	Dossier technique et réglementaire / <i>technical and regulatory document</i> POLYSORBATE 80 POLYSORBATE 80-RSPO-MB	Novembre 2024 / November 2024
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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 80**

N°CAS: 9005-65-6

N°EINECS/ELINCS: 500-019-9

DESCRIPTION / DESCRIPTION:

Mono-oléate de sorbitan éthoxylé (20 moles) / *Ethoxylated sorbitan mono-oleate (20 moles)*

Ce produit est conforme à la Pharmacopée Européenne en vigueur (monographie : polysorbate 80) / *This Product in accordance with the current European Pharmacopoeia (monograph: Polysorbate 80)*

Matière première d'origine végétale / *Raw material of vegetable origin.*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS
Aspect à 20°C / <i>Aspect at 20°C</i>	Liquide jaune clair / <i>Clear yellow liquid</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>	65 – 80 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>Oxide ethylene content</i>	≤ 1 ppm
Couleur (Gardner) / <i>Color (Gardner)</i>	≤ 7

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

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

pH 5% : 5-8

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:


IBC de 1000kg – Fût plastique de 200 kg – Tonnelet 25/50 kg / *1000kg IBC – 200 kg plastique drum – 25/50 kg keg*

A conserver dans un emballage original bien fermé à 20 - 25°C. En cas de turbidité ou de sédimentation, homogénéiser avant utilisation (une élévation de température peut aider) / *Store in well closed original package at 20 – 25°C. If turbidity or sedimentation occurs, homogenize before use (rise of temperature may help)*

Additives	For this product we do not intentionally introduce the following substances groups: Polybrominated biphenyls (PBB), Polychlorinated biphenyls (PCB), Polychlorinated
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	terphenyls (PCT), Polybrominated diphenyl ethers (PBDE).	
Allergen	This product doesn't contain cosmetic allergen (regulation 1223/2009) and food allergen (regulation EU No 1169/2011 annex II)	
Animal Testing	This product has not been tested on animals	
BSE - Bovine Spongiform Encephalopathy	No risk of BSE	
California Prop 65	This product (CAS: 9005-65-6) 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 80	
Cosmetic	This product complies with Cosmetic directive 1223/2009/CEE	
Cosmos / Ecocert	This product contains chemical derivates – Not accepted by Cosmos	
Danger	This product isn't classified as dangerous in accordance with CLP and ADR	
Dioxane	This product contains dioxane (≤ 10 ppm), this impurity is unavoidable for ethoxylation process	
Ecolabel	<i>No data available</i>	
European Pharmacopeia	This product complies with the current European Pharmacopoeia	
Food	FEMA No.: 2917 CFR Title 21 - Prohibited in human food: None - This product is free from any listed substance prohibited from use in human food. CFR Title 21 - Prohibited in animal food or feed: None - This product is free from any listed substance prohibited from use in animal food or feed. PART 172 -- FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION Subpart F - Flavoring Agents and Related Substances Sec. 172.515 Synthetic flavoring substances and adjuvants. PART 173 -- SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION Subpart D - Specific Usage Additives Sec. 173.340 Defoaming agents	
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	

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Irradiation / ionization	There is no ionization / irradiation during the manufacturing process 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>
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 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
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	This product doesn't contain phthalate
Preservative	No preservative is intentionally added to this product.
Process	Fatty acid + sorbitol → Esterification → Ethoxylation
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 oil derivate (PO). Our reference " POLYSORBATE 20 " is not RSPO certified If you want RSPO certified grade, you must order " POLYSORBATE 20-RSPO-MB "
Shelf Life before re-check	2 years
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.

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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.*