

# MATERIAL SAFETY DATA SHEET

LustreClear™ LC 103

FMC BioPolymer

MSDS Ref. No.: F18-26-8  
Date Approved: 01/27/2006  
Revision No.: 4

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This document has been prepared to meet the requirements of the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200; the Canada's Workplace Hazardous Materials Information System (WHMIS) and, the EC Directive, 2001/58/EC.

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## 1. PRODUCT AND COMPANY IDENTIFICATION

**PRODUCT NAME:** LustreClear™ LC 103  
**CHEMICAL NAME:** Microcrystalline cellulose / Carrageenan-Based Coating  
**CHEMICAL FAMILY:** Carbohydrate, Polysaccharide  
**SYNONYMS:** Microcrystalline Cellulose (INCI name): MCC, cellulose gel;  
Carrageenan: Chondrus Crispus (Carrageenan)(INCI name),  
Carrageenin, Irish moss extract, Condrous extract  
**GENERAL USE:** Tablet coating

### MANUFACTURER

FMC BioPolymer  
1735 Market Street  
Philadelphia, PA 19103  
(800) 526-3649 (General Information)

FMC Europe NV  
Avenue Mounier 83  
1200 Brussels, Belgium  
+32 2 / 775 8311 (General Information - Brussels)

### EMERGENCY TELEPHONE NUMBERS

(302) 451-0100 (FMC Plant - Newark, Delaware)

(303) 595-9048 (Medical - U.S. - Call Collect)

For leak, fire, spill, or accident emergencies, call:  
(800) 424-9300 (CHEMTREC - U.S.A. & Canada)  
(703) 527-3887 (CHEMTREC - All Other Countries)

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## 2. HAZARDS IDENTIFICATION

### EMERGENCY OVERVIEW:

- White to off-white, free-flowing powder.
- Powder becomes slippery when wet.
- Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed.
- Contamination of product with strong acids will initiate accelerated hydrolysis.

**POTENTIAL HEALTH EFFECTS:** No adverse human effects known.

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Wt.%	EC No.	EC Class
Microcrystalline cellulose	9004-34-6		232-674-9	Not classified
Polyethylene glycol	25322-68-3		None	Not classified
Carrageenan	9000-07-1		232-524-2	Not classified

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### 4. FIRST AID MEASURES

**EYES:** Flush with water for at least 15 minutes. If irritation occurs and persists, obtain medical attention.

**SKIN:** Wash with plenty of soap and water. Get medical attention if irritation occurs and persists.

**INGESTION:** Drink 1 or 2 glasses of water. Never induce vomiting or give anything by mouth to an unconscious person. If any discomfort persists, obtain medical attention.

**INHALATION:** Remove to fresh air. If breathing difficulty or discomfort occurs and persists, obtain medical attention.

**NOTES TO MEDICAL DOCTOR:** This product is expected to have low oral, dermal and inhalation toxicity. It is expected to be minimally irritating to the skin and eyes, and to be non-sensitizing to the skin. Treatment is symptomatic and supportive.

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### 5. FIRE FIGHTING MEASURES

**EXTINGUISHING MEDIA:** Water

**FIRE / EXPLOSION HAZARDS:** The accumulation of excessive dust of overhead structures may produce explosive concentrations when disturbed and dispersed.

**FIRE FIGHTING PROCEDURES:** For fires involving this material, do not enter any enclosed or confined fire space without wearing full protective clothing and self-contained breathing apparatus (SCBA) approved for firefighting. This is necessary to protect against the hazards of heat, products of combustion and oxygen deficiency. Do not breathe smoke, gases or vapors generated.

**FLAMMABLE LIMITS:** Not applicable

## 6. ACCIDENTAL RELEASE MEASURES

**RELEASE NOTES:** Powder becomes slippery when wet. Maintain good housekeeping practices to minimize accumulation of settled dust, especially on overhead surfaces. Sweep up the spilled material and dispose of in accordance with the waste disposal method outlined in Section 13, "Disposal Considerations".

## 7. HANDLING AND STORAGE

**HANDLING AND STORAGE:** Use local exhaust or general dilution ventilation to control exposure to dust. Always use safe lifting techniques when manually moving containers, especially when shipping containers weigh more than 50 pounds (22.7 kg). Open container in well-ventilated area. Store in a dry area for product quality assurance. Avoid storing near strong acids (e.g., hydrochloric acid, sulfuric acid). Contamination of product with strong acids will initiate accelerated hydrolysis. Pallets should be stacked in a stable manner. Maintain adequate clearance from structural members and sprinklers. NFPA and U.S. OSHA state a minimum of 18 inches (45.7 cm) clearance shall be maintained between the top of storage and the ceiling sprinkler deflectors.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE LIMITS

Chemical Name	ACGIH	OSHA	Supplier
Microcrystalline cellulose	10 mg/m <sup>3</sup> (TWA)	15 mg/m <sup>3</sup> (PEL) (total dust) 5 mg/m <sup>3</sup> (PEL) (respirable fraction of dust)	

### PERSONAL PROTECTIVE EQUIPMENT

**EYES AND FACE:** Whenever airborne dust concentrations are high, appropriate protective eyewear, such as mono-goggles, should be worn to prevent eye contact.

**RESPIRATORY:** Whenever dust in the worker's breathing zone cannot be controlled with ventilation or other engineering means, workers should wear respirators or dust masks approved by

NIOSH/MSHA, EU CEN or comparable certification organization to protect them against airborne dust.

**PROTECTIVE CLOTHING:** No special clothing is required.

**GLOVES:** Wear chemical protective gloves made of materials such as nitrile or neoprene. Thoroughly wash the outside of gloves prior to removal. Inspect regularly for leaks.

## COMMENTS:

### ADDITIONAL EXPOSURE LIMITS:

#### Cellulose:

Australia (TWA) 10 mg/m<sup>3</sup>

Belgium (TWA) 10 mg/m<sup>3</sup> (inhalable dust)

China (STEL): 25 mg/m<sup>3</sup>

China (TWA): 10 mg/m<sup>3</sup>

Hong Kong (TWA): 10 mg/m<sup>3</sup>

Ireland (TWA): 10 mg/m<sup>3</sup> (inhalable dust)

Korea (TWA): 10 mg/m<sup>3</sup>

New Zealand (TWA): 10 mg/m<sup>3</sup> (respirable dust with no asbestos and less than 1% free silica)

Singapore (PEL): 10 mg/m<sup>3</sup>

Switzerland (TWA): 3 mg/m<sup>3</sup> MAK (respirable)

United Kingdom (STEL): 10 mg/m<sup>3</sup> (total inhalable dust)

United Kingdom (TWA): 10 mg/m<sup>3</sup> (total inhalable dust); 4 mg/m<sup>3</sup> (respirable dust)

#### Polyethylene glycol:

Germany (TWA): 1000 mg/m<sup>3</sup> (inhalable fraction)

Switzerland (TWA): 1000 ppm MAK

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>ODOR:</b>	Slight
<b>APPEARANCE:</b>	White to off-white, free-flowing powder
<b>AUTOIGNITION TEMPERATURE:</b>	440 °C (824 °F) (± 2°C)
<b>BOILING POINT:</b>	Decomposes upon heating
<b>COEFFICIENT OF OIL / WATER:</b>	(Octanol/Water) Not applicable
<b>EVAPORATION RATE:</b>	(Butyl acetate = 1) Not applicable
<b>FLASH POINT:</b>	Not applicable
<b>FREEZING POINT:</b>	Not applicable
<b>MELTING POINT:</b>	Decomposes upon heating
<b>pH:</b>	(In solution) 5.0 - 8.0 (4% solids dispersion)
<b>SOLUBILITY IN WATER:</b>	(% by weight) Water dispersible

<b>SPECIFIC GRAVITY:</b>	(H <sub>2</sub> O = 1) Bulk density, 0.5 - 0.6 g/cc
<b>VAPOR DENSITY:</b>	(Air = 1) Not applicable
<b>VAPOR PRESSURE:</b>	Not applicable

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## 10. STABILITY AND REACTIVITY

<b>CONDITIONS TO AVOID:</b>	None known
<b>STABILITY:</b>	Stable
<b>HAZARDOUS DECOMPOSITION PRODUCTS:</b>	Will produce oxides of sulfur on burning.

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## 11. TOXICOLOGICAL INFORMATION

**EYE EFFECTS:** No data available for the product.

MCC: Non-irritating (rabbit)

Carrageenan: Minimally irritating (rabbit)

Polyethylene glycol: Non- to minimally irritating (rabbit)

**SKIN EFFECTS:** No data available for the product.

MCC: Non-irritating (rabbit) Primary Irritating Index = 0/8.0

Carrageenan: Non-irritating (rabbit)

Polyethylene glycol: Non- to minimally irritating (human, rabbit)

**DERMAL LD<sub>50</sub>:** No data available for the product.

MCC: > 2,000 mg/kg (rat)

Carrageenan: > 2,000 mg/kg (rabbit)

**ORAL LD<sub>50</sub>:** No data available for the product.

MCC: > 5,000 mg/kg (rat)

Carrageenan: > 5,000 mg/kg (rat)

Polyethylene glycol: > 50,000 mg/kg (rat, guinea pig, rabbit, mice)

**INHALATION LC<sub>50</sub>:** No data available for the product.

MCC: > 5.05 mg/l (4 h) (rat) Maximum attainable concentration - zero mortality

Carrageenan: > 0.93 mg/l (4 h) (rat) Maximum attainable concentration - zero mortality

**SENSITIZATION:** No data available for the product.

MCC: (Skin) Non-sensitizing (guinea pig)

Carrageenan: (Skin) Non-sensitizing (guinea pig)

Polyethylene glycol: (Skin) Non- to minimally sensitizing (guinea pig)

**ACUTE EFFECTS FROM OVEREXPOSURE:** No data available for the product.

The ingredients in this product are expected to have low oral, dermal and inhalation toxicity. They are expected to be non-irritating or minimally irritating to the skin and eyes, and to be non-sensitizing to the skin.

**CHRONIC EFFECTS FROM OVEREXPOSURE:** No data available for the product. All of the ingredients in this product have low chronic toxicity when administered in the diet in lifetime feeding studies in laboratory animals. They are not expected to be mutagenic or carcinogenic.

Microcrystalline cellulose is considered an inert dust, which is not toxic to the lung when exposures are properly controlled. A 90-day animal study showed no adverse effects when administered in the diet. Microcrystalline cellulose was negative in the Ames mutagenicity assay, and caused no chromosome damage in the mouse micronucleus assay. No adverse human effects are known.

Carrageenan is not expected to have any significant effects. Reproductive toxicity and long term and lifetime feeding studies with carrageenan in laboratory animals were negative, as were results of mutagenicity studies.

Polyethylene glycol (PEG) has low chronic toxicity when fed to rats in the diet for two years. Topical applications of this material should be avoided in burn victims and individuals with impaired renal function. PEG was not found to be genotoxic, mutagenic or teratogenic in a battery of tests, and was not found to have reproductive effects. PEG showed no adverse effects in a 5-week, 1 year and a 2 year subchronic study. A 90-day study in rats showed no effects at up to 4 and 16% in the diet; however, minor kidney effects at  $\geq 80$  mg/kg/day and some testicular effects at  $\geq 230$  mg/kg/day were noted.

#### **CARCINOGENICITY:**

<b>NTP:</b>	Not listed
<b>IARC:</b>	Not listed
<b>OSHA:</b>	Not listed
<b>OTHER:</b>	Not Listed (ACGIH)

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## **12. ECOLOGICAL INFORMATION**

**ENVIRONMENTAL DATA:** No data available for the product. The components of this formulation are not expected to have significant environmental effects. Microcrystalline cellulose is inherently biodegradable in soil. It biodegrades in soil at a rate comparable to corn starch.

**ECOTOXICOLOGICAL INFORMATION:** No data available for the product. Carrageenan is an extract of seaweeds of the class Rhodophyceae (red seaweeds), and is not expected to have significant toxicity to aquatic organisms.

Microcrystalline cellulose:

96-hour  $LC_{50} > 100\%$ , Saturated solution; NOEC = 100% (rainbow trout)

48-hour  $LC_{50} > 100\%$ , Saturated solution; NOEC = 100% (daphnia)

96-hour  $EC_{50} > 100\%$ , Saturated solution; NOEC = 12.5% (algae)

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## 13. DISPOSAL CONSIDERATIONS

**DISPOSAL METHOD:** No special disposal methods are suggested. It is the user's responsibility to comply with all applicable local, state, and federal laws, rules, regulations and standards.

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## 14. TRANSPORT INFORMATION

### U.S. DEPARTMENT OF TRANSPORTATION (DOT)

**MARINE POLLUTANT:** None

**ADDITIONAL INFORMATION:** Not listed in Title 49 of the U.S. Code of Federal Regulations as a hazardous material.  
National Motor Freight Classification Item 71390, Flour Cellulose, Edible

### INTERNATIONAL MARITIME DANGEROUS GOODS (IMDG)

**ADDITIONAL INFORMATION:** Not applicable

### ADR - EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD

**ADDITIONAL INFORMATION:** Not applicable

### INTERNATIONAL CIVIL AVIATION ORGANIZATION (ICAO) / INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA)

**ADDITIONAL INFORMATION:** Not applicable

### OTHER INFORMATION:

Canada (TDG) : Not applicable

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## 15. REGULATORY INFORMATION

### UNITED STATES

#### SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT)

##### SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355, APPENDIX A):

Not listed

##### SECTION 311 HAZARD CATEGORIES (40 CFR 370):

None

##### SECTION 312 THRESHOLD PLANNING QUANTITY (40 CFR 370):

The Threshold Planning Quantity (TPQ) for this product, if treated as a mixture, is 10,000 lbs; however, this product contains the following ingredients with a TPQ of less than 10,000 lbs.:

None

##### SECTION 313 REPORTABLE INGREDIENTS (40 CFR 372):

This product does not contain any toxic chemicals subject to the reporting requirements of Section 313, Title III of the SARA (Superfund Amendments and Reauthorization Act) of 1986.

#### TSCA (TOXIC SUBSTANCE CONTROL ACT)

##### TSCA INVENTORY STATUS (40 CFR 710):

Listed (components)

### CANADA

#### WHMIS (WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEM):

Not a controlled product under the Canadian Workplace Hazardous Materials Information System (WHMIS).

Chemical Name:	Polyethylene glycol
Hazard Classification / Division:	Class D, 2B
Domestic Substance List:	Yes (components)

### E NUMBERS:

E 460 (microcrystalline cellulose)

E 407 (carrageenan)

### INTERNATIONAL LISTINGS

MCC

Australia (AICS): Listed

China: Listed

Japan (ENCS): (8)-568

Korea: KE-05339

Philippines (PICCS): Listed

Carrageenan

Australia (AICS): Listed

China: Listed  
Philippines (PICCS): Listed

Polyethylene glycol  
Australia (AICS): Listed  
China: Listed  
Japan (ENCS): (2)-442; (7)-129; (8)-429  
Korea: KE-20228  
Philippines (PICCS): Listed

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## 16. OTHER INFORMATION

### NFPA

Health	0
Flammability	1
Reactivity	0
Special	None

No special requirements

NFPA = National Fire Protection Association

Degree of Hazard Code:

4 = Extreme  
3 = High  
2 = Moderate  
1 = Slight  
0 = Insignificant

### **REVISION SUMMARY:**

This MSDS replaces Revision #3, dated April 29, 2004.

Changes in information are as follows:

Section 1 (Product and Company Identification)

Section 15 (Regulatory Information)

Section 16 (Other Information)

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