.</p>
(XVI) Manufacturing flow chart	<p>High pressure polymerization of ethylene.          The solid mass is then processed to convert it into pearls.</p>

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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	No tested for efficacy
(XXI) Storage and handling	Store in well-closed original package at room temperature (<30°C), and dry place, repaired from humidity, light or heat sources. Stability: stable material.
(XXII) Shelf Life	24 months from the production date, in the original sealed containers.

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