

	Dossier technique et réglementaire / <i>technical and regulatory document</i> POPLYSORBATE 80	Mars 2019 / March 2019
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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	METHODES / METHODS
Aspect à 20°C / <i>Aspect at 20°C</i>	Liquide jaune clair / <i>Clear yellow liquid</i>	Visuel / <i>Visual</i>
Indice d'acide / <i>Acid value</i>	≤ 2 mg KOH /g	AV031
Indice de saponification / <i>Saponification value</i>	45 – 55 mg KOH /g	AV041
Indice d'hydroxyle / <i>Hydroxyl value</i>	65 – 80 mg KOH /g	AV023
Teneur en eau / <i>Water content</i>	≤ 3 %	AV047
Teneur en dioxane / <i>Dioxane content</i>	≤ 10	AV018
Teneur en oxyde d'éthylène / <i>Oxide ethylene content</i>	≤ 1	AV019
pH (1 % eau/water)	6 – 7.5	AV027
Couleur (Gardner) / <i>Color (Gardner)</i>	≤ 6	AV011

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

Ces caractéristiques sont conformes aux précédentes spécifications datées de Février 2013 / *These features are in accordance with previous specifications dated on Février 2013*

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Ce produit est végétalien / *This product is vegan*

APPLICATIONS:

Additif pour aliments, matériaux en contact avec les aliments, cosmétiques, solubilisant et émulsifiant / *Additive for food, food contact materials, cosmetics, solubilizer and emulsifier.*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

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

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	This product doesn't contain additives
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

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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 doesn't contain CMR (directive 1272/2008/CE)
Composition	100% sorbitan monooleate polyglycolether
Cosmetic	This product complies with Cosmetic directive 1223/2009/CEE
Cosmos / Ecocert	This product contain chemical derivatives – Not accepted by Cosmos
Danger	This product isn't classified as dangerous in accordance with CLP and ADR
Dioxane	This product contain dioxane (≤ 5 ppm), this impurity is unavoidable for ethoxylation process
Ecolabel	<i>No data available</i>
European Pharmacopoeia	This product complies with the current European Pharmacopoeia
Food	Is a food grade product, conform to 231/2012 regulation (E433)
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, Korea KECL, Philippines PICCS, Australia AICS, Canada DSL
Geographic origin (for plant)	<i>No data available</i>
Glycol ether	This product is a polyglycolether
Halal	This product is not Halal certified
Heavy Metals	This product has a sum as Pb of heavy metals < 10 ppm
HS code	34021300
Irradiation / ionization	There is no ionization / irradiation during the manufacturing process in this product
Kosher	This product is not Kosher certified
Latex	This product doesn't contain latex
Manufacturing location	Germany
Microbiological data	Bacteria count < 200 No/g
Nanomaterials	This product doesn't contain nanomaterial (commission recommendation 2011/696 and regulation 1223/2009)
Nutritional data	This product has ~ 200 kcal/100g
Origin	32% vegetable (palm, sunflower, olive) and 68 % chemical / synthetic
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 sorbitan monooleate
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 is not certified RSPO
Shelf Life before re-check	2 years
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 cancel and replace all technical and regulatory previous documents.*