

MATERIAL SAFETY DATA SHEET

LustreSugar™ Coating System

FMC BioPolymer

MSDS Ref. No.: 160377
Date Approved: 05/30/2006
Revision No.: 4

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.

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: LustreSugar™ Coating System
CHEMICAL FAMILY: Carbohydrate; Polysaccharides
SYNONYMS: Microcrystalline cellulose (INCI name): MCC, cellulose gel;
Sucrose: Saccharose, cane sugar, sugar, granulated sugar, beet sugar
GENERAL USE: Pharmaceutical

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)

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)

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

- White free-flowing, odorless powder.
- Powder becomes slippery when wet.
- Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed.

POTENTIAL HEALTH EFFECTS: No significant health hazard expected.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Wt. %	EC No.	EC Class
Microcrystalline cellulose	9004-34-6		232-674-9	Not classified
Sucrose	57-50-1		200-334-9	Not classified

4. FIRST AID MEASURES

EYES: Flush with plenty of water. Get medical attention if irritation occurs and persists.

SKIN: Wash with plenty of soap and water.

INGESTION: Drink plenty of water. Never 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 non-irritating to the eyes and skin, and non-sensitizing to the skin. Treatment is symptomatic and supportive.

5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA: Water

FIRE / EXPLOSION HAZARDS: The accumulation of excessive dust on overhead structures may produce explosive concentrations when disturbed and dispersed. According to NFPA 68, (Explosion Venting Guide), the Hazard Class of Dust Deflagrations for microcrystalline cellulose is St-1, the lowest hazard class.

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 weighing more than 50 pounds (22.7 kg). To protect quality, store in a tight container in a dry place, at room temperature (approximately 25°C). 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 ³ (TWA)	15 mg/m ³ (PEL) (total dust) 5 mg/m ³ (PEL) (respirable fraction of dust)	
Sucrose	10 mg/m ³ (TWA)	15 mg/m ³ (PEL) (total dust) 5 mg/m ³ (PEL) (respirable 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: No special gloves are required.

COMMENTS:

ADDITIONAL EXPOSURE LIMITS:

MCC:

Australia (TWA) 10 mg/m³
 Belgium (TWA) 10 mg/m³ (inhalable dust)
 China (STEL): 25 mg/m³
 China (TWA): 10 mg/m³
 Hong Kong (TWA): 10 mg/m³
 Ireland (TWA): 10 mg/m³ (inhalable dust)
 Korea (TWA): 10 mg/m³
 New Zealand (TWA): 10 mg/m³ (respirable dust with no asbestos and less than 1% free silica)
 Singapore (PEL): 10 mg/m³
 Switzerland (TWA): 3 mg/m³ MAK (respirable)
 United Kingdom (STEL): 10 mg/m³ (total inhalable dust)
 United Kingdom (TWA): 10 mg/m³ (total inhalable dust); 4 mg/m³ (respirable dust)

Sucrose:

Australia (TWA) 10 mg/m³
 Belgium (TWA) 10 mg/m³
 France (TWA) 10 mg/m³
 Hong Kong (TWA): 10 mg/m³
 Ireland (STEL): 20 mg/m³
 Korea (TWA): 10 mg/m³
 Mexico (STEL) 20 mg/m³
 Mexico (TWA) 10 mg/m³ (nuisance particulate)
 Singapore (PEL): 10 mg/m³
 United Kingdom (TWA) 10 mg/m³
 United Kingdom (STEL) 20 mg/m³

9. PHYSICAL AND CHEMICAL PROPERTIES

ODOR:	Odorless
APPEARANCE:	White, free-flowing powder
AUTOIGNITION TEMPERATURE:	Not applicable
BOILING POINT:	Not applicable
COEFFICIENT OF OIL / WATER:	(Kow) Not applicable
EVAPORATION RATE:	(Butyl acetate = 1) Not applicable
FLASH POINT:	Not applicable
MELTING POINT:	Not applicable

OXIDIZING PROPERTIES:	Not applicable
PERCENT VOLATILE:	Typically 1 - 5 % water, by weight
pH:	5 - 8 (1% solution)
SOLUBILITY IN WATER:	(% by weight) Insoluble
SPECIFIC GRAVITY:	Not available
VAPOR DENSITY:	(Air = 1) Not applicable
VAPOR PRESSURE:	Not applicable
VISCOSITY:	375 cP

COMMENTS:

EXPLOSIVE PROPERTIES: Microcrystalline cellulose: St-1

MINIMUM IGNITION TEMPERATURE: Microcrystalline cellulose: 420°C

10. STABILITY AND REACTIVITY

CONDITIONS TO AVOID:	None known
STABILITY:	Stable
HAZARDOUS DECOMPOSITION PRODUCTS:	None known.

11. TOXICOLOGICAL INFORMATION

EYE EFFECTS: No data available for the formulation.

MCC: Non-irritating (rabbit)

SKIN EFFECTS: No data available for the formulation.

MCC: Non-irritating (PII = 0/8.0) (rabbit)

Sucrose: Non-irritating (rabbit)

DERMAL LD₅₀: No data available for the formulation.

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

ORAL LD₅₀: No data available for the formulation.

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

Sucrose: 2,970 mg/kg (rat)

INHALATION LC₅₀: No data available for the formulation.

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

SENSITIZATION: No data available for the formulation.

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

ACUTE EFFECTS FROM OVEREXPOSURE: This product is expected to have low oral, dermal and inhalation toxicity. It is expected to be non-irritating to the eyes and skin, and non-sensitizing to the skin. No significant acute toxicological effects are expected.

CHRONIC EFFECTS FROM OVEREXPOSURE: No data available for the formulation. 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. Sucrose is not carcinogenic and tested negative in a variety of in vitro mutagenicity assays. Some animal teratogenicity studies at high doses of sucrose have shown adverse effects on the fetus, possibly due to uncontrolled glucose concentrations in maternal blood.

CARCINOGENICITY:

NTP:	Not listed
IARC:	Not listed
OSHA:	Not listed
OTHER:	Not Listed (ACGIH)

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL DATA: No data available for the formulation. 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 formulation.

MCC:

48-hour $LC_{50} > 100\%$, saturated solution, NOEC = 100% (daphnia)
96-hour $LC_{50} > 100\%$, saturated solution, NOEC = 100% (rainbow trout)
96-hour $EC_{50} > 100\%$, saturated solution, NOEC = 12.5% (algae)

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.

14. TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION (DOT)

PROPER SHIPPING NAME: National Motor freight Classification Item
71390, Flour Cellulose, Edible.

MARINE POLLUTANT: None

ADDITIONAL INFORMATION: Not listed in Title 49 of the U.S. Code of
Federal Regulations as a hazardous
material.

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

15. REGULATORY INFORMATION

UNITED STATES

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT)

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

Not applicable

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.

CERCLA (COMPREHENSIVE ENVIRONMENTAL RESPONSE COMPENSATION AND LIABILITY ACT)

CERCLA DESIGNATION & REPORTABLE QUANTITIES (RQ) (40 CFR 302.4):

Not applicable

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).

Domestic Substance List: Listed (components)

E NUMBERS:

E 460(i) (microcrystalline cellulose)

INTERNATIONAL LISTINGS

MCC

Australia (AICS): Listed

China: Listed

Japan (ENCS): (8)-568

Korea: KE-05339

Philippines (PICCS): Listed

Sucrose

Australia (AICS): Listed

China: Listed

Korea: KE-17258

Philippines (PICCS): Listed

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 18, 2006.

Changes in information are as follows:

Section 1 (Product and Company Identification)

Section 16 (Other Information)

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