

PRODUCT SPECIFICATION – FOOD INGREDIENTS

LACTOSE 200MESH PHARM.

ConnectingChemistry



1. PRODUCT IDENTIFICATION

Supplier product name	LACTOSE 200MESH PHARM.		
Supplier product number	13467	Date of issue: 11/06/2020	Replaces: 19/09/2017
Origin	Pasteurised milk / Whey from cottage cheese / Quark		
Manufacturer	Danone GmbH		
Country	Germany		
Certification manufacturer:	HACCP, ISO 9001		

1.1 Composition

Single ingredient	
Chemical name	Lactose monohydrate
Chemical formula	$C_{12}H_{22}O_{11} \cdot H_2O$
Molecular weight	

1.2 Legislative information

CAS-N°	63-42-3
INTRASTAT CODE	1702110000
EINECS	200-559-2
Legal declaration	

2. PRODUCT INFORMATION

	Unit	Specification	Method
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2.1 Physical and Chemical properties

Appearance		Crystalline powder	
Colour		White	
Odour/taste		Odourless	
Water	%	4,5 – 5,5	Karl Fisher
Clarity of solution		clear	USP/ EP
Colour of solution (extinction 400nm)		max. 0,04	USP/ EP
Protein and light-absorbing impurities:			
Extinction (210-220) nm		max. 0,25	USP/ EP
Extinction (270-300) nm		max. 0,07	USP/ EP



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Acidity or Alkalinity (0,1N NaOH)	ml	max. 0, 4	USP/ EP
Specific rotation (cal. on anhydrous basis)	°	54,4 – 55,9	USP/ EP
pH (10% solution)		3,8 – 5,5	pH meter
Loss on drying		max. 0,5	USP/ EP
Particle size: < 63 µm	%	70 - 90	USP/ EP/ JP
< 90 µm	%	80 - 100	USP/ EP/ JP

2.2 Microbiological data

Total Plate count	cfu/g	max. 100	CASO-Agar 30°C/48h
Coli-test	/g	negative	LST-Bouillon 36°C/48h
Enterobacteriaceae	/g	Max. 1	VRBD-AGAR 37°C/24h
Moulds	cfu/g	max. 20	YGC-Agar 25°C/5d
Yeasts	cfu/g	max. 20	YGC-Agar 25°C/5d
E.coli	cfu/g	max. 0,3	LFGB L01.00-25(MPN)
Listeria monocytogenes	/25g	not detected	LFGB L00.00-32/ISO11290-1=
Salmonellae	/25g	not detected	LFGB L00.00-20
Bacillus cereus	cfu/g	max. 100	LFGB L01.00-72
Coagulase-positive staphylococcus	/g	not detected	DIN EN ISO 6888-3
Clostridium perfringens	cfu/g	max. 10	LFGB L00.00-57
Sulphite reducing anaerobic spore formers	cfu/g	max. 0,3	VDLUF A M7.18.4 (MPN)

2.3 Contaminants

2.3.1 Chemical contaminants

Heavy metals (Pb,Cd,Hg,As)	ppm	max. 0,5	EN ISO 17294-2:2004
Aflatoxin M1	ppm	max. 0,05	LFGB L01.00-34
Polychlorinated biphenyls		corresponds to pollutant max. quantities	
Pesticide		corresponds to residue max. quantities	

2.3.2 Physical contaminants

Foreign body control	Magnet, sieve, filters
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2.4 Nutritional Information (Directive 90/496/EC, amended by 2003/120/EC and 2008/100/EC)

2.4.1 Nutritional Values

Energy	kJ/100g	-	
Energy	kcal/100g	-	
Protein	g/100g	0	
Carbohydrate :	g/100g	0	
Of which Sugars	g/100g	0	
Polyols	g/100g	0	
Starches	g/100g	0	
Others	g/100g	0	
Fat :	g/100g	0	
Of which Saturated	g/100g	0	
Mono-unsaturated	g/100g	0	
Poly-unsaturated	g/100g	0	
Transfatty acids	g/100g	0	
Cholesterol	mg/100g	0	
Water	g/100g	-	
Organic acid	g/100g	-	

2.4.2 Minerals

Sodium	mg/100g		
Calcium	mg/100g		
Zinc	mg/100g		
Copper	mg/100g		
Phosphorus	mg/100g		
Others:	mg/100g	-	

3. FOOD INTOLERANCES

3.1 Allergens (Directives 2000/13/EC, 2003/89/CE 2007/68/EC)

	Y / N	Direct Contamination	Cross-Contamination (Risk)
Barley	N	N	N
Beef	N	N	N



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Cacao	N	N	N
Carrot	N	N	N
Celery and celery products	N	N	N
Cereals containing gluten and products produced with these (wheat, rye, oats, spelt, barley)	N	N	N
Chicken	N	N	N
Coriander	N	N	N
Crustaceans and Shellfish	N	N	N
Eggs and egg products	N	N	N
Fish and fish products	N	N	N
Glutamate	N	N	N
Lupin and products thereof	N	N	N
Milk and milk products (incl. Lactose)	Y	Y	Y
Molluscs and products thereof	N	N	N
Mustard and mustard products	N	N	N
Nuts and nut products (almonds, hazelnuts, walnuts)	N	N	N
Peanuts and peanut products	N	N	N
Pork	N	N	N
Sesame and sesame products	N	N	N
Soybean and soybean products	N	N	N
Sulphite (E221 - E228)	N	N	N
Sulphur dioxide (> 10 mg/kg)	N	N	N

3.2 Suitability for other diets

Coeliacs	N	Lactose intolerant	N
Halal	N	Vegans	N
Kosher	N	Vegetarian	N

3.3 GMO Declaration, acc. Regulations 298/2008/EC and 1830/2003/EC

LACTOSE 200MESH PHARM. does not contain genetically modified organisms and is not produced using raw materials of a genetically modified origin. At no stage during production does the product comes into contact with genetically modified organisms.

LACTOSE 200MESH PHARM. is falling under the scope of the EC Regulation n° 1829/2003 on genetically modified food and feed and the EC Regulation n° 1830/2003 on the traceability and labeling of genetically modified organisms and the traceability of products derived from them and to modification of Directive 2001/18/EC.



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3.4 Irradiation, acc. Directive 1999/2/EC and 1999/3/EC

This product was not subject to any kind of irradiation treatment

3.5 BSE/TSE Declaration

The used ingredients for LACTOSE 200MESH PHARM. are not of animal origin. The processing equipment and the packing material which is used to manufacture, pack or fill the products into the packing units do not come into contact with any meat or meat by- product.

3.6 Residual Solvents, complies with

For the manufacturing of the product, no solvents are used. This product is in compliance with the Guideline CPMP/ICH/283/95 and chapter <467> of the current edition of the USP-NF for residual solvents.

3.7 Regulatory information

The product complies with:

USP, EP

EC Regulation n° 1881/2006 setting maximum levels for certain contaminants in foodstuffs.

The production plant complies with:

EC Regulation n° 852/2004 on hygienic requirements for the manufacturing of raw materials in the food industry.

4. PACKAGING

Packaging description	Bags
Packaging net content	25 kg
Different packagings on request	Yes
Paletisation	

5. STORAGE CONDITIONS

Storage conditions	Must be kept in a cool, dry and well ventilated environment, in closed original packaging
Shelf life (recommended re-analysis)	36 months after production, under the above mentioned conditions

6. DISCLAIMER

The content of the Product Specification Sheet is completed to the best of our knowledge.
This document does not dismiss the user of his legal obligation with respect to food safety.



DISTRIBUTOR COMPANY INFORMATION			
name	BRENNTAG N.V.	BRENNTAG Nederland B.V.	BRENNTAG SOUTH AFRICA (PTY) LTD
address	Nijverheidslaam 38 8540 Deerlijk	Donker Duyvisweg 44 3316 BM Dordrecht	11 Mansell Road Killarney Gardens, 7441
country	Belgium	The Netherlands	South Africa
phone number	+32 (0)56 77 69 44	+31 (0)78 65 44 944	+27 (0)21 0201800
website	www.brenntag.be	www.brenntag.nl	www.brenntag.co.za
e-mail	info@brenntag.be	info@brenntag.nl	info@brenntag.co.za
activities	Distribution and export of chemicals and ingredients		
VAT number	BE0405317567	NL001375945B01	4740102209
emergency number(24/365)	+32 (0)56 77 69 44	+31 (0)78 6544 944	+27 (0)21 0201800
management systems: certifications	ISO 9001, ISO 14001, ISO 22000, FSSC 22000, GMP+ Feed, ESAD	ISO 9001, ISO 14001, ISO 22000, FSSC 22000, OHSAS 18001, GMP+ Feed, ESAD, AEO	ISO 9001, FSSC 22000