

PRODUCT
SPECIFICATION
BULLETIN

SeaSpen® PF
Carrageenan

Comments

- Designed for preparation of pharmaceutical suspensions
- Suitable for reconstitutable suspensions
- Forms highly thixotropic gel-like structure in cold water
- Flows readily when poured, recovers quickly to a gel-like structure

Compendial Standards

Specification

Water viscosity, cps	35 – 95
Loss on drying, %	NMT 12.5
pH	7.5 – 10.5
Particle size, % through 60 mesh (250 microns)	NLT 95.0
Arsenic, ppm	NMT 3
Lead, %	NMT 0.001
Heavy metals, %	NMT 0.004
Microbial limits:	
Total bacterial count, cfu/g	NMT 200
Mold and yeast, cfu/g	NMT 100
<i>Salmonella</i> species	Not detected by test
<i>Escherichia coli</i>	Not detected by test
<i>Staphylococcus aureus</i>	Not detected by test
<i>Pseudomonas aeruginosa</i>	Not detected by test

SeaSpen PF is a combination of Carrageenan, NF, Calcium Sulfate, and Trisodium Phosphate

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: 2 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.

NLT = Not Less Than
NMT = Not More Than

FMC Corporation

FMC BioPolymer

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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, SeaSpEn 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 SeaSpEn carrageenan products.

Regulatory Status

The carrageenan used in SeaSpEn[®] 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 Gelcarin in drug products. Gelcarin 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.

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