

SAFETY DATA SHEET
MICROCEL® MC-101

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier:

Product name: MICROCEL® MC-101

Product No.: 000000201661

Synonyms: MCC, Cellulose Gel, E 460(i) Microcrystalline cellulose

Chemical name: Cellulose

CAS-No.: 9004-34-6

INCI Name: CELLULOSE, MICROCRYSTALLINE CELLULOSE

1.2 Relevant identified uses of the substance or mixture and uses advised against:

Identified uses:	Uses advised against:
Pharmaceuticals., Compression agent, Extrusion aid, Food additive.,	None Reported

1.3 Details of the supplier of the safety data sheet:

Supplier:

ITACEL FARMOQUIMÍCA LTDA.
R. DR JOSÉ ALEXANDRE CROSGNAC, 645
06680-035 - ITAPEVI - SP - BRAZIL

Telephone: +55 11 4144-9400

E-mail: rbr.contacto@roquette.com

1.4 Emergency telephone number:

National Capital Poison Center: 1 800 222 1222 (24/24)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

This product is not hazardous according to OSHA 29CFR 1910.1200.

2.2 Label elements: Not applicable

2.3 Other hazards: Dust may form an explosive mixture in the atmosphere.

SECTION 3: Composition/information on ingredients

3.1 Substance:

Chemical name	Concentration	CAS-No.
Cellulose	>=93 - <=98.5%	9004-34-6

SECTION 4: First aid measures

4.1 Description of first aid measures:

Inhalation: Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.

Eye contact:	Promptly wash eyes with plenty of water while lifting the eye lids. Get medical attention if irritation persists after washing.
Skin contact:	Wash with soap and water.
Ingestion:	Drink plenty of water. Never give liquid to an unconscious person. Get medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed: Dust may irritate the eyes and the respiratory system.

4.3 Indication of any immediate medical attention and special treatment needed:

Treatment:	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media:	Water spray.
Unsuitable extinguishing media:	Dry chemicals or foams.

5.2 Special hazards arising from the substance or mixture: Fire or excessive heat may produce hazardous decomposition products. Dust may form an explosive mixture in the atmosphere. See Section 10.

5.3 Advice for firefighters:

Special Fire Fighting Procedures:	Prevent dust cloud.
Special protective equipment for fire-fighters:	Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:	See Section 8 of the SDS for Personal Protective Equipment.
6.2 Environmental precautions:	No special precautions. Do not discharge into drains, water courses or onto the ground.
6.3 Methods and material for containment and cleaning up:	Remove material, as much as possible, using mechanical equipment. Prevent dust cloud. Collect and dispose of spillage as indicated in section 13 of the SDS.
6.4 Reference to other sections:	For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1 Precautions for safe handling:

Avoid generation and spreading of dust. Avoid contact with eyes, skin, and clothing. Avoid heat, sparks, open flames and other ignition sources. Provide good ventilation.

7.2 Conditions for safe storage, including any incompatibilities:

Store in original container. Keep containers tightly closed. Keep container in a well-ventilated place. Store in a dry place. Avoid exposure to high temperatures or direct sunlight.

7.3 Specific end use(s):

Pharmaceuticals.,

SECTION 8: Exposure controls/personal protection

8.1 Control parameters:

Occupational exposure limits:

Chemical name	Type	Exposure Limit Values	Source
Cellulose	TWA	10 mg/m3	US. ACGIH Threshold Limit Values (01 2010)
Cellulose - Total	REL	10 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
Cellulose - Respirable.	REL	5 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
Cellulose - Total dust.	TWA	15 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
Cellulose - Respirable fraction.	TWA	5 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
Cellulose - Respirable fraction.	PEL	5 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Cellulose - Total dust.	PEL	15 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Cellulose - Respirable fraction.	TWA	5 mg/m3	US. Tennessee. OELs. Occupational Exposure Limits, Table Z1A (06 2008)
Cellulose - Total dust.	TWA	15 mg/m3	US. Tennessee. OELs. Occupational Exposure Limits, Table Z1A (06 2008)
Cellulose - Particulate.	AN ESL	5 <µg/m3	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (06 2010)
Cellulose - Particulate.	ST ESL	50 <µg/m3	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (06 2010)
Dust - Inhalable particles.	TWA	10 mg/m3	US. ACGIH Threshold Limit Values (01 2010)
Dust - Respirable particles.	TWA	3 mg/m3	US. ACGIH Threshold Limit Values (01 2010)
Dust - Respirable fraction.	PEL	5 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Dust - Total dust.	PEL	15 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Dust - Total dust.	TWA	15 mg/m3	US. OSHA Table Z-3 (29 CFR 1910.1000) (2000)
Dust - Respirable fraction.	TWA	5 mg/m3	US. OSHA Table Z-3 (29 CFR 1910.1000) (2000)

8.2 Exposure controls:

Appropriate engineering controls:

Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of dust.

Individual protection measures, such as personal protective equipment:

Eye/face protection:

Wear dust-resistant safety goggles where there is danger of eye contact.

Skin protection:

Hand Protection:

Wear suitable gloves.

Other:

Wear suitable protective clothing.

Respiratory Protection:

In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P1).

Hygiene measures:

Handle the product in accordance with the good hygiene practices and safety instructions.

Environmental exposure controls:

Do not allow runoff to sewer, waterway or ground.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Physical State:	solid
Form:	Powder
Water, moisture:	< 7 %
Color:	White
Odor:	Odorless
pH:	5.0 - 7.5
Melting Point:	Not Applicable No data available.
Boiling Point:	Not Applicable
Flash Point:	Not Applicable
Vapor pressure:	Not Applicable
Vapor density (air=1):	Not Applicable
Solubility in Water:	< 0.24 %(w/w)
Solubility in Water:	The product is insoluble in water.
Solubility (other):	Alkalies.
Partition coefficient (n-octanol/water):	No data available.
Decomposition Temperature:	~ 340 °C
Explosive properties: - CHILWORTH -Data from similar product.	
Ignition Temperature:	~ 440 °C (EN 50281-2-1) ~ 340 °C (EN 50281-2-1)
MIE (Minimum Ignition Energy):	100 - 200 mJ (EN 13821 (Without Inductance, <63 µm).)
dP/dtmax (Maximum Rate of explosion Pressure rise):	~ 393 bar/s (EN 14034-2)
Pmax (Maximum Explosion OverPressure) ±10%:	~ 7.9 bar (EN 14034-1)
Kst value (±20%):	~ 107 barm/s (EN 14034-2)
Dust Explosion Class:	st 1 (VDI 3673)
Volume resistivity:	> 10 ⁹ Ω.m (IEC 61241-2-2 / Group IIIB non-conductive dust.)
Moisture:	~ 3.79 % (ISO 589) 1.5 - 7 %
Mv (Median value):	~ 35.77 µm (NFX 11-666) 100 - 180 µm

9.2 Other information:

SECTION 10: Stability and reactivity

10.1 Reactivity:

Oxidizing agents.

10.2 Chemical stability:

Material is stable under normal conditions.

- 10.3 Possibility of hazardous reactions:** No hazardous reactions under ordinary conditions of use and storage.
- 10.4 Conditions to avoid:** Prevent dust cloud. Dust clouds may be explosive under certain conditions. Avoid dust close to ignition sources.
- 10.5 Incompatible materials:** Strong oxidizing substances.
- 10.6 Hazardous decomposition products:** Carbon Dioxide. Carbon Monoxide.

SECTION 11: Toxicological information

11.1 Information on toxicological effects:

Acute toxicity :

Test / Substance	Species	Type / Result	Exposure	Remarks
Cellulose	Rat	LD50 - Dermal : > 2,000 mg/kg		- Literature Reference -
Cellulose	Rat	LD50 - Oral : > 5,000 mg/kg		- Literature Reference -
Cellulose	Rat	LC50 - Inhalation : > 5.35 mg/l		- Literature Reference -

Skin irritation. :

Test / Substance	Species	Result	Exposure	Remarks
Cellulose	Rabbit	Not Irritating	4 h	- Literature Reference -

Serious eye irritation :

Test / Substance	Species	Result	Exposure	Remarks
Cellulose	Rabbit	Not Irritating	4 h	- Literature Reference -

Sensitization :

Test / Substance	Type	Species	Result	Remarks
Cellulose		Guinea Pig	Non-Sensitising	- Literature Reference -

Repeated dose toxicity :

Test / Substance	Species	Result	Exposure	Remarks
Scientific evaluation. Cellulose	Rat	NOEL : > 50 g/kg No treatment related effects.	90 day(s)	- Literature Reference -

Mutagenesis :

Test / Substance	Type	Species	Result	Remarks
Ames Cellulose		S. typhimurium	Negative	- Literature Reference -
micronucleus test Cellulose		Mouse	Negative	- Literature Reference -

Carcinogenicity :

Test / Substance	Species	Route of Exposure / Exposure	Result	Remarks
Scientific evaluation. Cellulose, carboxymethyl ether, sodium salt	Rat	Oral 104 Week(s).	Negative	- Literature Reference -
Scientific evaluation. Cellulose, carboxymethyl ether, sodium salt	Mouse	Oral 100 Week(s).	Negative	- Literature Reference -

Reproductive toxicity :

Test / Substance	Species	Route of Exposure / Exposure	Result	Remarks
Scientific evaluation. Cellulose	Rat	Oral	Negative	- Literature Reference -

Remarks:

The ingredients of this product are not classified as carcinogenic by the ACGIH, the CIRC, the OSHA or the NTP.

SECTION 12: Ecological information

12.1 Toxicity:

Acute toxicity:

Test / Substance	Species	Type/Result	Exposure	Remarks
Cellulose, carboxymethyl ether, sodium salt	Ceriodaphnia	EC50 : > 100 mg/l	48 h	- Literature Reference -
Cellulose, carboxymethyl ether, sodium salt	Rainbow Trout	LC50 : >20000 mg/l	96 h	- Literature Reference -

Chronic Toxicity:

No data available.

12.2 Persistence and degradability:

Test / Substance	Result	Remarks
Cellulose	> 70 % / Inherently biodegradable	- Literature Reference -

12.3 Bioaccumulative potential:

No data available.

12.4 Mobility in soil:

No data available.

12.5 Results of PBT and vPvB assessment:

No data available.

12.6 Other adverse effects:

None known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods:

Product:

Dispose of waste in an appropriate authorised treatment facility in accordance with regulations in force and product characteristics at time of disposal. (for example, energy recovery).

Packaging material:

Single use packaging. Collect for salvage or disposal.

SECTION 14: Transport information

This material is not subject to transport regulations (DOT, IMDG, IATA).'

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

SARA Title III (Superfund Amendments and Reauthorization Act) :

Section: 302 Not Applicable

Section: 311 Not listed

US. NFPA 325 - Guide to Fire Hazard Properties of Flammable Liquids, Gases, and Volatile Solids. :

NFPA Health Rating: 0

NFPA Flammability Rating: 1

NFPA Instability Rating: 0

NFPA Special Hazard: No

US. HMIS Chemical Ratings (Hazardous Materials Information System, Chemical Ratings Guide) :

Health hazard: 0

Flammability hazard: 1

Physical hazard: 0

Personal Protection: F

US. California Safe Drinking Water & Toxic Enforcement Act (Proposition 65) :

Not listed

International Inventories :

Australia. Inventory of Chemical Substances (AICS):	Listed.
China. Inventory of Existing Chemical Substances (IECSC):	Listed.
Japan. Pharmacopoeia Listing:	Listed.
Japan. Industrial Safety & Health Law (ISHL):	Listed.
Japan. Inventory of Existing & New Chemical Substances (ENCS):	Listed.
Korea. Existing Chemicals Inventory (KECI):	Listed.
Philippines. Inventory of Chemicals and Chemical Substances (PICCS):	Listed.
New Zealand. Inventory of Chemicals (NZIoC):	Listed.
Mexico. National Inventory of Chemical Substances (INSQ):	Listed.
Taiwan. Existing Chemicals Inventory (TCSI):	Listed.
US. Toxic Substances Control Act (TSCA):	Listed.

This Safety Data Sheet is in conformity with appendix D of the OSHA Hazard Communication Standard 29CFR 1910.1200.

SECTION 16: Other information

Revision Information: Not relevant.

Key literature references and sources for data: JECFA : Joint FAO/WHO Expert Committee on Food Additives.
ToxNet Database.

Abbreviations and acronyms used in the SDS.:

CAS: Chemical Abstracts Service (division of the American Chemical Society)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals

Disclaimer:

The information provided in this Safety Data Sheet (SDS) relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.
The information given is designed only as a guidance and is not to be considered a warranty or quality specification.
All information and instructions provided in this SDS are based on the current state of our knowledge at the latest revision date indicated.