

	Dossier technique et réglementaire / <i>technical and regulatory document</i> <b>POLYSORBATE 60</b> <b>POLYSORBATE 60-RSPO-MB</b>	Novembre 2024 / November 2024
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Ce document est utilisable pour nos 2 références : grade conventionnel et grade RSPO-MB. Veuillez à inclure la mention « RSPO-MB » dans votre commande si vous souhaitez cette qualité.

*This document is usable for our 2 references: conventional grade and RSPO-MB grade. Be careful to mention "RSPO-MB" in your order if you want this grade.*

INCI: **Polysorbate 60**  
N°CAS: 9005-67-8  
N°EINECS/ELINCS: –

#### DESCRIPTION / DESCRIPTION:

Monostéarate de sorbitan éthoxylé (20 moles) / *Ethoxylated sorbitan monostearate (20 moles)*

Ce produit est conforme à la Pharmacopée Européenne en vigueur (monographie : polysorbate 60) / *This Product in accordance with the current European Pharmacopoeia (monograph: Polysorbate 60)*

#### CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS
Aspect à 20°C / <i>Aspect at 20°C</i>	Pâte jaune / <i>Yellow paste</i>
Indice d'acide / <i>Acid value</i>	≤ 2 mg KOH /g
Indice de saponification / <i>Saponification value</i>	45 – 55 mg KOH /g
Indice d'hydroxyle / <i>Hydroxyl value</i>	81 – 96 mg KOH /g
Teneur en eau / <i>Water content</i>	≤ 3 %
Teneur en dioxane / <i>Dioxane content</i>	≤ 10 ppm
Teneur en oxyde d'éthylène / <i>Oxide ethylene content</i>	≤ 1 ppm

**Ces éléments seront repris sur nos BA / these elements will be on our CoA**

#### CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Density 20°C : ca 1.10

Viscosity 30°C : ca 400mPa.s

HLB value : 15

Ce produit est végétalien / *This product is vegan*

ISO 16128 : 0/0/0/0

#### APPLICATIONS:

solubilisant et émulsifiant / *solubilizer and emulsifier.*

#### CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Fût plastique OT de 200 kg – Tonnelet 25/50 kg / *200 kg plastique TO drum – 25/50 kg keg*

<b>Additives</b>	This product doesn't contain additives
<b>Allergen</b>	Products listed as likely to cause allergic reaction in Annex III are not expected to be present (regulation 1223/2009) food allergen (regulation EU No 1169/2011 annex II) : unlikely to be present. Therefore we don't analyze them.
<b>Animal Testing</b>	This product has not been tested on animals
<b>BSE - Bovine Spongiform Encephalopathy</b>	No risk of BSE

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<b>California Prop 65</b>	This product (CAS: 9005-67-8) is not listed	
<b>Carcinogenic, Mutagenic and Reprotoxic (CMR)</b>	It is not classified as a Carcinogenic, Mutagenic or Reproduction-toxic substance of category 1, 2 and 3 as defined in EC 1272/2008/EC and its amendments. For more information, please refer to the section 11 of the MSDS.	
<b>Composition</b>	100% INCI Polysorbate 60	
<b>Cosmetic</b>	This product complies with Cosmetic directive 1223/2009/CEE It contains substances listed on Annex II. The presence of those substances is unavoidable due to the process of production, even in the best application of good practices of production. <ul style="list-style-type: none"> <li>Ethylene oxide (CAS : 75-21-8) &lt; 1 ppm</li> <li>1,4-Dioxane (CAS : 123-91-1) &lt; 10 ppm</li> </ul>	
<b>Cosmos / Ecocert</b>	No data available	
<b>Danger</b>	This product is not classified as dangerous in accordance with CLP and ADR	
<b>Dioxane</b>	It contains substances listed on Annex II (1223/2009). The presence of those substances is unavoidable due to the process of production, even in the best application of good practices of production. <ul style="list-style-type: none"> <li>Ethylene oxide (CAS : 75-21-8) &lt; 1 ppm</li> <li>1,4-Dioxane (CAS : 123-91-1) &lt; 10 ppm</li> </ul>	
<b>Ecolabel</b>	No data available	
<b>European Pharmacopeia</b>	This product complies with the current European Pharmacopoeia	
<b>Food</b>	No data available	
<b>Genetically Modified Organisms (GMO)</b>	It does not contain any raw material that originates from genetically modified organisms as defined by guideline 2001/18/EC. Therefore, it doesn't need to be labeled in accordance with regulation EC 1829/2003 and EC 1830/2003 of 22-09-2003.	
<b>Inventories</b>	Listed in Australia AIIC Canada DSL China IECSC Japan ENCS	New Zealand NZIoC Philippines PICCS Taiwan TCSI Korea KECL United States of America (USA) TSCA
<b>Geographic origin (for plant)</b>	No data available	
<b>Glycol ether</b>	No data available	
<b>Halal</b>	Compliant with HALAL requirement as : <ul style="list-style-type: none"> <li>not derived from products from animal origin</li> <li>do not come into contact with any materials which could be derived from animal origin during manufacturing process</li> <li>do not contain ethanol, and ethanol has not been used in the manufacturing process</li> </ul>	
<b>Heavy Metals</b>	There is in no potential for heavy metals to be present in detectable concentration. Therefore, we do not analyze it. Total Heavy metal : ≤ 10 ppm	
<b>HS code</b>	3402399090	
<b>Irradiation / ionization</b>	There is no ionization / irradiation during the manufacturing process in this product	
<b>Kosher</b>	Compliant with KOSHER requirement as : <ul style="list-style-type: none"> <li>not derived from products from animal origin</li> <li>do not come into contact with any materials which could be derived from animal origin during manufacturing process</li> <li>do not contain ethanol, and ethanol has not been used in the manufacturing process</li> </ul>	
<b>Latex</b>	unlikely to be present. Therefore we don't analyze it.	
<b>Manufacturing location</b>	No data available	

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<b>Microbiological data</b>	No microbial activity is expected. The low activity of water makes the medium unfavorable for microbiological development. Therefore, we do not analyze it
<b>Nanomaterials</b>	Free of Nanoparticles or materials produced via nanotechnology. (6),(7),(8) <b>(6) EC 1223/2009:</b> “an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm” Completed by Cosmetics Europe: “for 10% or more of the particles in the number size distribution”. <b>(7) Decree n°2012-232:</b> “A manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm” <b>(8) 2011/696/EU:</b> “a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.”
<b>Nitrosamine</b>	unlikely to be present. Therefore we don't analyze it.
<b>Nutritional data</b>	<i>No data available</i>
<b>Origin</b>	vegetable (sorbitol stearate) and mineral origin (ethylene oxide)
<b>PAH</b>	unlikely to be present. Therefore we don't analyze it.
<b>Pesticide</b>	This product doesn't contain pesticide
<b>Phthalate</b>	unlikely to be present. Therefore we don't analyze it.
<b>Preservative</b>	It does not contain any preservatives (in particular parabens, formaldehyde, paraformaldehyde, phenoxyethanol, chloroacetamide).
<b>Process</b>	Ethoxylation of sorbitan monostearate
<b>REACH</b>	This product is a polymer - exempted from REACH
<b>Residual Solvents</b>	No potential for residual solvent as solvent is not used during manufacturing process or if used, is removed in a final step of the manufacturing process
<b>RSPO</b>	This product contains palm oil derivate (PO) and/or palm kernel oil derivate (PKO). Our reference “ <b>POLYSORBATE 60</b> ” is not RSPO certified If you want RSPO certified grade, you must order “ <b>POLYSORBATE 60-RSPO-MB</b> ”
<b>Shelf Life before re-check</b>	2 years
<b>Substances of Very High Concern (SVHC)</b>	<i>No data available</i>
<b>Volatiles organic compounds (VOC)</b>	It is not a VOC based on the following regulation. <ul style="list-style-type: none"> <li>• Solvents Directive (Dir. 2010/75/EU) (1)</li> <li>• Paints Directive (Dir. 2004/42/CE) (2)</li> <li>• Ordinance on the Incentive Tax on VOC (SR814018; 01/01/2017) (3)</li> <li>• EU Ecolabel – Paints and varnishes (Dir. 2015/886/EEU) (4)</li> <li>• EU Ecolabel – Cleaners (Dir. 2011/383/EU) (5)</li> </ul> <b>(1) Solvents Directive (Directive 2010/75/EU):</b> Any organic compound having at 293,15K a vapour pressure of 0.01 kPa or more, or having a corresponding volatility under the particular conditions of use <b>(2) Paints Directive (Directive 2004/42/CE):</b> Any organic compound having an initial boiling point less than or equal to 250°C measured at a standard pressure of 101,3 kPa <b>(3) Ordinance on the Incentive Tax on Volatile Organic Compounds (SR814018; 01/01/2017):</b> Organic compounds with a vapour pressure of at least 0.1 mbar at 20°C or a boiling point of maximum 240°C at 1013,25 mbar <b>(4) EU Ecolabel – Paints and varnishes ( Directive 2015/886/EEU):</b> Any organic compound having an initial boiling point less than or equal to 250°C measured at a standard pressure of 101,3 kPa as defined in Directive 2004/42/EC and which, in a capillary column, are eluting up to and including n-tetradecane (C14H30) <b>(5) EU Ecolabel – All-purpose cleaners and sanitary cleaners (Directive 2011/383/EU):</b> Any organic compound with a boiling point lower than 150°C

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Ce document annule et remplace tous documents techniques et réglementaires précédents / *This document cancels and replaces all technical and regulatory previous documents.*