

PRODUCT SPECIFICATION BULLETIN

Viscarin® GP-209 Carrageenan, NF

Comments

- General purpose water-thickening, non-gelling carrageenan
- Produces smooth, free flowing solutions
- Excellent hydration in cold water
- Produces smooth and pliable textures with clean mouthfeel and excellent freeze-thaw characteristics

Compendial Standards

Specification

Identification	Passes
Solubility	Passes
Water viscosity, 1.5%, mPa•s	NLT 5
Loss on drying, %	NMT 12.5
Acid-insoluble matter, %	NMT 2.0
Total ash, %	NMT 35.0
Arsenic, ppm	NMT 3
Lead, %	NMT 0.001
Heavy metals, %	NMT 0.004
Microbial limits:	
Total bacterial count, cfu/g	NMT 200
<i>Salmonella</i> species	Not detected by test
<i>Escherichia coli</i>	Not detected by test

Additional FMC Specifications

pH, 1.5%	7.5 – 10.5
Water viscosity, 0.5%, mPa•s	100 – 130
Water viscosity, 1.5%, mPa•s	450 – 750
Particle size, % through 100 mesh (150 microns)	NLT 95.0
Microbial limits:	
<i>Staphylococcus aureus</i>	Not detected by test
<i>Pseudomonas aeruginosa</i>	Not detected by test
Mold and yeast, cfu/g	NMT 100

This product meets the requirement for Organic Volatile Impurities 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: 1 year 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.

NLT = Not Less Than
NMT = Not More Than

FMC Corporation

FMC BioPolymer

U.S.A.:

1735 Market Street
Philadelphia, PA 19103
Technical Assistance: 1-215-299-6534
Fax: 1-215-299-6669
Customer Service: 1-800-526-3649
Fax: 1-215-299-6475

Europe:

Avenue E. Mounier 83, Box 2
1200 Brussels, Belgium
Phone: 32-2-775-8311
Fax: 32-2-775-8300

Asia:

Suite 1706 Central Plaza
18 Harbour Road, Wanchai
Hong Kong
Phone: 852-2839-6600
Fax: 852-2576-3770

Visit our web site at
www.fmcbiopolymer.com

Patents

FMC Corporation does not warrant against infringement of patents of third parties by reason of any uses made of the product in combination with other material or in the operation of any process; purchasers assume all risks of patent infringement by reason of any such use, combination, or operation.

Warranty

Because of the numerous factors affecting results, Viscarin carrageenan is sold on the understanding that purchasers will make their own test to determine the suitability of these products for their particular purpose. The several uses suggested by FMC Corporation 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 Corporation.

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 Viscarin carrageenan products.

Regulatory Status

Viscarin carrageenan meets the standards set forth in the *United States Pharmacopeia/National Formulary* and the *Food Chemicals Codex*. Carrageenan chondrus extract is generally recognized as safe (GRAS) by qualified experts and is in accordance with United States Food and Drug Regulations (21 CFR 182.7255). Carrageenan is approved as a food additive under 21 CFR 172.620. FMC maintains a Drug Master File with the U.S. Food and Drug Administration to support the use of Viscarin in drug products. Viscarin carrageenan is manufactured in accordance with Good Manufacturing Practices and is in compliance with the *Federal Food, Drug and Cosmetic Act* as amended and applicable regulations.

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, Aquacoat, Avicel, Endurance, Gelcarin, LustreClear, NovaMatrix, Protacid, Protanal, SeaSpen, Viscarin, TAP Total Advantage Program, The Science of Formulation, and The Science of Formulation Mark.

© 2003 FMC Corporation. All rights reserved. 03/16/04.RS