



azienda chimica e farmaceutica

PRODUCT INFORMATION

Regulatory Documentation for Food Product

Rev.N.0 Date 20/01/2016

Product : SORBITOLO PURO POLVERE FU-Ph.Eur. E420

ACEF CODE : 001389-25

CAS / CAS N.	50-70-4
EINECS / ELINCS	200-061-5
Formula	C6H14O6
Molecular Weight	182.08 g/mol

1. Product composition

<u>Source of active ingredients</u>	Yes	No	Comments
Synthesis	<input type="checkbox"/>	<input type="checkbox"/>	
Fermentation	<input type="checkbox"/>	<input type="checkbox"/>	
Vegetable	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Wheat and/or maize
Animal	<input type="checkbox"/>	<input type="checkbox"/>	
Mineral	<input type="checkbox"/>	<input type="checkbox"/>	

Composition:

Is the composition of the ingredient at 100%? Yes

If no, please provide a breakdown of all sub ingredients.

<u>Source of formulation ingredients</u>	Yes	No	Comments
Synthesis	<input type="checkbox"/>	<input type="checkbox"/>	
Fermentation	<input type="checkbox"/>	<input type="checkbox"/>	
Vegetable	<input type="checkbox"/>	<input type="checkbox"/>	
Animal	<input type="checkbox"/>	<input type="checkbox"/>	
Mineral	<input type="checkbox"/>	<input type="checkbox"/>	



azienda chimica e farmaceutica

Active ingredient permitted as food additive in compliance with specifications for food additives (Reg. EU 231/2012)

Yes	No	N.a.	Comments
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E 420(i)

2. Food labelling

Product allergen labelling (Reg. (EU) 1169/2011 Annex II)		
Please enter Y for Yes, N for No, N/A for Not Applicable or N/K for Not Known		
Present – The ingredient contains the allergen (as ingredient, component of ingredient, food additive or processing aid) or can contain traces to carry over. Cross contamination – There is a risk of cross contamination in the ingredient or in the supply chain. Consider lubricants, other products manufactured on the line and on site.	Present	Cross-Contamination
• Cereals containing gluten* i.e. wheat, rye barley, oats, spelt, kamut or their hybridised strains	Y ¹	N/A
• Crustaceans*	N	N/A
• Eggs*	N	N/A
• Fish*	N	N/A
• Peanuts*	N	N/A
• Soybeans*	N	N/A
• Milk and dairy products* (including lactose)	N	N/A
• Nuts and nut products* i.e. Almond (<i>prunus dulcis</i>), Hazelnut (<i>Corylus avellana</i>), Persian walnut, English walnut (<i>Juglans regia</i>), Cashew (<i>Anacardium occidentale</i>), Pecan nut (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nut (<i>Bertholletia excelsa</i>), Pistacho nut (<i>Pistacia vera</i>), Macadamia nut, Queensland nut (<i>Macadamia ternifolia</i>)	N	N/A
• Sesame seeds*	N	N/A
• Celery*	N	N/A
• Mustard*	N	N/A
• Sulphur dioxide and Sulphite at concentrations of more than 10mg/kg or 10mg/litre expressed as SO ₂	N	N
• Lupins*	N	N/A
• Molluscs*	N	N/A

*and products thereof

¹ Purified 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 1169/2011 Annex II regulation.



azienda chimica e farmaceutica

Nutritional labelling (Reg. (EU) 1169/2011 Annex I) (please, indicate the energy value and content of following nutrients)

- energy value: 240 Kcal/100g
- fat (saturates, mono-unsaturates, polyunsaturates): 0
- carbohydrate (sugars, polyols, starch): 99.5 g/100g
- salt: < 0.5 mg/100g
- fibre: 0
- protein: 0

3. Compliance with European food law

Key: Please enter Y for Yes, N for No, N/A for Not Applicable or N/K for Not Known.

Item	Yes, No, Comments
GMO: Not derived from Genetically Modified Organism (G.M.O.) – According to regulations 1829/2003/EC and 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and any amending legislation	Y
BSE/TSE : The product is free from risk of Bovine Spongiform Encephalopathies (according to EMEA 410/01 Rev02 Guidelines and with Regulation (EC) No 999/2001 and adjournments, laying down measures for prevention, control and eradication of certain transmissible encephalopathies)	N/A
Ionisation/Irradiation: Not irradiated (according to Directive 1999/2/EC and Directive 1999 /3/EC)	Y
Pesticides: According to Reg. CE 396/2005, D.M. 27/08/2004 and amendments	Y
Residual Solvents: According to Dir. 2009/32/EC and amendments	Y
Contaminants (Reg. EC 1881/2006): According to Reg. EC 1881/2006 for: - Dioxin/PCB - PAH (polycyclic Aromatic Hydrocarbons) - Mycotoxins	Y



azienda chimica e farmaceutica

CITES: Not derived from endangered species (please refer to CITES LIST/ www.cites.org)	Y
Free From Gelatin	Y
Free from foreign matter/metal	Y
Free from artificial colours	Y
Free from artificial flavours	Y
Free from artificial sweeteners	Y
Free from sugar (sucrose, dextrose, glucose)	Y
Free from artificial preservative	Y
Free from melamine	Y
Suitable for vegetarians	Y
Suitable for vegans	Y

ADDITIONAL DECLARATIONS

(Key: Please enter Y for Yes, N for No, N/A for Not Applicable or N/K for Not Known).

	Complies
WADA: We declare that the product/ raw material clearly identified doesn't contain any substance included in the World Anti-Doping Agency (WADA) Prohibited List (last Edition, 2007).	Y
European Food Law: We declare that the product/ raw material clearly identified is manufactured according to Hazard Analysis and Critical Control Points system and safety procedures in compliance with Commission Regulation (EC) No. 852/2004 853/2004, 854/2004, 178/2002 hence it is suitable for food application.	Y
Contaminants: We declare that the product/ raw material clearly identified complies with Regulation 1881/2006/CE and amendments on contaminants.	Y
Nanomaterial (Reg. UE 1169/2011): We declare that product is not an engineered nanomaterial	Y
Latex: We declare that the product/ raw material clearly identified doesn't contain ingredients derived from latex.	Y