

	Dossier technique et réglementaire / <i>technical and regulatory document</i> POLYSORBATE 20	Novembre 2019 / <i>November 2019</i>
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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)*

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

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect / <i>Aspect</i>	Liquide jaune clair / <i>Yellow light liquid</i>	Visuel / <i>Visual</i>
Indice d'acide / <i>Acid value</i>	≤ 2 mg KOH / g	DGF C – V 2
Indice de saponification / <i>Saponification index</i>	40 – 50 mg KOH / g	DGF C – V 3
Indice d'hydroxyle / <i>Hydroxyl value</i>	96 – 108 mg KOH / g	DGF C – V 17a
Teneur en eau / <i>Water content</i>	≤ 3%	DGF C-III 13a
Teneur en dioxane / <i>Dioxane content</i>	≤ 10 ppm	Headspace GC
Teneur en oxyde d'éthylène / <i>Ethylene oxide content</i>	≤ 1 ppm	Headspace GC
pH (1%)	6 – 8	DGF H-III 1
Couleur (Gardner) / <i>Color</i>	≤ 5	DIN 53995

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*: 330°C

Densité à 60°C / *Density at 60°C*: ca. 1.05 g / cm³

Viscosité dynamique à 40°C / *Dynamic viscosity at 40°C*: 350 mPas

Point de fusion / *Melting point*: < 0°C

Le produit est un émulsifiant / *The product is an emulsifier*

APPLICATIONS :

Solubilisant et émulsifiant / *Solubilizer and emulsifier*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

IBC de 1000 kg – Fût plastique de 200 kg – Tonnelet 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)*

Additives	No data available
Allergen	This product doesn't contain cosmetic allergen (7th amendment, directive 2003/15/CE and directive 1223/2009) and food allergen (directive 2003/89/CE)
Animal Testing	Has not been tested on animals

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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 doesn't contain CMR (directive 1272/2008/CE)
Composition	<i>No data available</i>
Cosmetic	This product complies with Cosmetic directive 1223/2009/CEE
Cosmos / Ecocert	This product contain chemical derivates – Not accepted by Cosmos
Danger	This product is not classified as dangerous in accordance with CLP and ADR
Dioxane	This product contain dioxin (≤ 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	Is a food grade product and doesn't contain food allergen (directive 2003/89/CE)
Genetically Modified Organisms (GMO)	Doesn't contain GMO (< 0.1 %; decree n°2012- 128 of 30/01/2012)
Inventories	Compliant with China IECSC, USA TSCA, New Zealand NZIoC, Japan ENCS, Korea KECI, Philippines PICCS, Australia AICS, Canada DSL
Geographic origin (for plant)	Europe
Glycol ether	This product doesn't contain glycol ether
Halal	<i>No data available</i>
Heavy Metals	This product doesn't contain heavy metals (< 10 ppm Σ Pb)
HS code	34021300
Irradiation / ionization	There is no ionization step in this product
Kosher	This product is Kosher certified
Latex	<i>No data available</i>
Manufacturing location	Germany
Microbiological data	<i>No data available</i>
Nanomaterials	This product doesn't contain nanomaterial (commission recommendation 2011/696 and regulation 1223/2009)
Nutritional data	<i>No data available</i>
Origin	30% vegetable (coco) and 70% chemical
Pesticide	This product doesn't contain pesticide
Phthalate	This product doesn't contain phthalate
Preservative	This product doesn't contain preservative (cosmetic regulation 1223/2009/CEE and 2003/15/CE)
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	This product doesn't contain residual solvents (note CPMP/ICH/283/95)
RSPO	This product doesn't contain palm – not concerned
Shelf Life	24 months
Substances of Very High Concern (SVHC)	This product doesn't contain SVHC
Volatiles organic compounds (VOC)	This product doesn't contain VOC (directive 2004/42/EC)

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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.*