



maple biotech pvt. ltd.

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Product Name: Micro Crystalline Cellulose Material Safety Data Sheet

This Document has been prepared to meet the requirements of the U.S. OSHA Hazard Communication standard, 29 CFR 1910.1200; the EU Directive, 93/122/eec and other regulatory requirements.

1. Company and Product Identification

Maple Biotech Pvt. Ltd.
J-253, M.I.D.C. Bhosari
Pune 411026
India

Chemical Name : Microcrystalline Cellulose
Brand Name: Ambicel 101,102,111, 112, 200, 302, SI-88. 591, 581,
Chemical Family: Carbohydrate
Formula : $(C_6H_5O_{10})_x$
Synonyms : Microcrystalline Cellulose, MCC/ Silicified Microcrystalline Cellulose./ Dispersible Cellulose

Emergency Telephone Numbers:

India : (91-20) 27470010/ 30628103
:(91-20) 24272428

2. Composition/Information on Ingredients

<u>Ingredient Name</u>	<u>CAS #</u>	<u>EU Symbol and Risk Phrases</u>
Microcrystalline Cellulose	900-34-6	Not Classified as dangerous

3. Hazards Identification

Emergency Overview:

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

Potential Health Effects: No significant effect expected

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.



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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.

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.

6. Accidental Release Measures

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

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 kgs). To protect quality store in a tight container in a dry place. Pallets should be stacked in a stable manner. Maintain adequate clearance from structural members and sprinklers. NFPA and OSHA state a minimum of 18 inches (45.7 cm) clearance shall be maintained between the top storage and the ceiling sprinkler deflectors.

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
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Belgium(TWA)	10 mg/m3	-	-
France(TWA)	-	10 mg/m3	-
Switzerland(TWA)	-	6 mg/m3	-



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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	-

9. Physical/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>	°C
<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 is 1)</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		

10. Stability and Reactivity

Stability : Stable Hazardous Decomposition Products : None known
Conditions/Materials to Avoid (Incompatibility) : None known

11. Toxicological Information

Eye Contact : Non-irritating (rabbit) Skin Contact: Non-irritating,
Primary Irritation Index = 0/8.0 (rabbit) Non-sensitizing (guines pig) Skin
Absorption : Dermal LD50~ 2,000 mg/kg (rabbit)
Inhalation : LC50~ 5.05 mg/L/4 hour (rat) (maximum attainable concentration, no mortality)
Ingestion : Oral LD50 ~ 5,000 mg/kg (rat)
Accute Effects From Overexposure : Micro crystalline Cellulose has low oral, dermal and inhalation toxicity. It is non-irritating to the skin and eyes, and is non-sensitizing to the skin.
Chronic Effects From Overexposure : Microcrystalline Cellulose is considered an inert dust which is not toxic to the lung when exposures are properly controlled. A ninety -day animal study has shown 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.
Carcinogenicity: IARC : No NTP : No Other (OSHA, ACGIH): No

12. Ecological Information

Environmental Fate: Biodegradation in soil: Inherently biodegradable
Environmental Effects:
Rainbow Trout: 96 hr LC50> 100%, Saturated solution. (NOEC = 100 %),
Daphnia: 48 hr LC50> 100 %, Saturated solution (NOEC = 100 %),
Algae: 96 hr EC50 > 100 %, Saturated solution (NOEC = 12.5 %),

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.



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14. Transportation Information

U.S. DOT : Not regulated 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

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. 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.

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.



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