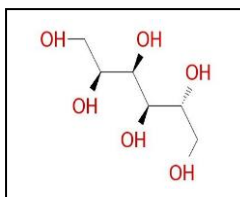


	Dossier technique et réglementaire / <i>technical and regulatory document</i> SORBITOL 70% PHARMA	Juillet 2025 / <i>July 2025</i>
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INCI: **Sorbitol**
N° CAS: 50-70-4
N°EINECS/ELINCS: 200-061-5

+ EAU 30%

DESCRIPTION / DESCRIPTION :

Liquide sirupeux et limpide à une température de 25°C / *Is a sirupy liquid and limpid at a temperature of 25 ° C.*
Produit à conforme a la Pharmacopée Européenne en vigueur (monographie: sorbitol liquide non cristallisable)
/ *Product in accordance with the European Pharmacopoeia in force (monograph: non-crystallizable liquid sorbitol)*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect / <i>Aspect</i>	Conforme / compliant	Ph. Eur
Identification A-B-C / <i>Identification A-B-C</i>	Conforme / compliant	Ph. Eur
Substance anhydre / <i>Dry substance</i>	68 – 72 %	Ph.Eur
D-glucitol (D-sorbitol, C ₆ H ₁₄ O ₆) / <i>D-glucitol (D-sorbitol, C₆H₁₄O₆)</i>	72 – 92 %	Ph. Eur
Sucres réducteurs / <i>Reducing sugars</i>	≥ 12.8 ml	Ph. Eur
Sucre total (après hydrolyse) / <i>Total sugars (after hydrolysis)</i>	≥ 8 ml	Ph. Eur
Conductivité / <i>Conductivity</i>	≤ 10 (µS/cm)	Ph. Eur
Teneur en eau / <i>Water content</i>	28 – 32 %	Ph. Eur

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

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

De nos jours, on produit le sorbitol de façon industrielle. Il est préparé par hydrogénation du D-glycose (dextrose) qui est lui aussi, présent a l'état naturel, soit tel quel, soit sous forme de son polymère l'amidon, dans un très grand nombre de plantes et de fruits. Chez l'homme, le D-glucose est présent dans le sang.
/ *Today, sorbitol is produced industrially. It is prepared by hydrogenation of D-glycose (dextrose) which is also present in the natural state, either as such, or in the form of its starch polymer, in a very large number of plants and fruits. In humans, D-glucose is present in the blood.*
Suitable for Vegan

ISO 16128 :

NI : 0

NOI : 1

OI : 0

OOI : 0

APPLICATIONS :

Industrie pharmaceutique, alimentaire, cosmétique, textile, des colles et adhésifs / *Pharmaceutical, cosmetic, food and textile industries, Glue and adhesive industry.*

CONDITIONNEMENT STANDARD / STANDARD PACKAGING :

Containers de 1300 kg - Fut plastique de 272 kg - Tonnelet de 60 kg / *Containers of 1300 kg – plastic barrel of 272 kg - Keg of 60 kg.*

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Additives	Not expected	
Allergen	Food allergen (1169/2011) & cosmetic allergen (1223/2009 & 2023/1545) are not expected excepted : Sulfur Dioxide and Sulfite – 50 ppm max	
Animal Testing	the product is not tested on animals	
BSE - Bovine Spongiform Encephalopathy	This product doesn't contain ingredients or derived products of animal origin, therefore doesn't contain BSE	
California Prop 65	This product (CAS: 50-70-4) is not listed	
Carcinogenic, Mutagenic and Reprotoxic (CMR)	No CMR are added in this product	
Composition	70% sorbitol + 30% water	
Cosmetic	Can be used in cosmetic industry – complying to cosmetic regulation 1223/2009 and its amendments	
Cosmos / Ecocert	<i>No data available</i>	
Danger	This product is not classified as dangerous in accordance with CLP and ADR	
Dioxane	Doesn't contain dioxane or 1.4 dioxine	
Ecolabel	<i>No data available</i>	
European Pharmacopeia	Conform to current European Pharmacopeia	
Food	Can be used in food industry	
Genetically Modified Organisms (GMO)	This product doesn't contain GMO	
Inventories	Cas 50-70-4 listed in China IECSC, USA TSCA, New Zealand NZIoC, Taiwan TCSI, Japan ENCS,	Korea KECL, Thailand TECI, Philippines PICCS Australia AIIC, Canada DSL
Geographic origin (for plant)	<i>No data available</i>	
Glycol ether	Not expected	
Halal	Halal certified	
Heavy Metals	Heavy metals level is in compliance with acceptance limits Iron < 2ppm Arsenic <3 ppm	Nickel < 1ppm Lead < 1ppm
HS code	<i>No data available</i>	
Irradiation / ionization	This product has not been irradiated	
Kosher	Kosher certified	
Latex	Doesn't contain	
Manufacturing location	Egypt,	
Microbiological data	Yeast < 100 cfu/g Mold < 100 cfu/g Total plate count < 1000 cfu/g	Salmonella absent E-coli absent
Microplastic	Doesn't contain (2023/2055)	
Nanomaterials	Doesn't contain nanomaterials (2011/696 & 1223/2009)	

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Nitrosamine	Doesn't contain			
Nutritional data	Nutritional information (for 100g):			
	Calories	180	Sugar Alcohols, g	70
	Total fat, g	0	Protein, g	0
	Cholesterol, mg	0	Vitamin D, mcg	0
	Sodium, mg	0	Calcium – Ca, mg	0
	Total Carbohydrate, g	70	Iron, mg	0
	Dietary Fiber, g	0	Potassium, mg	0
	Total sugar, g	0	Ash, g	<0.0*
	Added sugar, g		0	
	* Not present at a level of quantification			
Origin	100% Vegetable (corn)			
PAH/PFAS	Not expected			
Pesticide	Not expected			
Phthalate	Not expected			
Preservative	Doesn't contain (1223/2009 & 2003/15)			
Process	Glucose syrup → hydrogenation, decantation, filtration, demineralization, concentration, filtration → finish product			
REACH	Exempted from reach registration annex IV			
Residual Solvents	Doesn't contain (CPMP/ICH/283/95)			
RSPO	Doesn't contain palm oil – Not concerned			
Shelf Life	3 years			
Substances of Very High Concern (SVHC)	Not expected			
Volatiles organic compounds (VOC)	Not expected (2010/79)			

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