

PRODUCT
SPECIFICATION
BULLETIN

Avicel® RC-591
microcrystalline cellulose
and carboxymethylcellulose sodium NF, Ph. Eur.

Compendial Standards	Specifications
Identification	Passes
Viscosity, 1.2% solids, 120 sec, cps	39 - 91
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, %	8.3 - 13.8
Clarity of solution	Soluble
Additional FMC Specifications	
Particle size (Air Jet):	
wt. % + 60 mesh (250 microns)	NMT 0.1
wt. % + 325 mesh (45 microns)	NMT 45
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

FMC Corporation

FMC BioPolymer

United States:

Philadelphia, Pennsylvania

Sales/Technical

Assistance: 1 215 299 6534

Fax: 1 215 299 6669

Customer Service: 1 800 526 3649

Fax: 1 215 299 6475

Europe:

Brussels, Belgium

Sales/Technical

Assistance: + 32 2 775 8311

Fax: + 32 2 775 8300

Customer Service: + 353 21 4354 133

Fax: + 353 21 4353 057

Asia-Pacific:

Hong Kong

Tel: + 852 2839 6600

Fax: + 852 2576 3770

Tokyo, Japan

Tel: + 81 3 3402 3739

Fax: + 81 3 3402 3700

Shanghai, China

Tel: + 8621 5427 1177

Fax: + 8621 5427 0193

Latin America:

Montevideo, Uruguay

Tel/Fax: + 5982 6043030

Tel/Fax: + 5982 6043104

Middle East:

Amman, Jordan

Tel: + 962 6 4618150

Fax: + 962 6 4618156

Visit our web site at
www.fmcbiopolymer.com
e-Mail: pharm_info@fmc.com

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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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