

Avicel® PH-101 microcrystalline cellulose NF, Ph. Eur., JP

Product Specifications:

Chemical and Physical:

Loss on drying	3.0 - 5.0 %*
Bulk density	0.26 - 0.31 g/cc
Identification A, B	Passes
Degree of polymerization	NMT 350 units
pH	5.5 - 7.0*
Conductivity	NMT 75 µS/cm
Residue on ignition	NMT 0.05 %
Water soluble substances	NMT 12.5 mg/5g
Water soluble substances	NMT 0.25 %
Ether soluble substances	NMT 5.0 mg/10g
Heavy metals	NMT 0.001 %
Solubility in Copper Tetrammine Hydroxide	Soluble

Microbiological:

Total aerobic microbial count	NMT 100 cfu/g*
Total yeast and mold count	NMT 20 cfu/g*
Pseudomonas aeruginosa	Absent in a 10g sample
Escherichia coli	Absent in a 10g sample
Staphylococcus aureus	Absent in a 10g sample
Salmonella species	Absent in a 10g sample
Coliform species	Absent in a 10g sample

Additional FMC Specifications

	D10	D50	D90
Particle size distribution	14-30	40-75	77-156
Particle size (Air Jet):			
wt. % + 60 mesh (250 microns)	NMT 1.0		
wt. % + 200 mesh (75 microns)	NMT 30		

This product meets the requirements for Residual Solvents in the United States Pharmacopeia <467> and complies with the ICH Guide Q3C for Residual Solvents.

*More restrictive than compendium

NLT = Not Less Than

NMT = Not More Than

09302015/13-0: PH-101



Product Shelf-life / Re-evaluation Date

Store at ambient conditions. Keep containers sealed; material is very hygroscopic. Four (4) years from date of manufacture, if storage conditions stated above are observed. FMC recommends that after the above re-evaluation date, the customer perform the loss on drying and viscosity tests.

Safety Data Sheets (SDS) available on request.

Patents

FMC Corporation is owner and/or licensee of several patents related to its products. The products, processes and uses of such products referred to in this document may be covered by one or more patents or pending applications in the United States and/or other countries. FMC does not warrant against any infringement claim arising from the sale and/or use of any FMC product in combination with other materials; the use of any FMC product in the operation of any process; any FMC product manufactured to a customer's designs or specifications; or any FMC product manufactured by any process requested by a purchaser.

Product Suitability

The information contained in this document (as well as any advice or assistance) is provided by FMC only as a courtesy and is intended to be general in nature. Any uses suggested by FMC are presented only to assist our customers in exploring possible applications. FMC makes no warranty, express or implied, as to its accuracy or completeness, or the results to be obtained from such information, advice or assistance. Each customer is solely responsible for determining whether the FMC products are suitable for such customer's intended use, and for obtaining any necessary governmental registrations and approvals for such customer's production, marketing, sale, use and/or transportation of finished goods using or incorporating the FMC products.

FMC, FMC logo and Avicel are trademarks of FMC Corporation.
© 2003 FMC Corporation. All rights reserved.

09302015/13-0: PH-101