SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Date 17.08.2021

Version 2.0

Generic EU MSDS - No country specific data - No OEL data

TUNICELL TTC +M SAFETY DATA SHEET

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

NOTE: *This Safety Data Sheet is for informational purposes only, and represents a preliminary assessment for a new pre-commercial substance that has not been tested in safety evaluations. The information provided is based on the best available published and unpublished data for similar substances, as listed below.*

1.1 Product identifier

Product name:	TUNICELL TTC +M Medical Grade
Product Description:	TEMPO-mediated oxidized, sterilized cellulose nanofibrils 2.5% and 4.6% D-mannitol in cell culture grade pyrogen/endotoxin free water.
REACH no.:	At present, REACH does not require registration of cellulose nanomaterials and mannitol.
CAS no:	Cellulose (9004-34-6) (manufactured nanofibrillar form) Mannitol (69-65-8)
EC No:	Cellulose (232-674-9) Mannitol (200-711-8)

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

Relevant identified uses:	For use as substance in 3D Bioprinting, cell encapsulation and delivery, tissue engineering and regenerative medicine, biomedical devices, drug delivery for research.
Uses advised against:	Not for human use, for research only

1.3 Details of the Supplier of the Safety Data Sheet

Company:	Ocean TuniCell AS
Address:	Postboks 12, 5868 Blomsterdalen, Norway
Phone number:	+47 40 00 82 80
Email:	post@oceantunicell.com
Homepage:	www.oceantunicell.com

1.4 Emergency phone number

Norwegian Poison Center	+47 22 59 13 00
International	Call your national poison center, or a doctor/physician

SECTION 2: Hazard identification

NOTE: *The hazardous properties of this substance have not been evaluated. The classifications are based on available information for materials of similar chemistry, and apply to dried powder forms.*

2.1 Classification of the substance or mixture

Not classified as hazardous according to Regulation (EC) No. 1272/2008 [CLP].

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictogram:	GHS07: Exclamation mark 
Signal word:	WARNING
Hazard statements:	H335: May cause respiratory irritation
Precautionary statements:	***Precautionary statements – prevention*** P210: If dry, keep away from all ignition sources including heat, sparks, open flames. Prevent dust accumulations to minimize explosion hazard. P261: Avoid breathing dust P262: Do not get in eyes, on skin, or on clothing P271: Use only outdoors or in a well-ventilated area P280: Wear protective gloves/protective clothing/eye protection/face protection ***Precautionary statements – response*** P304+P340: IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312: Call a POISON CENTER or doctor/physician if you feel unwell. ***Precautionary statements – disposal*** P501: Dispose of contents/container in accordance with local/regional/national/international regulation.
Supplemental Hazard information (EU):	Not applicable

2.3 Other hazards

Explosion hazard: Dry particles may form combustible dust in air at high enough concentrations*
*if powder form.

Ocean TuniCell AS
Postboks 12,
5868 Blomsterdalen, Norway
post@oceantunicell.com
oceantunicell.com
+47 40 00 82 80

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name:	Cellulose Nanofibrils (CNF) and Mannitol [TUNICELL TTC +M Medical Grade]
CAS-No.:	Cellulose (9004-34-6) (manufactured nanofibrillar form) Mannitol (69-65-8)
EC No:	Cellulose (232-674-9) Mannitol (200-711-8)
Composition:	Gel – 2.5% CNF, 4.6% Mannitol, ~92.9% cell culture grade pyrogen/endotoxin free water

SECTION 4: Description of first aid measures

4.1 First aid measures

Inhalation:	If dry powder, move to fresh air. Get medical attention if symptoms appear.
Skin contact:	Soap wash. Get medical attention if irritation occurs.
Eye contact:	Remove any contact lenses. Irrigate immediately. Get medical attention if irritation occurs.
Ingestion:	Do not induce vomiting unless directed to do so by medical personnel.

4.2 Most important symptoms and effects, both acute and delayed

Acute effects:	Potential symptoms: (based on cellulose powders) irritation of eyes, skin, mucous membranes. Hoarseness, cough and phlegm. Exercise-induced dyspnea. For mannitol, LD50 Oral - Rat – 13,500 mg/kg.
Delayed effects:	No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Note to physician:	This product may contain nanoscale particles. At this time, there is no further guidance specific to nanomaterial exposure.

SECTION 5: Firefighting measures

Extinguishing media:	Use water, alcohol-resistant foam, dry chemical, or carbon dioxide.
Special hazards arising from the substance or mixture:	**Explosion**: Avoid generating dust; dispersed dust in air at sufficient concentrations and in the presence of an ignition source can create a severe explosion hazard. Manufactured nano-forms, particularly powders, might show unusually high reactivity, especially for fire, explosion and catalytic reactions, when compared with equivalent materials with larger particle sizes.
Advice for fire fighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective clothing.

Ocean TuniCell AS
Postboks 12,
5868 Blomsterdalen, Norway

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oceantunicell.com

+47 40 00 82 80

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:	For dry powders, remove any ignition sources and provide sufficient ventilation. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). No current guidelines available for nanoscale materials. Use current good practices. Wear full set of protective clothing and contained breathing apparatus for spills of solid material. Avoid inhalation of spilled powders, and avoid dermal contact with nano-powders and solutions. See section 8.3 for more details on protective equipment.
Environmental precautions:	In the case of accidental spill, keep away from drains, surface, and ground water.
Methods and materials for containment and cleaning up:	For dry powders, ensure the product is not present at a concentration level above cellulose and mannitol TLV (see section 8.1). Use HEPA-filtered vacuum cleaner or wet wiping methods and avoid re-dispersion of nanomaterial into the air. Clean liquid spills with absorbent materials/liquid traps. Immediately dispose of cleaning materials and do not dry and re-use contaminated materials.

SECTION 7: Handling and storage

Precautions for safe handling:	Use exhaust ventilation system with HEPA filter when handling nanomaterials in powder state. See section 8.3 for recommended personal protective measures. The same precautions taken for handling and storage of dusts and fine powders should be implemented, with the additional consideration for the long settling time of nanomaterials.
Conditions for safe storage, including any compatibilities:	Store in closed, tightly sealed containers in cool, well-ventilated area, away from sources of ignition, electrostatic sparks, and mechanical friction. Do not store food or beverages in areas where nanomaterials are handled. Do not smoke in work area where nanomaterials are stored.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

CNF	Cellulose dust	Mannitol
Gels do not represent an inhalation hazard; avoid inhalation exposure to if dried/powder forms and dusts. No exposure limits for nano-forms of cellulose. British Standards Institute has developed pragmatic guidance for OEL - for insoluble nanomaterials a factor of 0.066*OEL of micro-sized bulk material is proposed.	Belgium Limit Value (8h) – 10 mg/m^3 OSHA PEL - 15 mg/m^3 (total dust); 5 mg/m^3 (respirable fraction) TWA NIOSH REL – 10 mg/m^3 (total dust) TWA; 5 mg/m^3 (respirable fraction) TWA American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) - 10 mg/m^3 TWA British Columbia Occupational exposure limit - 10 mg/m^3 (total dust); 3 mg/m^3 (respirable fraction) United Kingdom – 10 mg/m^3 (total dust) TWA, 20 mg/m^3 (total dust) STEL; 4 mg/m^3 (respirable)	Canada – Ontario Occupational Exposure Limits – 10 mg/m^3 TWA US – Michigan Exposure Limits for Air Contaminants - 5 mg/m^3 TWA

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8.2 Exposure controls

Engineering controls:	If user operations generate dust, fume, or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. It is recommended that all dust control equipment contain explosion relief vents. Assess the most likely route of exposure and minimize risk. Refer to section 4.2.8.1 of ISO/TR 13329 for more information.	
Personal protection equipment:	At present, due to a lack of nanomaterial-specific data regarding PPE, good hygiene practices are recommended. For gel, dermal exposure is possible and gloves, protective clothing, and goggles are recommended. If powder, in the absence of confirmatory measurements, inhalation exposure to dry forms should be avoided through the use of appropriate respirators. See Guidance at: http://www.cdc.gov/niosh/topics/nanotech/pubs.html.	
	Gloves:	Preliminary evidence suggests that butyl rubber gloves may be more protective than nitrile gloves. Regular disposal and replacement of gloves is recommended.
	Protective Clothing:	Cover skin to minimize dermal exposure, avoid direct contact with abraded or lacerated skin. Nanomaterials may penetrate woven materials; therefore, non-woven protective clothing is preferable to woven fabric laboratory coats. Prolonged use or reuse should be avoided.
	Respirators and filters:	Some reports show that particles in the nano range have the highest penetrating ability for respirators (OECD 2009). Therefore, limiting dispersion of nano-powder into the air, minimizing handling of powders, containment of workers handling powders, and working with proper exhaust ventilation with HEPA filters is recommended.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties	**9.2 Particle -specific properties for cellulose (NOT REQUIRED BUT BEST PRACTICE (ISO TR 13329))**
Appearance: gel, optically transparent ***Odor:*** odorless ***Melting point/freezing point:*** 334 °F for Mannitol. ***Initial boiling point and boiling range:*** n/a ***Flash point:*** No data for TUNICELL TTC +M Medical Grade. Cellulose ca. 240 °C, Mannitol > 300 °F. ***Evaporation rate:*** n/a ***Flammability (solid, gas):*** No data for TUNICELL TTC +M Medical Grade. Cellulose may be combustible at high temperature (240 °C). ***Upper/lower flammability or explosive limits:*** No data for TUNICELL TTC +M Medical Grade. Cellulose dust explosion class "St 2 – strong explosion". Cellulose dust deflagration index Kst = 229. ***Vapor pressure/density*:** n/a ***Solubility(ies):*** Cellulose is insoluble in water; forms a gel. Mannitol is miscible in water. ***Partition coefficient: n-octanol/water*:** No data. ***Auto-ignition temperature:*** No data for TNUICELL TTC +M Medical Grade. Cellulose may self-ignite at high temperatures (ca. 240 °C). 860 °F for mannitol. ***Decomposition temperature:*** 268 °C for cellulose.	***Particle core size:*** Width of 6.20 ± 1.49 nm and length of 2262 ± 1026 nm ***Agglomeration/aggregation state:*** no data ***Shape (and aspect ratio):*** fiber-like, high aspect ratio of 365 ± 17 ***Specific surface area:*** 61.7 m^2/g ***Elemental composition:*** C, 42.72%; H, 6.14%; O, 48.14%; N, <0.05%; S, <0.10% ***Carboxylate content:*** 805 ± 29 µmol/g cellulose ***Surface charge (zeta potential):*** -40.3 ~ -57.2 mV ***Dustiness:*** No data available for TUNICELL TTC +M Medical Grade (CNF) ***Crystallinity:*** 86.83 ± 0.66%

Ocean TuniCell AS
Postboks 12,
5868 Blomsterdalen, Norway
post@oceantunicell.com
oceantunicell.com
+47 40 00 82 80

SECTION 10: Stability and reactivity

Reactivity:	Cellulose and Mannitol are stable.
Chemical stability:	No data for CNF. Mannitol is considered stable and hazardous polymerization will not occur.
Possibility of hazardous reactions:	No data for CNF. Cellulose is slightly flammable to flammable in presence of open flames and sparks, and non-flammable in the presence of shocks. Self-ignition may occur at high temperatures (240 °C).
Conditions to avoid:	For dust: High temperatures, extreme pressure, electrostatic sparks, collisions, mechanical friction.
Incompatible materials:	No data for CNF. Fire and explosions may occur from reactions involving pentafluoride, acetic acid and microcrystalline cellulose. Contact between cellulose and sodium nitrite at elevated temperatures results in vigorous burning from decomposition reaction. Strong oxidizing agents should be avoided for mannitol.
Hazardous decomposition products:	No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

11.1.1 Likely routes of exposure

If in powder form: inhalation, eye; If a gel: dermal.

11.1.2 Immediate, delayed, or chronic effects

SHORT TERM EXPOSURE

	CNF	Cellulose dust	Mannitol
Inhalation:	Data are limited; however, dust may be harmful if inhaled. A single study in mice reported acute immune response in the lung following exposure to CNF containing biocide (SUNPAP 2012).	May be harmful if inhaled. An *in vivo* rat study showed intratracheal exposure to high concentrations ("dust overload conditions") may lead to long term effects such as lung lesions (Muhle 1997). Exposure to lower concentrations or subchronic inhalation may result in acute inflammatory lung effects, which resolve after 30 days (Cullen 2000; Nagato 2008).	No data available. *
Ingestion:	No data available. *	Acute exposure to Cellan 300 in rats found LOEC >3160 mg/kg (unpublished report, WHO 1998). LD50 > 5 g/kg for cellulose (RTECS MSDS).	LD50 Oral - Rat – 13,500 mg/kg
Dermal contact:	No data available. *	One study reported no dermal irritation after acute exposure up to 2000 mg/kg of microcrystalline cellulose (MCC) (unpub. report, WHO 1998).	No data available. *
Eye contact:	No data available. *	One study with MCC reported minimal irritation after acute ocular instillation in rabbit (unpublished report, WHO 1998).	No data available. *

Ocean TuniCell AS
Postboks 12,
5868 Blomsterdalen, Norway
post@oceantunicell.com
oceantunicell.com
+47 40 00 82 80

*The short-term exposure effects of this material have not been determined. Therefore, appropriate precautions should be taken when using, storing, handling or disposing of this material.

LONG TERM EXPOSURE

	CNF	Cellulose	Mannitol
Inhalation:	No data available. **	Occupational studies have shown long term exposure to dust and fibers in a factory setting (>10 mg/m3) may lead to decreased lung function (not able to determine specific effect of cellulose) (Kraus 2004).	No data available. *
Ingestion:	No data available. **	No adverse effects in rats consuming a 30% MCC diet for 72 days (unpublished report, WHO 1998).	No data available. *
Dermal contact:	No data available. **	No data available.	No data available. *
Eye contact:	No data available. **	No data available.	No data available. *

**The long-term exposure effects of this material have not been determined. Therefore, appropriate precautions should be taken when using, storing, handling or disposing of this material.

11.1.3 Other measures of toxicity

	CNF (mechanically ground)	Cellulose	Mannitol
Immunotoxicity:	Based on in vitro tests, no effect on cytokine or chemokine production >300 mg/L CNF (Vartiainen 2011).	Exposure to lower concentrations or subchronic inhalation of cellulose may result in acute inflammatory lung effects, which resolve after 30 days (Cullen 2000; Nagato 2008).	No data available.
Neurotoxicity:	No data available	No data available.	No data available.
Genotoxicity:	Highest tolerated dose >240 mg/L in bacterial Ames test; no mutagenicity (Pitkänen 2010).	No data available.	No data available.
Carcinogenicity:	No data available.	Rats fed MCC at 30% of diet for 72 weeks were not reported to have an increase in tumorigenicity (unpublished report, WHO 1998).	No data available.
Reproductive toxicity:	No data available.	Rats fed MCC at 30% of diet for 72 weeks were not reported to have any adverse reproductive effects (unpublished report, WHO 1998).	No data available.
Biodurability/ Biopersistence	No data available.	Cellulose highly biopersistent. Half time of cellulose fiber clearance around 1000 days after 1-time intratracheal instillation of 2 mg (dust overload condition) in rats (Muhle 1997). After 7 days in lung fluid, MCC did not degrade (Seehra and Stefaniak 2013).	No data available.

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+47 40 00 82 80

SECTION 12: Ecological information

***NOTE**: The basic elements of CNF are abundant materials that are not likely to be harmful to the environment. However, environmental effects of this material have not been determined. Therefore, avoid releasing material to the environment.*

12.1 Toxicity

Note: *Data are for CNF produced by alternative processes. Surface properties/toxicology may be different for TUNICELL TTC +M Medical Grade.*

Acute data

Zebrafish embryo	CNF-TEMPO	LOEC = ~ 2000 mg/L	Harper et al. 2015
	CNF-homogenization	LOEC = 200 mg/L	Harper et al. 2015
	CNF-homogenization	No mortality up to 2000 mg/L	Harper et al. 2015
Bacteria (*V. fischeri)*	1250 mg/L CNF (mechanically produced)	9% fluorescence inhibition	Vartiainen et al. 2011
Algae (*C. vulgaris)*	1-100 mg/L CNF (chemically produced)	Decreased viability after 96h	Pereira et al. 2014
Rat	Mannitol	13,500 mg/kg	Richard J. Lewis 1996

Chronic data

No data for TUNICELL TTC +M Medical Grade or other CNF.

12.2 Persistence and biodegradability	No data for TUNICELL TTC +M Medical Grade. Cellulose fibers readily biodegradable: Using ISO 14855-1999 and EN 14046-2003, complete degradation by 25 days (Fernandes et al. 2011). Using EN14046 cellulose powder and Whatman cellulose paper were >60% after 28 days, and 82% and 69% after 65 days. CNF readily biodegradable: Non-functionalized NFC >70% degraded by day 28, approx. 90% degraded by day 70 (under "controlled composting conditions" (SUNPAP 2012). Using EN 14046, >60% degradation of NFC-based products (concentrated NFC granules, paper with 1.5% NFC additive, NFC film) after 65 days – 76%, 95%, and 100%, respectively (Vikman et al. 2014).
12.3 Bioaccumulative potential	No data available.
12.4 Mobility in soil	No data available.
12.5 PBT and vPvB assessment	No data available.
12.6 Other adverse effects	No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

All components are derived from natural materials and not anticipated to require specific handling for disposal. Avoid dust generation upon disposal. Not specifically listed as a hazardous waste under the Resource Conservation and Recovery Act (RCRA). However, if waste exhibits one or more of the following characteristics: ignitability, corrosivity, reactivity, or toxicity as described by 40 CFR 261.21-24, then waste must be classified as hazardous. At present, no nano-specific regulations exist. Waste must be disposed of in accordance with federal, state, and local environmental control regulations.

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SECTION 14: Transport information

UN number:	**None**
UN proper shipping name:	Not applicable
Transport hazard class:	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not classified as hazardous to the environment
Special precautions for user:	No additional information available
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	Not applicable

Cellulose is not a DOT controlled material (United States). At present, no nano-specific regulations exist.

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture:	None for CNF. For related substances**, OSHA regulations:** See Section 8. Mannitol (CAS: 69-65-8) is found on the following regulatory lists; "Canada Domestic Substances List (DSL)","Canada Toxicological Index Service - Workplace Hazardous Materials Information System - WHMIS (English)","CODEX General Standard for Food Additives (GSFA) – Additives Permitted for Use in Food in General, Unless Otherwise Specified, in accordance with GMP","International Fragrance Association (IFRA) Survey: Transparency List","US DOE Temporary Emergency Exposure Limits (TEELs)","US EPA High Production Volume Program Chemical List","US FDA CFSAN GRAS Substances evaluated by the Select Committee on GRAS Substances (SCOGS)","US FDA Maximum Recommended Therapeutic Dose (MRTD) Database","US Food Additive Database","US NFPA 499 Combustible Dusts","US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory","US TSCA Section 8 (a) Inventory Update Rule (IUR) - Partial Exemptions".
Chemical safety assessment:	No chemical safety assessment has been carried out for this substance by the supplier.

SECTION 16: Other information

SDS preparation date: November 2020
SDS last known revision date and changes made: Version 2.0, August 2021
SDS prepared by: Ocean TuniCell AS (www.oceantunicell.com)
SDS revised by: Ocean TuniCell AS (www.oceantunicell.com)

Other comments

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

See ISO TR 13329.

NFPA Rating:
Health 0; Flammability 0; Reactivity 0; Special information 0

Ocean TuniCell AS
Postboks 12,
5868 Blomsterdalen, Norway
post@oceantunicell.com
oceantunicell.com
+47 40 00 82 80

NOTE:
The information in the safety data sheet should be provided to all who will use, handle, store, transport or otherwise be exposed to this product. All information concerning this product and/or suggestions for handling and use contained herein are offered in good faith and are believed to be reliable as of the date of publication. No warranty is made regarding the accuracy of and/or sufficiency of such information. Nothing contained herein shall be construed as granting or extending any license under any patent. If the date on this document is more than three years old, call to make certain that this sheet is current.

References

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End of Material Safety Data Sheet

Ocean TuniCell AS
Postboks 12,
5868 Blomsterdalen, Norway

post@oceantunicell.com
oceantunicell.com

+47 40 00 82 80