

PRODUCT
SPECIFICATION
BULLETIN

LustreClear® LC-103

Test	Specifications
Identification	Passes
Loss on drying, %	NMT 6
Residue on ignition, %	NMT 7
Heavy metals, %	NMT 0.001
Total aerobic microbial count/gm	NMT 1000
Total yeast and mold count/gm	NMT 100
<i>Pseudomonas aeruginosa</i>	None present in a 10g sample
<i>Escherichia coli</i>	None present in a 10g sample
<i>Staphylococcus aureus</i>	None present in a 10g sample
<i>Salmonella</i> species	None present in a 10g sample

Re-evaluation Date: 3 years from date of manufacture if storage conditions stated below are observed.

Re-evaluation Requirements: FMC recommends that after the above re-evaluation date, the customer performs Loss on Drying.

Storage conditions: Store at ambient conditions and keep away from strong acids and oxidizers. Keep containers sealed; material is very hygroscopic.

All ingredients comply with current NF, EP and Japanese standards as applicable.

Manufactured under GMP's and Issued by FMC Corporation, 1301 Ogletown Road, Newark, Delaware, 19711 USA. This product is in substantial compliance with the requirements for Bulk Pharmaceutical Excipient GMP as developed by IPEC and also published in the USP General Chapter <1078>.

NMT = Not More Than

FMC Corporation

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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, and purchasers assume all risks of patent infringement by reason of any such use, combination or operation.

The products, processes and uses thereof described herein are covered by one or more patent applications or patents.

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 LustreClear®.

Regulatory Status

The ingredients used in LustreClear products are chosen to meet the appropriate regulations and compendial standards of the United States, Europe and Japan as applicable to the specific LustreClear product's use as a coating on dietary supplements or as a coating on pharmaceutical products in these countries.

LustreClear LC-103 was developed for use as a coating on pharmaceuticals.

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