

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	CELLULOSE, NF/EP (Microcrystalline) (Flocel® 101)
PRODUCT CODE	0567
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Based on available data, the classification criteria are not met.			
PICTOGRAM	Not Applicable			
SIGNAL WORD	Not applicable			
HAZARD STATEMENT(S)	Not applicable			
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not applicable			
PRECAUTIONARY STATEMENT(S)	Prevention	Not applicable		
	Response	Not applicable		
	Storage	Not applicable		
	Disposal	Not applicable		
HMS CLASSIFICATION	Health Hazard	0	Flammability	1
	Reactivity	0	Personal Protection	B

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	2-(hydroxymethyl)-6-[4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl] oxyoxane-3,4,5 triol
BOTANICAL NAME	Not applicable

SYNONYM	Not applicable								
CHEMICAL FORMULA	(C ₆ H ₅ O ₅) _n								
CHEMICAL FAMILY	Carbohydrate								
CAS NUMBER	9004-34-6								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	160 000 - 560 000								
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>CELLULOSE</td> <td>9004-34-6</td> <td>232-674-9</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	CELLULOSE	9004-34-6	232-674-9	100
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CELLULOSE	9004-34-6	232-674-9	100						

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES Pure microcrystalline cellulose manufactured from cellulose pulp from trees.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Not expected to be harmful.
IF INHALED	Not expected to be harmful.
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
FLAMMABLE PROPERTIES	Combustible at high temperature
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
NOTES	Danger of dust explosion. Fire class A (Fires of solids, mainly organic nature, which normally burn down under glow forming).

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
METHODS & MATERIAL FOR CONTAINMENT	On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE
PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: CELLULOSE CAS #: 9004-34-6

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	15(1) 5(1)	N/L	N/L	N/L	N/L	N/A	15(1) Inhalable fraction 5(1) Respirable fraction
ACGIH	USA	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	10(1) 5(1)	N/L	N/L	N/L	N/L	N/A	10(1) Inhalable fraction 5(1) Respirable aerosol
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	10(1)	N/L	N/L	N/L	N/L	N/A	(1) This value is for inhalable dust containing no asbestos and <1 % crystalline silica.
HSE	UK	N/L	10(1) 4(1)	N/L	20(1) (2)	N/L	N/L	N/A	10(1) Inhalable fraction 4(1) Respirable fraction 20 (1) (2) (1) Inhalable fraction (2) 15 minutes average value
GESTIS	Belgium	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada-Ontario	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada-Quebec	N/L	10(1)(2)	N/L	N/L	N/L	N/L	N/A	(1) Total dust (2) The standard corresponds to dust containing no asbestos and the percentage in crystalline silica is less than 1%.

GESTIS	France	N/L	10(1)	N/L	N/L	N/L	N/L	N/A	(1) Inhalable aerosol
GESTIS	Ireland	N/L	10	N/L	N/L	N/L	N/L	N/A	Inhalable fraction
GESTIS	Latvia	N/L	2	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	New Zealand	N/L	10(1)	N/L	N/L	N/L	N/L	N/A	(1) Inhalable fraction
GESTIS	China	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Singapore	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Korea	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Spain	N/L	10(1)	N/L	N/L	N/L	N/L	N/A	(1) inhalable aerosol
GESTIS	Switzerland	N/L	3(1)	N/L	N/L	N/L	N/L	N/A	(1) respirable aerosol
GESTIS	South Africa	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Africa Mining	N/L	10 (1) 5(1)	N/L	20 (1) (2)	N/L	N/L	N/A	10(1) Inhalable fraction 5(1) Respirable fraction 20(1)(2) (1) Inhalable fraction (2) 15 minutes average value

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

Fine, white or almost white, slightly hygroscopic, powder. It consists of free-flowing, nonfibrous particles.

SOLUBILITY

Insoluble in water, in dilute acids, and in most organic solvents; practically insoluble in sodium hydroxide solution (1 in 20)

ODOR

Odorless

FLAMMABILITY

Combustible at high temperature

AUTO-IGNITION TEMPERATURE

232°C, 449.6°F

BOILING POINT

Decomposes

DECOMPOSITION TEMPERATURE

(260 - 270)°C, (500-518)°F

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(260 - 270)°C, (500-518)°F (decomposes)
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	5.5 - 7.0 (11%)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	1.27 - 1.61	UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	Not available	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidizing agents. Fluorine.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): > 5000 Dermal: Rabbit LD50: (mg/kg): > 2000 Inhalation: Rat: LC50: (mg/L/4hr): > 5800
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. Local effects; Skin irritation; Result: Negative; Species: Rabbit
SERIOUS EYE DAMAGE/EYE IRRITATION	Based on available data, the classification criteria are not met. Local effects; Eye irritation; Result: Negative; Species: Rabbit
RESPIRATORY SENSITIZATION	Due to lack of data, the classification is not possible.
SKIN SENSITIZATION	Based on available data, the classification criteria are not met. Skin sensitization; Result: Negative; Species: Guinea pig.
GERM CELL MUTAGENICITY	Based on available data, the classification criteria are not met. Ames test; Result: Negative. Micronucleus test; Result: Negative. Mouse lymphoma assay; Result: Negative. Unscheduled DNA synthesis; Result: Negative.
CARCINOGENICITY	OSHA CELLULOSE is not listed. NTP CELLULOSE is not listed.

	IARC	CELLULOSE is not evaluated.
	California Proposition 65	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
ADDITIONAL CARCINOGENICITY INFORMATION		Based on available data, the classification criteria are not met. 30% Oral feed study; Result: Negative; Species: Rat; Test Duration: 72 weeks Subcutaneous implant; Result: Negative; Species: Rat; Test Duration: 2 years
REPRODUCTIVE TOXICITY		Based on available data, the classification criteria are not met. 4.6 mg/kg/day Reproductivity / developmental; Result: No adverse effects on the offspring observed.; Species: Rat
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE		Based on available data, the classification criteria are not met.
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE		Due to lack of data, the classification is not possible.
ASPIRATION HAZARDS		Based on available data, the classification criteria are not met.
SIGNS AND SYMPTOMS OF EXPOSURE		ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available DELAYED HEALTH EFFECT FROM EXPOSURE: Not available
POTENTIAL HEALTH EFFECTS	Inhalation	No adverse health effects expected from inhalation. May cause respiratory sensitization.
	Ingestion	Edible, therefore not expected to be harmful. Large doses may cause gastro-intestinal upset: diarrhea or vomiting.
	Skin	Not expected to be harmful. May cause skin irritation, dermatitis.
	Eyes	May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL	Not available
MOBILITY IN SOIL	Insoluble in water
OTHER ADVERSE EFFECTS	Not available This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
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UN NUMBER Not applicable
 CLASS Not applicable
 PACKING GROUP Not applicable

AUSTRALIA

HAZCHEM Not applicable

EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE Not Listed

ENVIRONMENTAL HAZARDS Not available

SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Right-to-know			California Prop 65
			Appendix A	Appendix B	Pennsylvania	New Jersey	Massachusetts	
CELLULOSE 9004-34-6	N/L	N/L	N/L	N/L	X	X	X	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
CELLULOSE 9004-34-6	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
CELLULOSE 9004-34-6	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

05/2025

SUPERSEDES

02/2023

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.