



**POLYSORBATE 20**  
**POLYSORBATE 20-RSPO-MB**

Ce document est utilisable pour nos 2 références : grade conventionnel et grade RSPO-MB. Veillez 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 20**  
N° CAS: 9005-64-5  
N°EINECS/ELINCS: Polymer

**DESCRIPTION / DESCRIPTION:**

Monolaurate de sorbitan ethoxylé (20 moles). Tensio-actif non ionique, hydrophile / *Ethoxylated sorbitan monolaurate (20 moles). Nonionic surfactant, hydrophilic*

Produit conforme à la Pharmacopée Européenne en vigueur (monographie: Polysorbate 20) / *Product in accordance with the current European Pharmacopoeia (monograph: Polysorbate 20)*

**CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:**

CARACTERISTIQUES	SPECIFICATIONS
Aspect / <i>Aspect</i>	Liquide jaune clair / <i>Yellow light liquid</i>
Indice d'acide / <i>Acid value</i>	≤ 2 mg KOH / g
Indice de saponification / <i>Saponification index</i>	40 – 50 mg KOH / g
Indice d'hydroxyle / <i>Hydroxyl value</i>	96 – 108 mg KOH / g
Teneur en eau / <i>Water content</i>	≤ 3%
Teneur en dioxane / <i>Dioxane content</i>	≤ 5 ppm
Teneur en oxyde d'éthylène / <i>Ethylene oxide content</i>	≤ 1 ppm
pH (5%)	5 – 8
Couleur (Gardner) / <i>Color</i>	≤ 6

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

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

Point d'éclair / *Flash point*: > 150°C

Densité à 20°C / *Density at 20°C*: ca. 1.1

Viscosité dynamique à 20°C / *Dynamic viscosity at 20°C*: 400 mPas

ISO 16128 : 0/0/0/0


**APPLICATIONS :**

Solubilisant et émulsifiant / *Solubilizer and emulsifier*


**CONDITIONNEMENT STANDARD / STANDARD PACKAGING:**

IBC de 1000 kg – Fût plastique de 200 kg – Tonnelet 50/25 kg / *1000 kg IBC – 200 kg plastic drum – 25 kg keg*  
Matière première non classifiée comme substance dangereuse / *Raw material classified not classified as dangerous substance*

A Conserver dans l'emballage d'origine à 20 – 25°C. En cas de turbidité ou de sédimentation, homogénéiser avant utilisation (une montée de température pourrait aider) / *Store the product in well closed original package at 20 – 25°C. If turbidity or sedimentation occurs, homogenize before use (Rise of temperature may help)*

	Dossier technique et réglementaire / <i>technical and regulatory document</i> <b>POLYSORBATE 20</b> <b>POLYSORBATE 20-RSPO-MB</b>	Novembre 2024 / November 2024
--	--	----------------------------------

<b>Additives</b>	For this product we do not intentionally introduce the following substances groups: Polybrominated biphenyls (PBB), Polychlorinated biphenyls (PCB), Polychlorinated terphenyls (PCT), Polybrominated diphenyl ethers (PBDE).	
<b>Allergen</b>	This product doesn't contain cosmetic allergen (1223/2009) and food allergen (regulation 1169/2011)	
<b>Animal Testing</b>	Has not been tested on animals	
<b>BSE - Bovine Spongiform Encephalopathy</b>	No risk of BSE	
<b>California Prop 65</b>	This product (CAS:9005-64-5) is not listed	
<b>Carcinogenic, Mutagenic and Reprotoxic (CMR)</b>	This product does not contain carcinogenic, mutagenic, or toxic for reproduction substances (CMR free) except for the following unavoidable impurities: -1,4 dioxane < 10 ppm -Ethylene oxide < 1 ppm	
<b>Composition</b>	100% INCI POLYSORBATE 20	
<b>Cosmetic</b>	This product complies with Cosmetic directive 1223/2009/CEE and its amendments	
<b>Cosmos / Ecocert</b>	This product contains chemical derivatives – Not accepted by Cosmos	
<b>Danger</b>	This product is not classified as dangerous in accordance with CLP and ADR	
<b>Dioxane</b>	This product contains dioxin ( $\leq 10$ ppm), this impurity is unavoidable for ethoxylation process	
<b>Ecolabel</b>	<i>No data available</i>	
<b>European Pharmacopeia</b>	Product in accordance with the current European Pharmacopoeia (monograph: Polysorbate 20)	
<b>Food</b>	This product is not suited for food nor feed applications. CFR Title 21 - Indirect Food Additives: Listed in 172.515 - Synthetic flavoring substances and adjuvants. 173.310 - Boiler water additives. 175.105 - Adhesives.	
<b>Genetically Modified Organisms (GMO)</b>	To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms (GMO).	
<b>Inventories</b>	Listed in Australia AIIC Canada DSL China IECSC Japan ENCS Korea KECI	New Zealand NZIoC Philippines PICCS Switzerland EINECS Taiwan TCSI United States of America (USA) TSCA
<b>Geographic origin (for plant)</b>	<i>No data available</i>	
<b>Glycol ether</b>	<i>No data available</i>	
<b>Halal</b>	This product does not contain natural L-cysteine extracted from hair or feathers; animal fats and/or animal extracts; bloods of any origins; blood plasma; pork; and/or other meat by-products. Additionally, none of the components listed above are known by us to be present as impurities or by-products in any of the ingredients used to make this product. Finally, ethanol is not used as a processing aid nor known to be intentionally present in the composition.	
<b>Heavy Metals</b>	Contains a minimum level of heavy metals according to EU 2023/915.	
<b>HS code</b>	3402399090	
<b>Irradiation / ionization</b>	There is no irradiation / ionization step in this product	
<b>Kosher</b>	Not certified but suitable for kosher diet.	
<b>Latex</b>	<i>No data available</i>	
<b>Manufacturing location</b>	Europe	
<b>Microbiological data</b>	<i>No data available</i>	
<b>Microplastic</b>	The products comply with EU 2023/2055 regulation because they are not considered	

	Dossier technique et réglementaire / <i>technical and regulatory document</i> <b>POLYSORBATE 20</b> <b>POLYSORBATE 20-RSPO-MB</b>	Novembre 2024 / November 2024
--	--	----------------------------------

	microplastics due to their solubility above 2 g/L according to Annex 16 of this regulation
<b>Nanomaterials</b>	This product complies to the provisions of Article 18 of EU Regulation 1169/2011 about the List of ingredients, as far as applicable; no 'nano' labelling is required. This product complies to the provisions of Article 16 of EU Regulation 1223/2009 about nanomaterials, as far as applicable; no 'nano' labelling is required. The product is in compliance with the definition of Nanomaterials, laid down within 2011/696/EC and is not affected by this classification. The product neither consist of Nanomaterials nor are Nanomaterials intentionally added during processing, packaging and transport.
<b>Nutritional data</b>	<i>No data available</i>
<b>Origin</b>	vegetable and chemical origin
<b>Pesticide</b>	This product complies with Regulation 396/2005/EC (as amended) on maximum residue levels of pesticides in or on food and feed, as far as applicable.
<b>Phthalate</b>	For this product, we do not intentionally introduce phthalates
<b>Preservative</b>	No preservative is intentionally added to this product.
<b>Process</b>	Ethoxylation of sorbitanester. Under the reaction conditions during the ethoxylation, dioxan is always formed as a by-product, independent from the kind of raw material
<b>REACH</b>	This product is a polymer - exempted from REACH
<b>Residual Solvents</b>	No solvent has been used during its manufacturing process. None of the Class 1, Class 2, and Class 3 Residual Solvents specified in USP General Chapter <467> effective on 1 DEC 2020 are used in the manufacture of this product.
<b>RSPO</b>	This product contains palm kernel oil derivate (PKO). Our reference " <b>POLYSORBATE 20</b> " is not RSPO certified If you want RSPO certified grade, you must order " <b>POLYSORBATE 20-RSPO-MB</b> "
<b>Shelf Life</b>	24 months
<b>Substances of Very High Concern (SVHC)</b>	This product is free from any substance identified as "SVHC" (Substances of Very High Concern) which are referred to in the "candidate list" as published by ECHA in the context of the REACH Regulation (EC) No 1907/2006 above of the 0.1% w/w threshold. This statement includes all substances listed by ECHA including the last update
<b>Volatiles organic compounds (VOC)</b>	Free from Volatile Organic Substances.

----- END

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