



azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **SORBITOLO SOLUZIONE 70% Ph.Eur.**

SPECIFICA	METODO	Lim. Inf. - Lim. Sup.	u.m.
Aspetto	Ph.Eur.	liquido sciropposo, limpido, incolore	
<i>Identificazione</i>			
- Rotazione ottica specifica	Ph.Eur.	1,50 - 3,50	°
- Identificazione A	Ph.Eur.	conforme	
- Identificazione B		conforme	
- Identificazione C		conforme	
Aspetto della soluzione	Ph.Eur.	limpida e incolore	
Zuccheri riducenti			
- Zuccheri riducenti	Ph.Eur.	<=0,20	%
- Zuccheri riducenti	Ph.Eur.	>=12,8	ml
Nichel	Ph.Eur.	<=1	ppm
Piombo	Ph.Eur.	<=0,50	ppm
Titolo (sull'anidro)	Ph.Eur.	72,00 - 92,00	%
Titolo (sull'anidro)	USP	>=45,00	%
Acqua	Ph.Eur.	28,00 - 32,00	%
Dietilenglicol		<=1.000	ppm
Etilenglicol		<=1.000	ppm
<i>Identificazione</i>			
- Identificazione IR	interno	conforme alla specifica	
Conducibilità	Ph.Eur.	<=10	microS.cm
Resistività			KOhm/cm
Conta totale microrganismi aerobi (TAMC)	Ph.Eur.-USP	<=1.000	CFU/g
Lieviti e muffe	Ph.Eur.-USP	<=100	CFU/g
E.coli	Ph.Eur.-USP	assente/1g	
Salmonella	Ph.Eur.-USP	assente/10g	
Materia secca			
- Materia secca			%
- Zuccheri totali/Tiosolfato		<=9,3	%
Zuccheri totali/Tiosolfato			
- Zuccheri totali/Tiosolfato		>8,0	ml
- Ceneri solforiche		<=0,10	%
pH (sol 14%)		5,0 - 7,5	

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati



azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **SORBITOLO SOLUZIONE 70% Ph.Eur.**

Revisione Capitolato		3	
Data Approvazione		12/06/2015	

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati



azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **SORBITOLO SOLUZIONE 70% Ph.Eur.**

AGENTS	Presence in the product	Presence in the processing line/workshop	Presence in the factory	Is the risk of cross contamination controlled?
	“-“ for absence, “+” for presence			Y, N or N/A
Wheat, gluten and products thereof	See footnote ¹		+	N/A
Other cereals containing gluten ² and product thereof	-	-	-	N/A
Crustaceans and product thereof	-	-	-	N/A
Eggs and product thereof	-	-	-	N/A
Fish and product thereof	-	-	-	N/A
Peanuts and product thereof	-	-	-	N/A
Soya and product thereof	-	-	-	N/A
Milk, constituents ³ and product thereof	-	-	-	N/A
Nuts ⁴ and product thereof	-	-	-	N/A
Celery and product thereof	-	-	-	N/A
Mustard and product thereof	-	-	-	N/A
Sesame and product thereof	-	-	-	N/A
Sulphur dioxide and sulphites in concentration higher than 10 ppm	-	-	+	Y
Lupin and product thereof	-	-	-	N/A
Molluscs and product thereof	-	-	-	N/A

¹Purified product derived from maize starch and/or wheat starch hydrolysis. Absence of wheat gluten when tested with the best available technique R5 Sandwich ELISA Kit. In Europe, this product does not have to support any allergen labeling according to the 2007/68/EC directive.

²Cereals (i.e. rye, barley, oat, spelt, kamut, rice and wild rice, sorghum, buckwheat, millet, quinoa)

³Constituents (i.e. cow's milk proteins, lactose)

⁴Nuts (i.e. Almond [*Amygdalus communis* L.], Hazelnut [*Corylus avellana*], Walnut [*Juglans regia*], Cashew nut [*Anacardium occidentale*], Pecan nut [*Carya illinoensis* (Wangenh.) K. Koch], Brazil nut [*Bertholletia excelsa*], Pistachio nut [*Pistacia vera*], Macadamia nut, Queensland nut [*Macadamia ternifolia*])

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati



azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **SORBITOLO SOLUZIONE 70% Ph.Eur.**

AGENTS	Presence in the product	Presence in the processing line/workshop	Presence in the factory	Is the risk of cross contamination controlled?
	“-“ for absence, “+” for presence			Y, N or N/A
VEGETABLE ORIGIN				
Maize and product thereof	+	+	+	N/A ¹
Pea and product thereof	-	-	+	Y
Potato and product thereof	-	-	+	Y
Caffeine	-	-	-	N/A
Cocoa	-	-	-	N/A
Coconut	-	-	-	N/A
Colza	-	-	-	N/A
Ethanol	-	-	-	N/A
Fruits (dried and fresh fruits) and products thereof	-	-	-	N/A
Fructose	-	-	-	N/A
Other legumes, pulses and beans	-	-	-	N/A
Latex	-	-	-	N/A
Latex group (as banana, avocado, kiwi...)	-	-	-	N/A
Liliaceae (as garlic, onion...)	-	-	-	N/A
Mushrooms	-	-	-	N/A
Other prunoids	-	-	-	N/A
Saccharose (added)	-	-	-	N/A
Seeds (as poppy, sunflower, cottonseed...)	-	-	-	N/A
Other Solanaceae (as tomato...)	-	-	-	N/A
Spices ² and product thereof	-	-	-	N/A
Tree nuts and products thereof (Pine nut, Chestnut, Hickory...)	-	-	-	N/A
Umbellifereae (as carrot, coriander, parsley, parsnip...)	-	-	-	N/A
Other vegetables and products therof	-	-	-	N/A
ANIMAL ORIGIN				
Honey	-	-	-	N/A
Meat (beef, chicken, lamb / mutton, pork)	-	-	-	N/A
Propolis	-	-	-	N/A
Royal jelly	-	-	-	N/A
Phenylalanine	-	-	-	N/A
Yam and products thereof	-	-	-	N/A

¹Purified product derived from maize and/or wheat starch hydrolysis

²Spices (i.e cardamom, cinnamon, cumin, curcuma, nutmeg, paprika, pepper...)



azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **SORBITOLO SOLUZIONE 70% Ph.Eur.**

AGENTS	Presence in the product	Presence in the processing line/workshop	Presence in the factory	Is the risk of cross contamination controlled?
	“-“ for absence, “+” for presence			Y, N or N/A
OTHERS				
AZO colorants (E102 / E104 / E110 / E122 / E123 / E124 / E129 / E151)	-	-	-	N/A
Benzoic acid and PHB (E210 to E219)	-	-	-	N/A
BHA / BHT (E320 / E321)	-	-	-	N/A
Flavour components	-	-	-	N/A
Gallates (E310 / E312)	-	-	-	N/A
Gelatin	-	-	-	N/A
Glutamate, ribonucleic inosinates and derivatives	-	-	-	N/A
Histamine	-	-	-	N/A
Nitrates / Nitrites	-	-	-	N/A
Propionates	-	-	-	N/A
Propylene oxide	-	-	-	N/A
Rennet	-	-	-	N/A
Vanillin / vanilla	-	-	-	N/A
Yeast	-	-	-	N/A

GMO STATEMENT:

The product is GMO free.

Product origin – Raw material used :

The product has a vegetable origin: Maize and/or Wheat (Zea mays L. / Triticum aestivum L.). The cereals have been grown in Europe.

TSE information :

According to the note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products - Revision 3 (EMA / 410 / 01 Rev.03 - July 2011) adopted by the European Commission on 3 May 2011, (2011/C 73/01), We certify that the above product(s) and the associated substances used during the manufacturing process are not of animal origin. Therefore there is no objective reason to suspect the presence of the Transmissible Spongiform Encephalopathies infectious agents in the product. We commit ourselves on notification you of any change in this information.

Residual solvent :

The solvents listed in USP <467> and EP < 5.4.> Residual solvents – Class 1, 2 and 3 solvents are not used in the manufacture, packaging, handling or storage of the above listed product. In addition the solvents listed under ICH guidelines (as “current ICH Q3C” and “CPMP/ICH/82260/06”) – Class 1, 2 and 3 solvents are not used in the manufacture, packaging, handling or storage of the above listed product.

Water is the only solvent used for the manufacturing of the above listed product.

However, even if not used as a solvent, ethylene glycol may be present as a by-product of the hydrogenation reaction. Amount of ethylene glycol will be analyzed on each batch which will be released to your production site and will be stated in the certificate of analysis of each delivery.

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati



azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **SORBITOLO SOLUZIONE 70% Ph.Eur.**

Animal testing

We can attest that the products manufactured in our manufacturing plants are in compliance with Regulation 1223/2009/EC related to the cosmetics products.

The regulation 1223/2009/EC (Chapter 5, Article 18) specifies the conditions which have to be applied in order to mention that no animal tests have been carried out on the cosmetics products or its ingredients.

Based on this regulation, The product have not been tested on animals for the purpose of developing new cosmetics ingredients

Irradiation

Our products do not contain compounds treated with ionizing radiation and are not submitted to an ionizing treatment at any stage of the production. Therefore, they do not fall within the scope of Directives 1999/2/CE and 1999/3/CE concerning Foods and Food ingredients treated with ionizing radiation.

Ethylene Oxide treatment.

We certify that the product is not treated with ethylene oxide.

Nanoparticles

The official definition that we are using is that of the European Union as contained in Regulation (EU) No 1169/2011 of the European Parliament and the Council dated 25 October 2011 relating to information for consumers about foodstuffs:

« *Manufactured nanomaterials:*

- *any **intentionally** produced material that has one or more dimensions of the order of 100 nm or less,*
- *or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates that may have a size above 100 nm, but retain characteristics that are typical of the nanoscale. »*

On the basis of this definition, we are in a position to confirm that to date, we do not use nanotechnologies in our manufacturing processes and do not incorporate nanomaterials in the products we are supplying

California Proposition 65

We confirm that none of chemical substances known to cause cancer or reproductive toxicity are added or are present as impurity above the recommended level of proposition 65 California in the product

Viral status

None of the following active substances or product used:

groups Penicillins, Cephalosporins, Other β -lactam antibiotics, Cytotoxic substances, cytostatics, Steroids / Hormones.

Latex statement

We confirm that latex is not a synthesis intermediate for the manufacture of Sorbitol

Melamine absence

We confirm that no melamine is added to the product(s) mentioned above. Furthermore no melamine is used in the production process, as starting material or has been added to a starting material.

CMR

There is no substance present in the raw material classified as Carcinogenic, Mutagenic or Toxic to Reproduction (CMR) according to the Commission Directive 2004/93/EC and Directive 76/768/EEC.

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati



azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **SORBITOLO SOLUZIONE 70% Ph.Eur.**

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati