

# 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 CTC 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 The information provided is based on the best available published and unpublished data for similar substances, as listed below.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 CTC Medical Grade
<b>Product Description:</b>	Carboxymethylated, sterilized cellulose nanofibrils 2.5% in cell culture grade
	pyrogen/endotoxin free water
Other common	Cellulose nanofibrils, microfibrillated cellulose, nanofibrils, microfibrils,
names or synonyms:	nanofibrillated cellulose, cellulose nanofibers
REACH no.:	At present, REACH does not require registration of cellulose nanomaterials. Cellulose
	pulp is exempt from obligations to register under REACH (Article 2(7)(a) - Annex IV).
CAS no:	Cellulose (9004-34-6) (manufactured nanofibrillar form)
EC No:	Cellulose (232-674-9)

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

<b>Relevant identified uses:</b>	Manufacture of substances, Laboratory chemicals
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

Classification according to Regulation (EC) No. 1272/2008 [CLP]; if dried or powder form: STOT SE 3 (H335: May cause respiratory irritation)

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

### 2.3 Other hazards

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



# **SECTION 3: Composition/information on ingredients**

### **3.1 Substances**

Chemical name:	Cellulose Nanofibrils (CNF) [TUNICELL CTC Medical Grade]
CAS-No.:	Cellulose (9004-34-6) (manufactured nanofibrillar form)
EC No:	Cellulose (232-674-9)
Composition:	Gel – 2.5% CNF, ~97.5% 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. Get medical attention if
	symptoms appear.

# 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.
<b>Delayed effects:</b>	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	Explosion: Avoid generating dust; dispersed dust in air at sufficient concentrations
arising from the	and in the presence of an ignition source can create a severe explosion hazard.
substance or mixture:	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	As in any fire, wear self-contained breathing apparatus pressure-demand,
fighters:	MSHA/NIOSH (approved or equivalent) and full protective clothing.



# SECTION 6: Accidental release measures

Personal precautions,	For dry powders, remove any ignition sources and provide sufficient ventilation.
protective equipment	Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). No
and emergency	current guidelines available for nanoscale materials. Use current good practices. Wear
procedures:	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	In the case of accidental spill, keep away from drains, surface, and ground water.
precautions:	
Methods and materials	For dry powders, ensure the product is not present at a concentration level above
for containment and	cellulose TLV (see section 8.1). Use HEPA-filtered vacuum cleaner or wet wiping
cleaning up:	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
Gels do not represent an inhalation hazard;	Belgium Limit Value (8h) – 10 mg/m <sup>3</sup>
avoid inhalation exposure to if dried/powder	OSHA PEL - 15 mg/m <sup>3</sup> (total dust); 5 mg/m <sup>3</sup> (respirable
forms and dusts.	fraction) TWA
No exposure limits for nano-forms of	NIOSH REL – 10 mg/m <sup>3</sup> (total dust) TWA; 5 mg/m <sup>3</sup> (respirable
cellulose.	fraction) TWA
British Standards Institute has developed	American Conference of Governmental Industrial Hygienists
pragmatic guidance for OEL - for insoluble	(ACGIH) Threshold Limit Value (TLV) - 10 mg/m <sup>3</sup> TWA
nanomaterials a	British Columbia Occupational exposure limit - 10 mg/m <sup>3</sup> (total
factor of 0.066*OEL of micro-sized bulk	dust); 3 mg/m <sup>3</sup> (respirable fraction)
material is proposed.	United Kingdom – 10 mg/m <sup>3</sup> (total dust) TWA, 20 mg/m <sup>3</sup> (total
	dust) STEL; 4 mg/m <sup>3</sup> (respirable)



# 8.2 Exposure controls

Engineering controls: Personal protection equipment:	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. 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 electhing, and googles are recommended. If neuder in the absence of confirmatory	
	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.	
	<b>Gloves:</b> 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
	NOT REQUIRED BUT BEST
	PRACTICE (ISO TR 13329)
Appearance: gel, optically transparent	<i>Particle core size:</i> Width of 4.99 $\pm$
Odor: odorless	1.28 nm and length of $2017 \pm 1063$
<i>Melting point/freezing point:</i> n/a	nm
Initial boiling point and boiling range: n/a	Agglomeration/aggregation state:
Flash point: No data for TUNICELL CTC Medical Grade (CNF). Cellulose	no data
ca. 240 °C	Shape (and aspect ratio): fiber-like,
<i>Evaporation rate:</i> n/a	high aspect ratio of $412 \pm 76$
Flammability (solid, gas): No data for TUNICELL CTC Medical Grade	<i>Elemental composition:</i> C, 42.72%
(CNF). Cellulose may be combustible at high temperature (240 °C)	<i>Elemental composition:</i> C, 42.72%;
Upper/lower flammability or explosive limits: No data for TUNICELL	H, 6.14%; O, 48.14%; N, <0.05%; S,
CTC Medical Grade (CNF). Cellulose dust explosion class "St 2 – strong	<0.10%
explosion". Cellulose dust deflagration index Kst = 229. Note:	<i>Carboxymethyl content:</i> $660.8 \pm 2.6$
nanomaterials may pose a greater explosion hazard than bulk material.	µmol/g cellulose
<i>Vapor pressure/density</i> : n/a	<b>DS:</b> 11.3 ± 0.1%
Solubility(ies): Insoluble in water; forms a gel	Surface charge (zeta potential): -
Partition coefficient: n-octanol/water: No data.	$34.8\pm2.9\ mV$
Auto-ignition temperature: No data for TUNICELL CTC Medical Grade	Dustiness: No data available for
(CNF). Cellulose may self-ignite at high temperatures (ca. 240 °C).	TUNICELL CTC Medical Grade
<i>Decomposition temperature:</i> 296.35 ± 3.04 °C	(CNF)



# **SECTION 10: Stability and reactivity**

**NOTE**: TUNICELL CTC Medical Grade (CNF) has not been evaluated for these properties. Data provided are for similar substances produced by alternative processes. Surface properties and toxicology may be different for TUNICELL CTC Medical Grade (CNF).

Reactivity:	Cellulose is stable.
·	Cellulose dust is classified as "St 2 – risk of strong explosion", due to dust
	deflagration index Kst = 229 (OSHA CPL 03-00-008). At present, no data is
	available for nano-sized cellulose. However, materials that are inert in the size
	range of ca. 10-1000 microns may become highly reactive in the air when
	manufactured in the nanoscale. For example, the explosion risks of some metals
	increase significantly with a decrease in particle size in the microscale range.
Chemical stability:	No data for CNF.
Possibility of hazardous	No data for CNF. Cellulose is slightly flammable to flammable in presence of
reactions:	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.
Hazardous decomposition	No known hazardous decomposition products.
products:	
	SECTION 11: Toxicological information

**NOTE:** TUNICELL CTC Medical Grade (CNF) has not been tested in safety evaluations. The information provided here is for similar substances. Data for CNF is for substance produced by alternate chemical/mechanical processes. Chemistry/toxicology may be different for TUNICELL CTC Medical Grade (CNF).

# 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
Inhalation:	Data are limited; however, dust may	May be harmful if inhaled.
	be harmful if inhaled.	An <i>in vivo</i> rat study showed intratracheal exposure to high
	A single study in mice reported acute	concentrations ("dust overload conditions") may lead to
	immune response in the lung	long term effects such as lung lesions (Muhle 1997).
	following exposure to CNF	Exposure to lower concentrations or subchronic inhalation
	containing biocide (SUNPAP 2012).	may result in acute inflammatory lung effects, which
		resolve after 30 days (Cullen 2000; Nagato 2008).
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).



Dermal	No data available.*	One study reported no dermal irritation after acute
contact:		exposure up to 2000 mg/kg of microcrystalline cellulose
		(MCC) (unpub. report, WHO 1998).
Eye	No data available.*	One study with MCC reported minimal irritation after
contact:		acute ocular instillation in rabbit (unpublished report,
		WHO 1998).

\*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
Inhalation:	No data available.**	Occupational studies have shown long term exposure to dust and
		fibers in a factory setting (>10 mg/m <sup>3</sup> ) may lead to decreased lung
		function (not able to determine specific effect of cellulose) (Kraus
		2004).
Ingestion:	No data available.**	No adverse effects in rats consuming a 30% MCC diet for 72 days
_		(unpublished report, WHO 1998).
Dermal contact:	No data available.**	No data available.
Eye contact:	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

	<b>CNF (mechanically ground)</b>	Cellulose
Immunotoxicity:	Based on in vitro tests, no effect on	Exposure to lower concentrations or
	cytokine or chemokine	subchronic inhalation of cellulose
	production >300 mg/L CNF	may result in acute inflammatory
	(Vartiainen 2011).	lung effects, which resolve after 30
		days (Cullen 2000; Nagato 2008).
Neurotoxicity:	No data available	No data available.
Genotoxicity:	Highest tolerated dose >240 mg/L	No data available.
	in bacterial Ames test; no	
	mutagenicity (Pitkänen 2010).	
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).
<b>Reproductive toxicity:</b>	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).
<b>Biodurability/ Biopersistence</b>	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).



## **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 CTC Medical Grade (CNF).* 

Zebrafish embryo	CNF-TEMPO	$LOEC = \sim 2000 \text{ mg/L}$	Harper et al. 2015
	CNF-homogenization	LOEC = 200  mg/L	Harper et al. 2015
	CNF-homogenization	No mortality up to 2000	Harper et al. 2015
		mg/L	
Bacteria (V. fischeri)	1250 mg/L CNF	9% fluorescence	Vartiainen et al. 2011
	(mechanically produced)	inhibition	
Algae (C. vulgaris)	1-100 mg/L CNF	Decreased viability after	Pereira et al. 2014
	(chemically produced)	96h	

### Acute data

### Chronic data

No data for TUNICELL CTC Medical Grade (CNF)/other CNF.

12.2 Persistence and	No data for TUNICELL CTC Medical Grade (CNF). Cellulose fibers
biodegradability	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.



## **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	Not applicable
MARPOL73/78 and the IBC code:	

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, <b>OSHA regulations:</b> See Section 8.
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 Rat	ting (ba	ised on cellulose dus	t):			
Health	0;	Flammability	0;	Reactivity	0;	Special information

#### 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.

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#### References

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## **End of Material Safety Data Sheet**



# 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 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 Medical Grade	
<b>Product Description:</b>	TEMPO-mediated oxidized, sterilized cellulose nanofibrils 2.5% in cell culture grade	
	pyrogen/endotoxin free water	
Other common	TEMPO cellulose nanofibrils (T-CNF), cellulose nanofibrils, microfibrillated cellulose,	
names or synonyms:	nanofibrils, microfibrils, nanofibrillated cellulose, cellulose nanofibers	
REACH no.:	At present, REACH does not require registration of cellulose nanomaterials. Cellulose	
	pulp is exempt from obligations to register under REACH (Article 2(7)(a) - Annex IV).	
CAS no:	Cellulose (9004-34-6) (manufactured nanofibrillar form)	
EC No:	Cellulose (232-674-9)	

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

<b>Relevant identified uses:</b>	Manufacture of substances, Laboratory chemicals
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

Classification according to Regulation (EC) No. 1272/2008 [CLP]; if dried or powder form: STOT SE 3 (H335: May cause respiratory irritation)

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

### 2.3 Other hazards

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



# **SECTION 3: Composition/information on ingredients**

### **3.1 Substances**

Chemical name:	Cellulose Nanofibrils (CNF) [TUNICELL TTC Medical Grade]
CAS-No.:	Cellulose (9004-34-6) (manufactured nanofibrillar form)
EC No:	Cellulose (232-674-9)
Composition:	Gel – 2.5% CNF, ~97.5% 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. Get medical attention if
	symptoms appear.

# 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.
<b>Delayed effects:</b>	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	Explosion: Avoid generating dust; dispersed dust in air at sufficient concentrations	
arising from the	and in the presence of an ignition source can create a severe explosion hazard.	
substance or mixture:	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	As in any fire, wear self-contained breathing apparatus pressure-demand,	
fighters:	MSHA/NIOSH (approved or equivalent) and full protective clothing.	



# **SECTION 6: Accidental release measures**

Personal precautions,	For dry powders, remove any ignition sources and provide sufficient ventilation.
protective equipment	Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). No
and emergency	current guidelines available for nanoscale materials. Use current good practices. Wear
procedures:	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	In the case of accidental spill, keep away from drains, surface, and ground water.
precautions:	
Methods and materials	For dry powders, ensure the product is not present at a concentration level above
for containment and	cellulose TLV (see section 8.1). Use HEPA-filtered vacuum cleaner or wet wiping
cleaning up:	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
Gels do not represent an inhalation hazard;	Belgium Limit Value (8h) – 10 mg/m <sup>3</sup>
avoid inhalation exposure to if dried/powder	OSHA PEL - 15 mg/m <sup>3</sup> (total dust); 5 mg/m <sup>3</sup> (respirable
forms and dusts.	fraction) TWA
No exposure limits for nano-forms of	NIOSH REL – 10 mg/m <sup>3</sup> (total dust) TWA; 5 mg/m <sup>3</sup> (respirable
cellulose.	fraction) TWA
British Standards Institute has developed	American Conference of Governmental Industrial Hygienists
pragmatic guidance for OEL - for insoluble	(ACGIH) Threshold Limit Value (TLV) - 10 mg/m <sup>3</sup> TWA
nanomaterials a	British Columbia Occupational exposure limit - 10 mg/m <sup>3</sup> (total
factor of 0.066*OEL of micro-sized bulk	dust); 3 mg/m <sup>3</sup> (respirable fraction)
material is proposed.	United Kingdom – 10 mg/m <sup>3</sup> (total dust) TWA, 20 mg/m <sup>3</sup> (total
	dust) STEL; 4 mg/m <sup>3</sup> (respirable)



# 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 see	ction 4.2.8.1 of ISO/TR 13329 for more information.	
Personal protection	At present, due to a lack	of nanomaterial-specific data regarding PPE, good hygiene	
equipment:	practices are recommended	d. 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 res	pirators. 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.		
	<b>Respirators and filters:</b>	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
	NOT REQUIRED BUT BEST
	PRACTICE (ISO TR 13329)
Appearance: gel, optically transparent	<i>Particle core size:</i> Width of $6.20 \pm 1.49$
Odor: odorless	nm and length of $2262 \pm 1026$ nm
<i>Melting point/freezing point:</i> n/a	Agglomeration/aggregation state: no
<i>Initial boiling point and boiling range:</i> n/a	data
Flash point: No data for TUNICELL TTC Medical Grade (CNF).	Shape (and aspect ratio): fiber-like,
Cellulose ca. 240 °C	high aspect ratio of $365 \pm 17$
<i>Evaporation rate:</i> n/a	<i>Specific surface area:</i> 61.7 m <sup>2</sup> /g
Flammability (solid, gas): No data for TUNICELL TTC Medical Grade	<i>Elemental composition:</i> C, 42.72%;
(CNF). Cellulose may be combustible at high temperature (240 °C)	H, 6.14%; O, 48.14%; N, <0.05%; S,
Upper/lower flammability or explosive limits: No data for TUNICELL	<0.10%
TTC Medical Grade (CNF). Cellulose dust explosion class "St 2 – strong	<i>Carboxylate content:</i> $805 \pm 29 \mu mol/g$
explosion". Cellulose dust deflagration index Kst = 229. Note:	cellulose
nanomaterials may pose a greater explosion hazard than bulk material.	Surface charge (zeta potential): -40.3
<i>Vapor pressure/density</i> : n/a	~ -57.2 mV
Solubility(ies): Insoluble in water; forms a gel	Dustiness: No data available for
Partition coefficient: n-octanol/water: No data.	TUNICELL TTC Medical Grade
Auto-ignition temperature: No data for TNUICELL TTC Medical Grade	(CNF)
(CNF). Cellulose may self-ignite at high temperatures (ca. 240 °C).	<i>Crystallinity:</i> 86.83 ± 0.66%
<b>Decomposition temperature:</b> 268 °C	



# **SECTION 10: Stability and reactivity**

**NOTE**: TUNICELL TTC Medical Grade (CNF) has not been evaluated for these properties. Data provided are for similar substances produced by alternative processes. Surface properties and toxicology may be different for TUNICELL TTC Medical Grade (CNF).

Reactivity:	Cellulose is stable.	
	Cellulose dust is classified as "St 2 – risk of strong explosion", due to dust	
	deflagration index Kst = 229 (OSHA CPL 03-00-008). At present, no data is	
	available for nano-sized cellulose. However, materials that are inert in the size	
	range of ca. 10-1000 microns may become highly reactive in the air when	
	manufactured in the nanoscale. For example, the explosion risks of some metals	
	increase significantly with a decrease in particle size in the microscale range.	
Chemical stability:	No data for CNF.	
Possibility of hazardous	No data for CNF. Cellulose is slightly flammable to flammable in presence of	
reactions:	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.	
Hazardous decomposition	No known hazardous decomposition products.	
products:		

# **SECTION 11: Toxicological information**

**NOTE:** TUNICELL TTC Medical Grade (CNF) has not been tested in safety evaluations. The information provided here is for similar substances. Data for CNF is for substance produced by alternate chemical/mechanical processes. Chemistry/toxicology may be different for TUNICELL TTC Medical Grade (CNF).

# **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
Inhalation:	Data are limited, however dust may	May be harmful if inhaled.
	be harmful if inhaled.	An <i>in vivo</i> rat study showed intratracheal exposure to high
	A single study in mice reported acute	concentrations ("dust overload conditions") may lead to
	immune response in the lung	long term effects such as lung lesions (Muhle 1997).
	following exposure to CNF	Exposure to lower concentrations or subchronic inhalation
	containing biocide (SUNPAP 2012).	may result in acute inflammatory lung effects, which
		resolve after 30 days (Cullen 2000; Nagato 2008).



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).
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).
Eye contact:	No data available.*	One study with MCC reported minimal irritation after acute ocular instillation in rabbit (unpublished report, WHO 1998).

\*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
Inhalation:	No data available.**	Occupational studies have shown long term exposure to dust and fibers in a factory setting (>10 mg/m <sup>3</sup> ) may lead to decreased lung function (not able to determine specific effect of cellulose) (Kraus 2004).
Ingestion:	No data available.**	No adverse effects in rats consuming a 30% MCC diet for 72 days (unpublished report, WHO 1998).
Dermal contact:	No data available.**	No data available.
Eye contact:	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

	<b>CNF (mechanically ground)</b>	Cellulose
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).
Neurotoxicity:	No data available	No data available.
Genotoxicity:	Highest tolerated dose >240 mg/L in bacterial Ames test; no mutagenicity (Pitkänen 2010).	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).
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).
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).



## **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 Medical Grade (CNF).* 

Zebrafish embryo	CNF-TEMPO	$LOEC = \sim 2000 \text{ mg/L}$	Harper et al. 2015
	CNF-homogenization	LOEC = 200  mg/L	Harper et al. 2015
	CNF-homogenization	No mortality up to 2000	Harper et al. 2015
		mg/L	
Bacteria (V. fischeri)	1250 mg/L CNF	9% fluorescence	Vartiainen et al. 2011
	(mechanically produced)	inhibition	
Algae (C. vulgaris)	1-100 mg/L CNF	Decreased viability after	Pereira et al. 2014
	(chemically produced)	96h	

#### Acute data

#### **Chronic data** No data for TUNICELL TTC Medical Grade (CNF)/other CNF.

12.2 Persistence and	No data for TUNICELL TTC Medical Grade (CNF). Cellulose fibers	
biodegradability	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.



## **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	Not applicable
MARPOL73/78 and the IBC code:	

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, <b>OSHA regulations:</b> See Section 8.
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 2020 **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 (based on cellulose dust):							
Health	0;	Flammability	0;	Reactivity	0;	Special information	0

#### 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.



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## **End of Material Safety Data Sheet**



# SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Date 10.08.2021

Version 3.0

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

# TUNICELL ETC 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 ETC Medical Grade
<b>Product Description:</b>	Enzymatically pretreated, sterilized cellulose nanofibrils 2.5% in cell culture grade
	pyrogen/endotoxin free water
Other common	Cellulose nanofibrils, microfibrillated cellulose, nanofibrils, microfibrils,
names or synonyms:	nanofibrillated cellulose, cellulose nanofibers
<b>REACH no.:</b>	At present, REACH does not require registration of cellulose nanomaterials. Cellulose
	pulp is exempt from obligations to register under REACH (Article 2(7)(a) - Annex IV).
CAS no:	Cellulose (9004-34-6) (manufactured nanofibrillar form)
EC No:	Cellulose (232-674-9)

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

<b>Relevant identified uses:</b>	Manufacture of substances, Laboratory chemicals
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:	Postbox 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

Classification according to Regulation (EC) No. 1272/2008 [CLP]; if dried or powder form: STOT SE 3 (H335: May cause respiratory irritation)

### 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
	<ul> <li>Precautionary statements – response</li> <li>P304+P340: IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing.</li> <li>P305+P351+P338: IF IN EYES Rinse cautiously with water for several minutes.</li> <li>Remove contact lenses, if present and easy to do. Continue rinsing.</li> <li>P312: Call a POISON CENTER or doctor/physician if you feel unwell.</li> </ul>
	Precautionary statements – disposal
	P501: Dispose of contents/container in accordance with
	local/regional/national/international regulation.
Supplemental Hazard	Not applicable
information (EU):	

### 2.3 Other hazards

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



# **SECTION 3: Composition/information on ingredients**

### 3.1 Substances

Chemical name:	Cellulose Nanofibrils (CNF) [TUNICELL ETC Medical Grade]
CAS-No.:	Cellulose (9004-34-6) (manufactured nanofibrillar form)
EC No:	Cellulose (232-674-9)
Composition:	Gel – 2.5% CNF, ~97.5% 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. Get medical attention if
	symptoms appear.

# 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.
<b>Delayed effects:</b>	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	Explosion: Avoid generating dust; dispersed dust in air at sufficient concentrations
arising from the	and in the presence of an ignition source can create a severe explosion hazard.
substance or mixture:	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	As in any fire, wear self-contained breathing apparatus pressure-demand,
fighters:	MSHA/NIOSH (approved or equivalent) and full protective clothing.



# **SECTION 6: Accidental release measures**

Personal precautions,	For dry powders, remove any ignition sources and provide sufficient ventilation.		
protective equipment	Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). No		
and emergency	current guidelines available for nanoscale materials. Use current good practices. Wear		
procedures:	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	In the case of accidental spill, keep away from drains, surface, and ground water.		
precautions:			
Methods and materials	For dry powders, ensure the product is not present at a concentration level above		
for containment and	cellulose TLV (see section 8.1). Use HEPA-filtered vacuum cleaner or wet wiping		
cleaning up:	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	Use exhaust ventilation system with HEPA filter when handling nanomaterials in		
handling:	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.		
<b>Conditions for safe</b>	Store in closed, tightly sealed containers in cool, well-ventilated area, away from		
storage, including	sources of ignition, electrostatic sparks, and mechanical friction. Do not store food or		
any compatibilities:	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
Gels do not represent an inhalation hazard;	Belgium Limit Value (8h) – 10 mg/m <sup>3</sup>
avoid inhalation exposure to if dried/powder	OSHA PEL - 15 mg/m <sup>3</sup> (total dust); 5 mg/m <sup>3</sup> (respirable
forms and dusts.	fraction) TWA
No exposure limits for nano-forms of	NIOSH REL $-10 \text{ mg/m}^3$ (total dust) TWA; 5 mg/m <sup>3</sup> (respirable
cellulose.	fraction) TWA
British Standards Institute has developed	American Conference of Governmental Industrial Hygienists
pragmatic guidance for OEL - for insoluble	(ACGIH) Threshold Limit Value (TLV) - 10 mg/m <sup>3</sup> TWA
nanomaterials a	British Columbia Occupational exposure limit - 10 mg/m <sup>3</sup> (total
factor of 0.066*OEL of micro-sized bulk	dust); 3 mg/m <sup>3</sup> (respirable fraction)
material is proposed.	United Kingdom – 10 mg/m <sup>3</sup> (total dust) TWA, 20 mg/m <sup>3</sup> (total
	dust) STEL; 4 mg/m <sup>3</sup> (respirable)



# 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 ris	k. Refer to section 4.2.8.1 of ISO/TR 13329 for more	
	information.		
Personal protection	At present, due to a lack of	f nanomaterial-specific data regarding PPE, good hygiene	
equipment:	practices are recommended	d. For gel, dermal exposure is possible and gloves,	
	protective clothing, and go	oggles are recommended. If powder, in the absence of	
	confirmatory measurement	ts, 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.		
	<b>Protective Clothing:</b>	<b>Protective Clothing:</b> 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.		
	<b>Respirators and filters:</b> 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
	NOT REQUIRED BUT BEST
	PRACTICE (ISO TR 13329)
Appearance: gel, white or off-white	<i>Particle core size:</i> Width of $8.55 \pm$
Odor: odorless	3.37 nm and length of $2519 \pm 827$
<i>Melting point/freezing point:</i> n/a	nm to several μm
Initial boiling point and boiling range: n/a	Agglomeration/aggregation state:
Flash point: No data for TUNICELL ETC Medical Grade (CNF).	no data
Cellulose ca. 240 °C	Shape (and aspect ratio): fiber-
<i>Evaporation rate:</i> n/a	like, high aspect ratio of $296 \pm 97$
Flammability (solid, gas): No data for TUNICELL ETC Medical Grade	<i>Specific surface area:</i> 161.3 m <sup>2</sup> /g
(CNF). Cellulose may be combustible at high temperature (240 °C)	<i>Elemental composition:</i> C,
Upper/lower flammability or explosive limits: No data for TUNICELL	42.72%; H, 6.14%; O, 48.14%; N,
ETC Medical Grade (CNF). Cellulose dust explosion class "St 2 – strong	<0.05%; S, <0.10%
explosion". Cellulose dust deflagration index Kst = 229. Note:	Surface charge (zeta potential): -
nanomaterials may pose a greater explosion hazard than bulk material.	7.48 ~ -16.9 mV
<i>Vapor pressure/density</i> : n/a	Dustiness: No data available for
Solubility(ies): Insoluble in water; forms a gel	TUNICELL ETC Medical Grade
Partition coefficient: n-octanol/water: No data.	(CNF)
Auto-ignition temperature: No data for TUNICELL ETC Medical Grade	<i>Crystallinity:</i> 89.07 ± 1.60%
(CNF). Cellulose may self-ignite at high temperatures (ca. 240 °C).	
<i>Decomposition temperature:</i> >325 °C	



# **SECTION 10: Stability and reactivity**

**NOTE**: TUNICELL ETC Medical Grade (CNF) has not been evaluated for these properties. Data provided are for similar substances produced by alternative processes. Surface properties and toxicology may be different for TUNICELL ETC Medical Grade (CNF).

Reactivity:	Cellulose is stable.		
	Cellulose dust is classified as "St 2 – risk of strong explosion", due to dust		
	deflagration index Kst = 229 (OSHA CPL 03-00-008). At present, no data is		
	available for nano-sized cellulose. However, materials that are inert in the size		
	range of ca. 10-1000 microns may become highly reactive in the air when		
	manufactured in the nanoscale. For example, the explosion risks of some metals		
	increase significantly with a decrease in particle size in the microscale range.		
Chemical stability:	No data for CNF.		
Possibility of hazardous	No data for CNF. Cellulose is slightly flammable to flammable in presence of		
reactions:	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.		
Hazardous decomposition	No known hazardous decomposition products.		
products:			

# **SECTION 11: Toxicological information**

**NOTE:** TUNICELL ETC Medical Grade (CNF) has not been tested in safety evaluations. The information provided here is for similar substances. Data for CNF is for substance produced by alternate chemical/mechanical processes. Chemistry/toxicology may be different for TUNICELL ETC Medical Grade (CNF).

### 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
Inhalation:	Data are limited; however, dust may	May be harmful if inhaled.
	be harmful if inhaled.	An <i>in vivo</i> rat study showed intratracheal exposure to high
	A single study in mice reported acute	concentrations ("dust overload conditions") may lead to
	immune response in the lung	long term effects such as lung lesions (Muhle 1997).



	following exposure to CNF containing biocide (SUNPAP 2012).	Exposure to lower concentrations or subchronic inhalation may result in acute inflammatory lung effects, which resolve after 30 days (Cullen 2000; Nagato 2008).
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).
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).
Eye contact:	No data available.*	One study with MCC reported minimal irritation after acute ocular instillation in rabbit (unpublished report, WHO 1998).

\*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
Inhalation:	No data available.**	Occupational studies have shown long term exposure to dust and fibers in a factory setting (>10 mg/m <sup>3</sup> ) may lead to decreased lung function (not able to determine specific effect of cellulose) (Kraus 2004).
Ingestion:	No data available.**	No adverse effects in rats consuming a 30% MCC diet for 72 days (unpublished report, WHO 1998).
Dermal contact:	No data available.**	No data available.
Eye contact:	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
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).
Neurotoxicity:	No data available	No data available.
Genotoxicity:	Highest tolerated dose >240 mg/L in bacterial Ames test; no mutagenicity (Pitkänen 2010).	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).
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).
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).
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### **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 ETC Medical Grade (CNF).* 

#### Acute data

Zebrafish embryo	CNF-TEMPO	$LOEC = \sim 2000 \text{ mg/L}$	Harper et al. 2015
	CNF-homogenization	LOEC = 200  mg/L	Harper et al. 2015
	CNF-homogenization	No mortality up to 2000	Harper et al. 2015
		mg/L	
Bacteria (V. fischeri)	1250 mg/L CNF	9% fluorescence	Vartiainen et al. 2011
	(mechanically produced)	inhibition	
Algae (C. vulgaris)	1-100 mg/L CNF	Decreased viability after	Pereira et al. 2014
	(chemically produced)	96h	

### Chronic data

No data for TUNICELL ETC Medical Grade (CNF)/other CNF.

12.2 Persistence and	No data for TUNICELL ETC Medical Grade (CNF). Cellulose fibers		
biodegradability	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

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present, no nano-specific regulations exist. Waste must be disposed of in accordance with federal, state, and local environmental control regulations.

### **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	Not applicable
MARPOL73/78 and the IBC code:	

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, <b>OSHA regulations:</b> See Section 8.
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 3.0, 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 (based on cellulose dust):

Flammability

0:

Health

0; Reactivity

ty 0;

Special information

0

#### 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.

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## **End of Material Safety Data Sheet**