



azienda chimica e farmaceutica

PRODUCT INFORMATION

Regulatory Documentation for Food Product

Rev.N.0 Date 02/10/2015

Product : PROLINA-L USP-Ph.Eur.

ACEF CODE : 001235-20

CAS / CAS N.	147-85-3
EINECS / ELINCS	205-702-2
Formula	C ₅ H ₉ NO ₂
Molecular Weight	115.13

1. Product composition

<u>Source of active ingredients</u>	Yes	No	Comments
Synthesis	☐	☐	
Fermentation	☒	☐	
Vegetable	☐	☐	
Animal	☐	☐	
Mineral	☐	☐	

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	☐	☐	
Fermentation	☐	☐	
Vegetable	☐	☐	
Animal	☐	☐	
Mineral	☐	☐	



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

Yes No N.a. Comments

☐ ☐ ☒

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.	Present	Cross-Contamination
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.		
• Cereals containing gluten* i.e. wheat, rye barley, oats, spelt, kamut or their hybridised strains	N	N
• Crustaceans*	N	N
• Eggs*	N	N
• Fish*	N	N
• Peanuts*	N	N
• Soybeans*	N	N
• Milk and dairy products* (including lactose)	N	N
• 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 illinoiesis (Wangenh.) K. Koch</i>), Brazil nut (<i>Bertholletia excelsa</i>), Pistacho nut (<i>Pistacia vera</i>), Macadamia nut, Queensland nut (<i>Macadamia ternifolia</i>)	N	N
• Sesame seeds*	N	N
• Celery*	N	N
• Mustard*	N	N
• Sulphur dioxide and Sulphite at concentrations of more than 10mg/kg or 10mg/litre expressed as SO ₂ .	N	N
• Lupins*	N	N
• Molluscs*	N	N

*and products thereof



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

- energy value: 4 Kcal/g
- fat (saturates, mono-unsaturates, polyunsaturates): 0
- carbohydrate (sugars, polyols, starch): 0
- salt: 0
- fibre: 0
- protein: 1.000 mg/g as L-Proline

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	N/A
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)	Y
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



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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 has not been in contact and doesn't contain ingredients derived from latex.	Y