

PRODUCT
SPECIFICATION
BULLETIN

Avicel® CL-611
microcrystalline cellulose
and carboxymethylcellulose sodium, NF, Ph. Eur.

Compendial Standards	Specifications
Identification	Passes
Viscosity, 2.6% solids, 120 sec, cps	50 - 118
pH	6.0 - 8.0
Loss on drying, %	NMT 6.0 *
Residue on ignition, %	NMT 5.0
Heavy metals, %	NMT 0.001
Assay for sodium carboxymethylcellulose, %	11.3 - 18.8
Clarity of solution	Soluble

Additional FMC Specifications

Particle size (Air Jet):	
wt. % + 60 mesh (250 microns)	NMT 0.1
wt. % + 325 mesh (65 microns)	NMT 50
Microbial limits:	
Total aerobic microbial count, cfu/g	NMT 100
Total yeast and mold count, cfu/g	NMT 20
<i>Pseudomonas aeruginosa</i>	Absent in a 10g sample
<i>Escherichia coli</i>	Absent in a 10g sample
<i>Staphylococcus aureus</i>	Absent in a 10g sample
<i>Salmonella</i> species	Absent in a 10g sample

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

Storage conditions: Store at ambient conditions. Keep containers sealed; material is very hygroscopic.

Re-evaluation date: Three (3) years from date of manufacture, if storage conditions stated above are observed.

Re-evaluation requirements: FMC recommends that after the above re-evaluation date, the customer perform the loss on drying and viscosity tests.

*More restrictive than compendium
NMT = Not More Than

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Warranty

Because of the numerous factors affecting results, FMC ingredients are sold on the understanding that purchasers will make their own tests to determine the suitability of these products for their particular purpose. The several uses suggested by FMC BioPolymer are presented only to assist our customers in exploring possible applications. All information and data presented are believed to be accurate and reliable, but are presented without the assumption of any liability by FMC BioPolymer.

Technical Service

The information contained in this bulletin is intended to be general in nature. Techniques and data pertaining to specific uses for FMC ingredients and new developments will be published periodically in the form of supplemental application bulletins. Our technical staff is ready to offer assistance in the use of Avicel® microcrystalline cellulose products.

Regulatory Status

Avicel® RC/CL colloid-forming, attrited mixtures of microcrystalline cellulose and carboxymethylcellulose sodium meet the standards set forth in the *United States Pharmacopeia/National Formulary* for microcrystalline cellulose and carboxymethylcellulose sodium and in the *European Pharmacopoeia* for microcrystalline cellulose and carmellose sodium.

Microcrystalline cellulose is generally recognized as safe (GRAS) by qualified experts. FMC maintains a Type IV Drug Master File at the U.S. Food and Drug Administration.

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