

MATERIAL SAFETY DATA SHEET

Lattice® NT Microcrystalline Cellulose



MSDS Ref. No: 9004-34-6-5
Version: Global
Date Approved: 10/16/1998
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 EU Directive, 91/155/EEC and other regulatory requirements.

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Lattice® NT Microcrystalline Cellulose

CHEMICAL NAME: Microcrystalline Cellulose

CHEMICAL FAMILY: Carbohydrate

MOLECULAR FORMULA: (C₆H₁₀O₅)_x

SYNONYM(S): Microcrystalline Cellulose, MCC

BRAND NAME(S): Lattice® NT 006, 013, 020, 050, 100, 200

FMC CORPORATION
Pharmaceutical Division
1735 Market Street
Philadelphia, PA 19103 USA

General Information: (215) 299-6000

FMC EUROPE NV
Pharmaceutical Division
Avenue Louise 480-B9
1050 Brussels, Belgium

General Information: 32 2 645 5511
(Brussels)

Customer Service: 353 21 354 133 (Cork, Ireland)

Emergency Phone: 01 (303) 595-9048
(USA - Medical)

Customer Service: 01 (800) 362-3773
(USA - Plant, Newark DE)

Emergency Telephone Numbers:

Emergency Phone (303) 595-9048
(Medical)

Emergency Phone (302) 451-0100
(Plant - Newark, DE)

CHEMTREC (800) 424-9300
(U.S.A. & Canada)

(202) 483-7616 (All other countries)

2. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Chemical Name</u>	<u>CAS #</u>	<u>EC Class</u>
Microcrystalline cellulose	9004-34-6	Not classified as hazardous

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

IMMEDIATE CONCERNS:

- Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed.

POTENTIAL HEALTH EFFECTS: Minimally irritating to the eyes and non-irritating to the skin. No adverse human effects known.

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 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 has very low toxicity. Treatment is symptomatic and supportive only.

5. FIRE FIGHTING MEASURES

FLASH POINT AND METHOD: Not applicable

FLAMMABLE LIMITS: Not applicable

AUTOIGNITION TEMPERATURE: Not available

EXTINGUISHING MEDIA: Water

EXPLOSION HAZARDS: Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed. The propagation of flame through air-floated dusts takes place usually following a small explosion which shakes down accumulated dust. 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.

HAZARDOUS DECOMPOSITION PRODUCTS: None known.

6. ACCIDENTAL RELEASE MEASURES

RELEASE NOTES: 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" below.

7. HANDLING AND STORAGE

GENERAL PROCEDURES: 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). Avoid exposure to excessive heat. 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

<u>Chemical Name</u>	<u>TWA</u> <u>(ACGIH)</u>	<u>STEL/Ceiling</u> <u>(ACGIH)</u>	<u>PEL</u> <u>(OSHA)</u>	<u>STEL/Ceiling</u> <u>(OSHA)</u>
Microcrystalline cellulose	10 mg/m ³		15 mg/m ³ (inhalable dust) ⁽¹⁾	

1.5 mg/m³ (resp dust)

PERSONAL PROTECTIVE EQUIPMENT

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

RESPIRATORY: Whenever dust, in the worker's breathing zone, cannot be controlled with ventilation, workers should wear respirators which are approved for protection against airborne dust (by U.S. NIOSH/MSHA, EU CEN or comparable certification organization).

PROTECTIVE CLOTHING: Not required.

GLOVES:
Not required.

ADDITIONAL EXPOSURE LIMITS

Cellulose:

Belgium (TWA) 10 mg/m³ (inhalable dust)
France (TWA) 10 mg/m³ (respirable dust)
Switzerland (TWA) 6 mg/m³ (respirable dust)
United Kingdom (TWA) 10 mg/m³ (inhalable dust)
5 mg/m³ (respirable dust)
20 mg/m³ (STEL)

9. PHYSICAL AND CHEMICAL PROPERTIES

ODOR: Odorless

APPEARANCE: White, free-flowing powder

pH: (In solution) 5.0 - 7.0 (11% solids dispersion)

PERCENT VOLATILE: Approximately 5% water, by weight

VAPOR PRESSURE: Not applicable

VAPOR DENSITY: (Air = 1) Not applicable

BOILING POINT: Not applicable

MELTING POINT: Not applicable

SOLUBILITY IN WATER: Insoluble

EVAPORATION RATE: (Butyl Acetate = 1) Not applicable

SPECIFIC GRAVITY: (H₂O = 1) Bulk density, 0.2 - 0.4 g/cc

COEFF. OIL/WATER: (K_{ow}) Not applicable

OXIDIZING PROPERTIES: Not applicable

COMMENTS:

MINIMUM IGNITION TEMPERATURE :

Microcrystalline cellulose: 420°C

EXPLOSIVE PROPERTIES:

Microcrystalline cellulose: St-1

FAT SOLUBILITY : Not available

10. STABILITY AND REACTIVITY

CONDITIONS TO AVOID: None known

STABILITY: Stable

HAZARDOUS DECOMPOSITION PRODUCTS: None known

11. TOXICOLOGICAL INFORMATION

EYE EFFECTS: Non-irritating (rabbit) [FMC Study Numbers I82-621, I82-626]

(microcrystalline cellulose)

SKIN EFFECTS: Non-irritating (rabbit) [FMC Study Numer I82-625]

Primary Irritating Index = 0/8.0

(microcrystalline cellulose)

DERMAL LD₅₀: >2000 mg/kg (rabbit) [FMC Study Numbers I82-620, I82-624]

ORAL LD₅₀: >5000 mg/kg (rat) [FMC Study Number I82-623]

INHALATION LC₅₀: >5.05 mg/L/4 hr (rat) (max. attain. concentration, no mortality) [FMC Study Numbers I82-622, I82-627]

SENSITIZATION: (Skin) Non-sensitizing (guinea pig) [FMC Study Number I91-1184]

(microcrystalline cellulose)

ACUTE EFFECTS FROM OVEREXPOSURE: No significant hazard in animal toxicity tests.

CHRONIC EFFECTS FROM OVEREXPOSURE:

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 [FMC Study Number I92-1464]. Microcrystalline cellulose was negative in the Ames mutagenicity assay [FMC Study Number I91-1189], and caused no chromosome damage in the mouse micronucleus assay [FMC Study Number I94-1837]. No adverse human effects are known.

CARCINOGENICITY:

IARC: Not listed

NTP: Not listed

OSHA: Not listed

OTHER: (ACGIH) Not listed

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL DATA: Biodegradation in soil: Inherently biodegradable [FMC Study Number I92-1300]

ECOTOXICOLOGICAL INFORMATION:

Rainbow Trout: 96-hour LC50 > 100%, Saturated solution; NOEC = 100%

[FMC Study Number I92-1297]

Daphnia: 48-hour LC50 > 100%, Saturated solution; NOEC = 100%
[FMC Study Number I92-1298]

Algae: 96-hour EC50 > 100%, Saturated solution; NOEC = 12.5%
[FMC Study Number I92-1299]

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

COMMENTS:

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

Shipping Name : National Motor Freight Classification Item 71390, Flour Cellulose, Edible.

UN (IMO/IMDG) : Not applicable

MARPOL Designation : None

Canada (TDG) : Not applicable

15. REGULATORY INFORMATION

UNITED STATES

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT)

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. 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 REGULATORY (40 CFR 707.60): Yes

STATE REGULATIONS

PROPOSITION 65 STATEMENT: To the best of our knowledge, this product does not contain any chemicals currently on the California's list of known carcinogens and reproductive toxins.

CANADA

WHMIS (WORKER HAZARDOUS MATERIALS INFORMATION SYSTEM): Not a controlled product under the Canadian Workplace Hazardous Materials Information System (WHMIS).
GENERAL COMMENTS:

EU EINECS NO.

Microcrystalline Cellulose:
cellulose 232-674-9
hydrochloric acid 231-595-7

NOTE: Under the EINECS reporting guidelines, the reactants are reportable, the post-reacted natural polymer is not reportable.

EU Symbols : Not classified as hazardous.
EU Risk Phrases : Not classified as hazardous.
EU Safety Advise Phrases : Not classified as hazardous.

COMMENTS: Approved by the U.S. EPA as an inert ingredient in pesticide formulations applied to growing crop, raw agricultural commodities after harvest and animals (40 CFR 180.1001 Subpart D(c) and (e) List 4A).

16. OTHER INFORMATION

REVISION SUMMARY Revision #: 4

This MSDS replaces the October 16, 1998 MSDS. Any changes in information are as follows:

NFPA RATING	
HEALTH:	0
FLAMMABILITY	1
REACTIVITY:	0
SPECIAL:	None

Prepared by: FMC Corporation

Section(s) Revised: Section 1

Lattice and FMC Logo - FMC Trademarks

NFPA - Degree of Hazard Code:

4 = Extreme

3 = High

2 = Moderate

1 = Slight

0 = Insignificant

NFPA = National Fire Protection Association