

AEROSIL® 200 Pharma

Colloidal silicon dioxide

Characteristic physico-chemical data

Properties and test methods	Unit	Value
Specific surface area (BET)	m ² /g	175 - 225
pH value tested according to Ph. Eur., USP/NF, IP**		3.5 - 5.5
Loss on drying (moisture) tested according to Ph. Eur., USP/NF, JP	%	≤ 2.5/≤ 7.0
Tamped density*	g/l	approx. 50
SiO ₂ content tested acc. to Ph. Eur., USP/NF, JP, IP**	%	≥ 99.0/98.0
Al content tested according to JP		pass
Fe content tested according to JP	ppm	≤ 500
Ca content tested according to JP		pass
As content tested according to USP/NF, IP**, JP		≤ 8.0/≤ 5.0
Chloride tested according to Ph. Eur., IP**, JP	ppm	≤ 250/≤ 110
Heavy Metals tested according to IP**, JP	ppm	≤ 25/≤ 40
IPEC-GMP		Yes
* ex plant		
** for Rheinfelden and Antwerp products only		

AEROSIL® 200 Pharma is a high purity amorphous anhydrous colloidal silicon dioxide for use in pharmaceutical products which fulfils the analytical requirements of the currently valid versions of the European Pharmacopeia (Ph. Eur.), United States Pharmacopeia (USP/NF), Japanese Pharmacopeia (JP) and Indian Pharmacopoeia** (IP). It fulfils purity criteria of E551 according to 231/2012 EU.

Our manufacturing plants have implemented a system based on Good Manufacturing Practices and Hazard Analysis and Critical Control Points for food additives.

TAMC (total aerobic microbial count) and TYMC (total combined yeast and mould count) are tested on a regular basis acc. to USP.

Applications and properties

Applications

- Pharmacy, all types of dosage forms
- Food

Properties

- Free flow and anti-caking agent to improve powder properties
- Improves tablet properties such as hardness and friability
- Used as viscosity increasing agent to thicken and thixotropize liquids
- Used as anti-setting, thickening and anti-sagging agent
- High purity, low humidity content
- No influence on taste
- Does not alter natural colour of powder formulations

Registrations (substance or product components)

AEROSIL® 200 Pharma

CAS-No.	REACH (Europe)	TSCA (USA)	DSL (Canada)	AICS (Australia)	ENCS (Japan)	IECSC (China)	KECI (Korea)
112 945-52-5 7631-86-9	registered	registered	registered	registered	registered	registered	registered

Safety and handling

Information concerning the safety of this product is listed in the corresponding Safety Data Sheet, which will be sent with the first delivery or upon updating. Such information is also available from Evonik Operations, Product Safety Department, E-MAIL sds-im@evonik.com We recommend to read carefully the safety data sheet prior to the use of our product.

Packaging and storage

AEROSIL® 200 Pharma is supplied in multiple layer 10 kg and 10 lbs bags. We recommend to store the product in closed containers under dry conditions and to protect the material from volatile substances. AEROSIL® 200 Pharma should be used within 2 years after production.

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