



MATERIAL SAFETY DATA SHEET

Micro Crystalline Cellulose

According to the European Directive 1907/2006/ EC

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Chemical Name : Microcrystalline Cellulose
Brand Name: Ambicel 101,102,111, 112, 200, 302, SI-88. 591, 581,
Chemical Family: Carbohydrate
Formula : (C₆H₅O₁₀)_x
Synonyms : Microcrystalline Cellulose, MCC/ Silicified Microcrystalline Cellulose./
Dispersible Cellulose

Manufacturer: Maple Biotech Pvt. Ltd.

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SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name : Microcrystalline Cellulose

<u>Ingredient Name</u>	<u>CAS #</u>	<u>EU Symbol and Risk Phrases</u>
Microcrystalline Cellulose	9004-34-6	Not Classified as dangerous

SECTION 3. HAZARDS IDENTIFICATION

Most important hazards..... None



Effects of the product:

- Adverse effects to human health..... None
- Environmental effects..... None
- Physical and chemical hazards..... None
- Specific hazards..... None

Main symptoms..... May cause eyes irritation.

SECTION 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.

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

Ingestion: Drink plenty of water. Never give anything by mouth an unconscious person. If any discomfort persists, obtain medical attention.

Notes to Medical Doctor: Microcrystalline Cellulose has low oral, dermal and inhalation toxicity. It is non-irritating to the skin and eyes, and is non-sensitizing to the skin. Treatment is symptomatic and supportive only.

SECTION 5. FIRE FIGHTING MEASURES

Extinguishing Media : Water

Unusual Fire and Explosion Hazard : 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.

Special 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 breath smoke, gases or vapors generated.

Hazardous Decomposition Products : None known.



SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions..... Avoid causing dust and ensure adequate ventilation. Remove all ignition sources.
- Environmental precautions..... No special measures required.
- Emergency procedures and alarm systems..... No special measures required.
- Methods for clean-up..... Minimize accumulation of settled dust. Wear protective clothing. Absorb with inert material. Sweep material to a trash container. After collected and discarded, wash the area with water.
- Leak/ Spill..... Avoid contact with water until all material has been collected and discarded. Area can then be washed down with water.

SECTION 7. HANDLING AND STORAGE

- Handling:
 - Handling procedures..... Handle the product carefully in accordance with good industrial hygiene practices and avoid personal contact.
 - Precautions and guidelines for safe handling..... Wash hands thoroughly after handling. Use local exhaust ventilation. Use appropriate equipment.
- Storage:
 - Storage procedures..... Store in a dry and ventilated area to maintain the integrity of the product. Avoid excessive heat. Preserve in tight containers under the right conditions.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

- Respiratory** : Whenever dust in the worker's breathing zone cannot be controlled with ventilation, workers should wear respirators which are approved by NIOSH/MSHA (or equivalent agency) for protection against airborne dust.
- Eyes:** : Whenever airborne dust concentrations are high, appropriate protective eyewear, such as monogoggles, should be worn to prevent eye contact.
- Gloves** : Not required.
- Special clothing and equipment** : Not required.
- Exposure Limits** : Cellulose.

Inhalable Dust	Respirable Dust	STEL
Belgium(TWA)	10 mg/m3	-



France(TWA)	-	10 mg/m ³	-
Switzerland(TWA)	-	6 mg/m ³	-
United Kingdom(TWA)	10 mg/m ³	5 mg/m ³	20 mg/m ³
USA(ACGIH TWA)	10 mg/m ³	-	-
USA (OSHA TWA)	15 mg/m ³	5 mg/m ³	-

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<u>Appearance</u>	: White, free flowing powder	<u>Flash Point</u>	:Not applicable.
<u>Odor</u>	: Odorless	<u>Flammable Limits (Air)</u>	
<u>Melting Point</u>	: Not applicable	<u>Upper:</u>	:Not applicable
<u>Boiling Point</u>	: Not applicable	<u>Lower:</u>	:Not applicable.
<u>Vapor Pressure</u>	: Not applicable	<u>Autoignition Temperature</u>	o
<u>Vapor Density(Air-1)</u>	: Not applicable	<u>Minimum Ignition Temp</u>	: 420 C
<u>pH (in soln)</u>	: 5.0-7.0 as an 11% solids dispersion	<u>Explosive Properties</u>	: St-I
<u>Specific Gravity(H₂O is1)</u>	: Bulk density, 0.2 - 0.5 g/cc	<u>Oxidizing Properties</u>	:Not applicable
<u>% Volatiles by Volume</u>	: Typically 1 - 5 % water, by weight	<u>Partition Coefficient(Kow)</u>	:Not applicable
<u>Solubility in Water</u>	: Insoluble	<u>Fat Solubility:</u>	:Not applicable
	<u>Evaporation Rate(butyl acetate = 1)</u>		: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Chemical stability.....	Stable under ordinary conditions of use and storage.
Reactivity.....	Strong oxidizers.
Possibility of hazardous reactions.....	No
Conditions to avoid.....	Heat, flame and ignition sources.
Incompatibilities.....	Strong oxidizing agents.
Hazardous decomposition products.....	Carbon monoxide and dioxide may form when heated to decomposition.
Hazardous polymerization.....	Will not occur.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity (LD 50/ rat – oral).....	The material is not considered to be toxic, according to definitions listed in 16CFR 1500.3 (C) (2) (1).
Effects of acute exposure.....	No adverse effects are expected from occupational exposures.
Effects of chronic exposure.....	No adverse effects from available information.
Carcinogenicity.....	Not listed on NTP, IARC or OSHA.
Reproductive effects.....	None
Sensitizing capability of material.....	None



Synergistic materials..... None

SECTION 12. ECOLOGICAL INFORMATION

Environmental effects..... The product is not hazardous for the ecosystem.

SECTION 13. DISPOSAL CONSIDERATIONS

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.

SECTION 14. TRANSPORT INFORMATION

National and international regulations..... Not regulated. Product not classified as hazardous under transport regulations.

SECTION 15. REGULATORY INFORMATION

U.S. TSCA Inventory : Yes

U.S. SARA Title III ---

Section 311/312 : None

Section 213 (40 CFR 372) : This product does not contain any toxic chemicals subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA) and 40 CFR part 372.

California Proposition 65 : This product does not contain any chemicals currently on the California list of known carcinogens and reproductive toxins.

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

EU EINECS No. : 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 dangerous.

EU Risk Phrases : Not classified as dangerous.

EU Safety Advise Phrases : Not classified as dangerous.

Additional Regulatory Information : Microcrystalline Cellulose meets the standards set forth in the United States Pharmacopeia/ National Formulary, European Pharmacopoeia, British Pharmacopoeia, Indian Pharmacopoeia. The Pharmacopoeia of Japan and the Food Chemicals Codex. Microcrystalline cellulose is generally recognized as safe (GRAS) by qualified experts and is in accordance with the United States Food and Drug Regulations. Maple Biotech Pvt. Ltd. maintains a Drug Master File with the U.S. Food and Drug Administration, to support the use of Micro Crystalline Cellulose in drug products. The Microcrystalline Cellulose products are manufactured in accordance with Current Good Manufacturing Practice, and are in compliance with the Federal Food, Drug and Cosmetic Act, as amended, and applicable regulations.

SECTION 16.

OTHER INFORMATION

NFPA Designation 704

	<u>Degree of Hazard</u>	<u>Degree of Hazard Code</u>	
Red	Fire:	1	4= Extreme
Blue	Health:	0	3= High
Yellow	Reactivity:	0	2= Moderate
White	Special Hazard:	None	1= Slight

0= Insignificant.

MSDS #: 9004-34-6

Issue No. 1

Issue date: 01.04.2011

Revision No. 3

Revision date: 03.07.2015