

PRODUCT SPECIFICATION – PHARMA INGREDIENTS

CALCIUM CARBONATE 450 PHARM.

ConnectingChemistry



1. PRODUCT IDENTIFICATION

Supplier product name	CALCIUM CARBONATE 450 PHARM.		
Supplier product number	11210	Date of issue: 14/12/2016	Replaces: 16/06/2015
Origin	Mineral		
Manufacturer	Several		
Country	-		
Certification manufacturer:	ISO 9001		

1.1 Composition

Single ingredient	
Chemical name	Calcium carbonate
Chemical formula	CaCO ₃
Molecular weight	100,09

1.2 Legislative information

CAS-N°	471-34-1
INTRASTAT CODE	283650
EINECS	207-439-9
Legal declaration	E170

2. PRODUCT INFORMATION

	Unit	Specification	Method
2.1 Physical and Chemical properties			
Appearance		Fine powder	
Colour		White	
Odour/taste		Odourless	
Assay	wt%	98,5 – 100,5	
Loss on drying	wt%	max. 2,0	E170
Solubility		Practically insoluble in water and alcohol	
Acid Insoluble substances	%	max. 0,2	E170
Bulk density	g/l	460	
Tapped density	g/l	680	
pH value		8,5 – 9,5	

PRODUCT SPECIFICATION – PHARMA INGREDIENTS

CALCIUM CARBONATE 450 PHARM.

ConnectingChemistry



Whiteness L*			approx. 98,6	
Particle size	d99%	µm	6,5	
	d50%	µm	1,8	
	d25%	µm	1,0	

2.2 Microbiological data

Totally aerobic count	cfu/g		max. 1000	
Moulds & yeasts	cfu/g		max. 100	
E-Coli	cfu/g		absent	
Salmonella	cfu/g		absent	

2.3 Contaminants

2.3.1 Chemical contaminants

Magnesium carbonate (MgCO ₃)	%		approx. 0,33	
Silicon oxide (SiO ₂)	%		approx. 0,02	
Aluminium oxide (Al ₂ O ₃)	%		approx. 0,005	
Iron oxide (Fe ₂ O ₃)	%		approx. 0,005	
Arsenic (As)	ppm		max. 3	Ph.Eur./E170
Cadmium (Cd)	ppm		max. 1	Ph.Eur./E170
Chloride (Cl)	ppm		max. 330	
Fluoride (F)	ppm		max. 50	E170
Iron (Fe)	ppm		max. 200	
Magnesium and alkali salts	%		max. 1	E170
Heavy metals	ppm		max. 20	
Lead (Pb)	ppm		max. 3	Ph.Eur., E170
Sulphate (SO ₄)	%		max. 0,25	
Residual Solvents			Meets the requirements	
Mercury (Hg)	ppm		max. 0,5	
Antimony (Sb)	ppm		max. 100	Singly
Copper (Cu)	ppm		max. 100	or in

BRENTAG N.V. • Korte Lozanastraat 20-26 • BE-2018 ANTWERPEN

Tel. +32(0)3/242.44.70 • Fax +32(0)3/238.07.63 • export@brenntag.be • www.brenntagexport.com

BRENTAG N.V. • Boulevard du textile 2 • BE-7700 MOUSCRON

Tel. +32(0)56/34.25.16 • Fax +32(0)56/34.56.48 • export@brenntag.be • www.brenntagexport.com

BRENTAG Nederland B.V. • Donker Duyvisweg 44 • NL-3316 BM DORDRECHT

Tel. +31(0)78/65.44.950 • Fax +31(0)78/65.44.919 • export@brenntag.nl • www.brenntagexport.com

PRODUCT SPECIFICATION – PHARMA INGREDIENTS

CALCIUM CARBONATE 450 PHARM.

ConnectingChemistry



Chromium (Cr)	ppm	max. 100	combination
Zinc (Zn)	ppm	max. 100	max 100ppm
Barium (Ba)	ppm	max. 100	E170

2.3.2 Physical contaminants

Foreign body control	Sieve
----------------------	-------

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	0	
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

Ferrous	mg/100g	max. 20	
Sodium	mg/100g	3,84	
Zinc	mg/100g	max. 10	
Phosphorus	mg/100g	-	
Others:	mg/100g	-	

BRENNTAG N.V. • Korte Lozanastraat 20-26 • BE-2018 ANTWERPEN

Tel. +32(0)3/242.44.70 • Fax +32(0)3/238.07.63 • export@brenntag.be • www.brenntagexport.com

BRENNTAG N.V. • Boulevard du textile 2 • BE-7700 MOUSCRON

Tel. +32(0)56/34.25.16 • Fax +32(0)56/34.56.48 • export@brenntag.be • www.brenntagexport.com

BRENNTAG Nederland B.V. • Donker Duyvisweg 44 • NL-3316 BM DORDRECHT

Tel. +31(0)78/65.44.950 • Fax +31(0)78/65.44.919 • export@brenntag.nl • www.brenntagexport.com

PRODUCT SPECIFICATION – PHARMA INGREDIENTS

CALCIUM CARBONATE 450 PHARM.

ConnectingChemistry



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
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)	N	N	N
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

Vegetarian	Y
Vegans	Y
Kosher	Y

PRODUCT SPECIFICATION – PHARMA INGREDIENTS

CALCIUM CARBONATE 450 PHARM.

ConnectingChemistry



Halal	Y
Lactose intolerant	Y
Coeliacs	Y

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

CALCIUM CARBONATE 450 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 come into contact with genetically modified organisms.

CALCIUM CARBONATE 450 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.

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 CALCIUM CARBONATE 450 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:

Ph. Eur., USP, E170

EC Regulation 231/2012/EC on food additives listed in Annexes II and III (CALCIUM CARBONATE).

The production plant complies with:

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

PRODUCT SPECIFICATION – PHARMA INGREDIENTS

CALCIUM CARBONATE 450 PHARM.

ConnectingChemistry



4. PACKAGING

Packaging description	PE-inlined paper bags
Packaging net content	25 kg
Different packagings on request	
Paletisation	Wooden pallet

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)	24 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.

COMPANY INFORMATION DISTRIBUTOR		
name	BRENNTAG N.V.	BRENNTAG Nederland B.V.
address	Nijverheidslaan 38 8540 Deerlijk	Donker Duyvisweg 44 3316 BM Dordrecht
country	Belgium	The Netherlands
phone number	+32 (0)56 77 69 44	+31 (0)78 65 44 944
fax number	+32 (0)56 77 57 11	+31 (0)78 65 44 919
website	www.brenntag.be	www.brenntag.nl
e-mail	info@brenntag.be	info@brenntag.nl
activities	Distribution and export of chemicals and raw materials	
VAT number	BE0405317567	NL001375945B01
recall procedure available	Yes	
emergency number (24/365)	+32 (0)56 77 69 44	+31 (0)78 6544 944
QUALITY SYSTEMS		
ISO 9001	Yes	Yes
ISO 14001	Yes	Yes
ISO 22000	Yes	Yes
FSSC 22000	Yes	Yes
GMP+ -feed	Yes	Yes
OHSAS18001	-	Yes
ESAD	Yes	Yes
other	-	AEO