

PRODUCT
SPECIFICATION
BULLETIN

Ac-Di-Sol[®] SD-711
croscarmellose sodium, NF, Ph. Eur., JPE

Compendial Standards	Specifications
Identification	Passes
NaCl and NaGly, %	NMT 0.50 *
Degree of substitution	0.63 - 0.85 *
Content of water soluble material, %	1.0 - 5.5 *
Setting volume, mL	10.0 - 30.0
pH	5.9 - 7.0 *
Loss on drying, %	NMT 6.0 *
Heavy metals, %	NMT 0.001
Sulfated ash %	14.0 - 28.0
Arsenic, ppm	NMT 2
Microbial limits:	
Total aerobic count, cfu/g	NMT 100*
Total fungi (yeast and mold), cfu/g	NMT 20*
<i>Escherichia coli</i>	Not detected by test
<i>Pseudomonas aeruginosa</i>	Not detected by test
<i>Staphylococcus aureus</i>	Not detected by test
<i>Salmonella</i> species	Not detected by test
Additional FMC specifications	
Residual solvents, %	NMT 0.01
P.S.D., Malvern LD, μm, d10	NMT 25
P.S.D., Malvern LD, μm, d50	25-55
P.S.D., Malvern LD, μm, d90	NLT 60

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 test.

*More restrictive than compendium.

NMT = Not More Than

NLT = Not Less 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

Regulatory

Ac-Di-Sol croscarmellose sodium meets the standards set forth in the *United States Pharmacopeia/National Formulary* (USP/NF), the *European Pharmacopeia* (Ph. Eur.) and the *Japanese Pharmacopeia* (JP). A Type IV Drug Master File is on file with the US Food and Drug Administration for Ac-Di-Sol.

Trademark

The following are trademarks or service marks of FMC Corporation or its subsidiaries, which may be Registered U.S. Patent & Trademark Office and in other countries: FMC Logo, Ac-Di-Sol, The Science of Formulation and The Science of Formulation Mark.

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 Ac-Di-Sol croscarmellose sodium products.

The following are trademarks or service marks of FMC Corporation or its subsidiaries, which may be Registered U.S. Patent & Trademark Office and in other countries: FMC Logo, Ac-Di-Sol, The Science of Formulation Mark.

© 2005 FMC Corporation. All rights reserved. 04/01/09.RS