

# MATERIAL SAFETY DATA SHEET

Avicel® HFE-102

FMC BioPolymer

MSDS Ref. No.: HFE-M10DR050

Date Approved: 01/10/2008

Revision No.: 5

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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:** Avicel® HFE-102  
**CHEMICAL FAMILY:** Carbohydrate  
**SYNONYMS:** Microcrystalline cellulose (INCI name): MCC, cellulose gel;  
Mannitol: D-Mannitol, Manna sugar, 1,2,3,4,5,6-Hexanehexol  
**GENERAL USE:** Pharmaceutical Excipient

### MANUFACTURER

FMC BioPolymer  
1735 Market Street  
Philadelphia, PA 19103  
(800) 526-3649 (General Information)  
msdsinfo@fmc.com (Email - General Information)

FMC Europe NV  
Avenue Mounier 83  
1200 Brussels, Belgium  
353 21 435 4133 (General Information - Cork,  
Ireland)

### 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 - Collect - All Other Countries)

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## 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.

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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 |
| Mannitol                   | 69-65-8   |       | 200-711-8 | Not classified |

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### 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.

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### 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 <sup>3</sup> (TWA) | 15 mg/m <sup>3</sup> (PEL) (total dust)<br>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:** No special gloves are required.

**COMMENTS:****ADDITIONAL EXPOSURE LIMITS:****MCC:**

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> (respirable dust)  
 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)

**9. PHYSICAL AND CHEMICAL PROPERTIES**

|                                    |   |
|------------------------------------|---|
| <b>ODOR:</b>                       | Odorless  |
| <b>APPEARANCE:</b>                 | White, free-flowing powder                          |
| <b>AUTOIGNITION TEMPERATURE:</b>   | Not applicable                                      |
| <b>BOILING POINT:</b>              | Not applicable                                      |
| <b>COEFFICIENT OF OIL / WATER:</b> | (Kow) Not applicable                                |
| <b>EVAPORATION RATE:</b>           | (Butyl acetate = 1) Not applicable                  |
| <b>FLASH POINT:</b>                | Not applicable                                      |
| <b>MELTING POINT:</b>              | Not applicable                                      |
| <b>OXIDIZING PROPERTIES:</b>       | Not applicable                                      |
| <b>PERCENT VOLATILE:</b>           | Typically 1 - 5 % water, by weight                  |
| <b>pH:</b>                         | (In solution) 5.0 - 7.0 (11% solids dispersion)     |
| <b>SOLUBILITY IN WATER:</b>        | (% by weight) Insoluble                             |
| <b>SPECIFIC GRAVITY:</b>           | (H <sub>2</sub> O = 1) Bulk density, 0.2 - 0.5 g/cc |
| <b>VAPOR DENSITY:</b>              | (Air = 1) Not applicable                            |
| <b>VAPOR PRESSURE:</b>             | Not applicable                                      |

**COMMENTS:**

**EXPLOSIVE PROPERTIES:** Microcrystalline cellulose: St-1  
**MINIMUM IGNITION TEMPERATURE:** Microcrystalline cellulose: 420°C

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## 10. STABILITY AND REACTIVITY

|  |             |
|--|-------------|
| <b>CONDITIONS TO AVOID:</b>              | None known  |
| <b>STABILITY:</b>                        | Stable      |
| <b>HAZARDOUS DECOMPOSITION PRODUCTS:</b> | None known. |

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## 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)

**DERMAL LD<sub>50</sub>:** No data available for the formulation.  
MCC: > 2,000 mg/kg (rabbit)

**ORAL LD<sub>50</sub>:** No data available for the formulation.  
MCC: > 5,000 mg/kg (rat)  
Mannitol: 13,500 mg/kg (rat); 22,000 mg/kg (mouse)

**INHALATION LC<sub>50</sub>:** 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. Headaches, nausea, vomiting, chills, dizziness, polydipsia, lethargy, confusion and sensation of constriction or pain in the chest have been observed following infusion of mannitol. Fatalities have occurred after large doses. Common effects of large doses of mannitol include dehydration, massive diuresis, and acute increase in intravascular volume, resulting in congestive heart failure or intracranial hemorrhage.

**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. In studies with laboratory animals, using 98 - 100% pure D-mannitol, the National Toxicology Program (NTP) has concluded that D-mannitol was not carcinogenic.

**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 formulation.

Microcrystalline cellulose is inherently biodegradable in soil. It biodegrades in soil at a rate comparable to corn starch.

D-Mannitol is not expected to undergo hydrolysis in the environment due to the lack of hydrolyzable functional groups, nor to directly photolyze due to the lack of absorption in the environmental UV spectrum. An estimated BCF of 1 was calculated for D-mannitol, suggesting that the potential for bioconcentration in aquatic organisms is low. The Koc of D-mannitol is estimated as approximately 5, suggesting that it is expected to have very high mobility in soil.

**ECOTOXICOLOGICAL INFORMATION:** No data available for the formulation.

MCC:

48-hour LC<sub>50</sub> > 100%, saturated solution, NOEC = 100% (daphnia)

96-hour LC<sub>50</sub> > 100%, saturated solution, NOEC = 100% (rainbow trout)

96-hour EC<sub>50</sub> > 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)

|                                |   |
|--------------------------------|---|
| <b>MARINE POLLUTANT:</b>       | None  |
| <b>ADDITIONAL INFORMATION:</b> | Not listed in Title 49 of the U.S. Code of Federal Regulations as a hazardous material. |

**ADDITIONAL INFORMATION:**

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 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

**CANADA**

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

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

Domestic Substance List:            Listed

**E NUMBERS:**

E 460(i) (microcrystalline cellulose)

E 421 (mannitol)

**INTERNATIONAL LISTINGS**

MCC

Australia (AICS): Listed

China: Listed

Japan (ENCS): (8)-568

Korea: KE-05339

Philippines (PICCS): Listed

Mannitol

Australia (AICS): Listed

China: Listed

Japan (ENCS): (8)-49; (9)-1375

Korea: KE-23061

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 #4, dated January 8, 2008.

Changes in information are as follows:

Section 1 (Product and Company Identification)

Section 16 (Other Information)

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