

Product information

# **AEROSIL® 200 Pharma**

## Colloidal silicon dioxide

# Characteristic physico-chemical data

Properties and test methods	Unit	Value				
Specific surface area (BET)	m <sup>2</sup> /g	175 - 225				
pH value in 4% dispersion, tested according to Ph. Eur., USP/NF		3.7 - 4.5				
Loss on drying (moisture)* 2 hours at 105 °C, tested according to USP/NF; JP	%	≤ 1.52				
Tamped density*	g/l	арргох. 50				
SiO2 content based on ignited material, tested acc. to Ph. Eur., USP/NF; JP	%	> 99.8				
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; JP		≤ 8.0; ≤ 5.0				
Chloride tested according to Ph. Eur.; JP	ppm	≤ 250; ≤ 110				
Heavy Metals tested according to Ph. Eur.; JP	ppm	≤ 25; ≤ 40				
Volume Test tested according to JP	ml	≥ 70				
Residual Solvents tested according to USP/NF	ppm	pass				
HACCP, FAMI-QS, IPEC/GMP		Yes				
* ex plant The data represents typical values (no product specification)						

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) and Japanese Pharmacopeia (JP) and is tested and certified according to pharmacopoeia methods. It fulfils purity criteria of E551 according to 231/2012 EU.

In our production location in Rheinfelden, Germany AEROSIL® 200 Pharma is manufactured and packaged according to IPEC/GMP and HACCP/FAMI-QS guidelines. The production and packaging process has been audited and fulfills the requirements of regulation EC No. 852/2004.

## Applications and properties

#### **Applications**

- Pharmacy, all types of dosage forms
- Food
- Feed

#### **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
- Dessicant for moisture-sensitive actives
- Improves distribution of active pharmaceutical ingredients
- 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)	IECS (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 Resource Efficiency GmbH, Product Safety Department, E-MAIL sds-hu@evonik.com or can be downloaded from our homepage www.aerosil.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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