



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. Application cosmétique et pharmaceutique. / *Solubilizer and emulsifier. Cosmetic & pharmaceutical application.*

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> POLYSORBATE 20 POLYSORBATE 20-RSPO-MB	Mars 2026 / March 2026
--	--	---------------------------

Additives	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).	
Allergen	This product doesn't contain cosmetic allergen (1223/2009) and food allergen (regulation 1169/2011)	
Animal Testing	Has not been tested on animals	
BSE - Bovine Spongiform Encephalopathy	No risk of BSE	
California Prop 65	This product (CAS:9005-64-5) is not listed	
Carcinogenic, Mutagenic and Reprotoxic (CMR)	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	
Composition	100% INCI POLYSORBATE 20	
Cosmetic	This product complies with Cosmetic directive 1223/2009/CEE and its amendments	
Cosmos / Ecocert	This product contains chemical derivatives – Not accepted by Cosmos	
Danger	This product is not classified as dangerous in accordance with CLP and ADR	
Dioxane	This product contains dioxin (≤ 10 ppm), this impurity is unavoidable for ethoxylation process	
Ecolabel	<i>No data available</i>	
European Pharmacopeia	Product in accordance with the current European Pharmacopoeia (monograph: Polysorbate 20)	
Food	This product is not suited for food nor feed applications.	
Genetically Modified Organisms (GMO)	To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms (GMO).	
Inventories	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
Geographic origin (for plant)	<i>No data available</i>	
Glycol ether	<i>No data available</i>	
Halal	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.	
Heavy Metals	Contains a minimum level of heavy metals according to EU 2023/915.	
HS code	3402399090	
Irradiation / ionization	There is no irradiation / ionization step in this product	
Kosher	Not certified but suitable for kosher diet.	
Latex	<i>No data available</i>	
Manufacturing location	Europe	
Microbiological data	<i>No data available</i>	
Microplastic	The products comply with EU 2023/2055 regulation because they are not considered microplastics due to their solubility above 2 g/L according to Annex 16 of this regulation	
Nanomaterials	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	

	Dossier technique et réglementaire / <i>technical and regulatory document</i> POLYSORBATE 20 POLYSORBATE 20-RSPO-MB	Mars 2026 / <i>March 2026</i>
--	--	----------------------------------

	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.
Nutritional data	<i>No data available</i>
Origin	vegetable and chemical origin
PAH / PFAS	Doesn't contain PFAS
Pesticide	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.
Phthalate	For this product, we do not intentionally introduce phthalates
Preservative	No preservative is intentionally added to this product.
Process	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
REACH	This product is a polymer - exempted from REACH
Residual Solvents	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.
RSPO	This product contains palm kernel oil derivate PKO = 19 – 21% & PO = 0% Our reference “ POLYSORBATE 20 ” is not RSPO certified If you want RSPO certified grade, you must order “ POLYSORBATE 20-RSPO-MB ”
Shelf Life	24 months
Substances of Very High Concern (SVHC)	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
Volatiles organic compounds (VOC)	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.*