

# Nanulose

## Safety Data Sheet

according to Regulation (EU) 1907/2006

Date of issue: 01/06/2021 Revision date: 26/08/2021 Version: 1.0

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

**1.1 Product name:** Bacterial Cellulose

**1.2 EC:** 232-674-9

**1.3 CAS:** 9004-34-6 (cellulosa, made in nanofibers)

**1.4 REACH no:** At present, REACH does not require registration of cellulose nanomaterials.

Cellulose pulp is exempt from Registration according to the provisions of Article 2(7)(a) and Annex IV of REACH.

**1.5 Molecular formula**  $[(C_6H_{10}O_5)_x(C_6H_9O_4SO_4Na)_y]$

**1.6 Product form:** nanofibers.

**1.7 Use of the substance/mixture:** Additives, manufacture of substances.

**1.8 Details of the supplier of the safety data Sheet:**

Bio Inspired Materials, S.L.

Sarria, 33 PR2

08029 Barcelona

**1.9 Emergency Number:** 112 (24 hour service)-applicable to EU only

### SECTION 2: Hazards identification

**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 (if in powder form)

**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: Strong explosion hazard if dust is dispersed into air at high enough concentrations. \*

\*if powder form



## SECTION 3: Composition/information on ingredients

### 3.1 Substances OR 3.2 Mixtures

**Chemical name:** Cellulose Nanofibrils

**CAS no:** 9004-34-6 (Cellulose, manufactured nanofibril form)

**Composition:**

Material	CAS Number	EINECS Number	Weight %	Agency	Exposure Limits	Comments
Natural Cellulose Fiber	9004-34-6	265-998-8	2-98	OSHA OSHA ACGIH	15 mg/m <sup>3</sup> 5 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>	PEL Total dust PEL Respirable dust TLV Total dust
Water	N/A	N/A	98-2		N/A	N/A

## SECTION 4: First aid measures

### 4.1 Description of 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: Hoarseness, cough and phlegm. Exercise-induced dyspnea.
- **Delayed effects:** No data available.

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

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

## SECTION 5: Firefighting measures

**5.1 Extinguishing media:** Use water, alcohol-resistant foam, dry chemical or carbon dioxide.

**5.2 Special hazards arising from the substance or mixture: Explosion:** If powder, avoid generating dust.

**5.3 Advice for firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective clothing.

## SECTION 6: Accidental release measures

**6.1 Personal precautions, protective equipment and emergency procedures:** For dry powders, remove ignition sources and provide sufficient ventilation. Avoid dispersal of powder in air (i.e. clearing with compressed air), use current good practices. If powder, wear full set of protective clothing and contained breathing apparatus for spills, avoid inhalation, and wash skin following contact. See section 8 for more details on protective equipment.

**6.2 Environmental precautions:** In the case of accidental spill, keep away from drains, surface, and ground water. No acute environmental hazard.

**6.3 Methods and materials for containment and cleaning up:** For dry powders, ensure the product is not present at concentration level above cellulose TLV (section 8.1). Use HEPA-filtered vacuum or wet wiping methods and avoid re-dispersion of nanomaterial powder into the air. For gel spills, use absorbent materials/liquid traps. Immediately dispose of cleaning materials and do not dry and re-use contaminated materials.

**6.4 Reference to other sections:** For further information, refer to section 13. For disposal of residues refer to section 13: Disposal considerations.

## SECTION 7: Handling and storage

**7.1 Precautions for safe handling:** If powder form, the same precautions taken for handling and storage of dusts and fine powders should be implemented.

**7.2 Conditions for safe storage, including any compatibilities:** Store in closed, tightly sealed containers in cool (4°C), dry, well-ventilated area, away from sources of ignition, electrostatic sparks, extreme heat, or mechanical friction.

Prevent gels from drying to powder. Protect from freezing. Do not store food or beverages in areas where materials are handled. Do not smoke in work area where nanomaterials are stored.

## SECTION 8: Exposure controls/personal protection

8.1 Control parameters	
CNF (Cellulose Nanofibrils)	Cellulose dust
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.	OSHA PEL - 15 mg/m <sup>3</sup> (total dust); 5 mg/m <sup>3</sup> (respirable fraction) TWA NIOSH REL – 10 mg/m <sup>3</sup> (total dust) TWA; 5 mg/m <sup>3</sup> (respirable fraction) TWA American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) - 10 mg/m <sup>3</sup> TWA European country specific exposure limits **: <ul style="list-style-type: none"> <li>- Spain VLA-ED (mg/m<sup>3</sup>) – 10 mg/m<sup>3</sup></li> <li>- Belgium Limit Value (8h) – 10 mg/m<sup>3</sup></li> <li>- 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)</li> </ul>

### 8.2 Exposure controls

**Appropriate engineering controls:** provide adequate ventilation.

**Personal protective 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.

- **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. Non-woven protective clothing is preferable to woven fabric laboratory coats. Prolonged use or reuse should be avoided.
- **Respirators and filters:** if in powder form, limit dispersion of powder into the air, minimizing handling of powders, contain operations for handling powders, and working with proper exhaust ventilation with HEPA filters is recommended.

**Personal protective equipment symbols:**



## 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)
<p><b>Appearance:</b> Powder or gel, white or off-white. Solid (nanomaterial).</p> <p><b>Odor:</b> Odorless</p> <p><b>Odor threshold:</b> n/a</p> <p><b>pH:</b> 7</p> <p><b>Melting point/freezing point:</b> n/a</p> <p><b>Initial boiling point and boiling range:</b> n/a</p> <p><b>Flash point:</b> No data available for CNF. Cellulose ca. 240°C</p> <p><b>Evaporation rate:</b> n/a</p> <p><b>Flammability (solid, gas):</b> No data available for CNF. Cellulose may be combustible at high temperature (240°C)</p> <p><b>Upper/lower flammability or explosive limits:</b> No data for CNF. Cellulose dust explosion class “St 2 – strong explosion”. Cellulose dust deflagration index Kst = 229.</p> <p><b>Vapor pressure:</b> n/a</p> <p><b>Vapor density:</b> n/a</p> <p><b>Relative density:</b> no data available</p> <p><b>Water Solubility:</b> Insoluble; forms a gel</p> <p><b>Partition coefficient: n-octanol/water:</b> No data.</p> <p><b>Auto-ignition temperature:</b> No data available for CNF. Cellulose may self-ignite at high temperatures (ca. 240°C).</p> <p><b>Decomposition temperature:</b> &gt;349°C</p> <p><b>Viscosity:</b> no data available</p> <p><b>Oxidizing properties:</b> no data available</p>	<p><b>Particle core size:</b> 5-200 nm width and 130nm to 225µm length.</p> <p><b>Particle size distribution:</b> 5 nm - 200 nm</p> <p><b>Agglomeration/aggregation state:</b> no data available</p> <p><b>Shape and aspect ratio:</b> Fiber-like, and aspect ratio of 14-23.</p> <p><b>Specific surface area:</b> no data available</p> <p><b>Surface chemistry/elemental composition:</b> no data available</p> <p><b>Surface charge (zeta potential):</b> -48 to -5 mV</p> <p><b>Dustiness:</b> no data available</p> <p><b>Crystallinity:</b> 67-88%.</p>

## SECTION 10: Stability and reactivity

**10.1. Reactivity:** None under normal conditions.

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 available for nanoscale cellulose.

**10.2. Chemical stability:** Stable under normal conditions of use.

**10.3. Possibility of hazardous reactions:** None known. Hazardous polymerization will not occur.

**10.4. Conditions to avoid:** Avoid ignition sources.

**10.5. Incompatible materials:** Oxidizing agents, strong.

**10.6. Hazardous decomposition products:** None known.

## SECTION 11: Toxicological information

*NOTE: where available, data reported for CNF. Where not, rely on studies with cellulose.*

**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**

	<b>CNF (Nanocellulose)</b>	<b>Cellulose</b>
<b>Inhalation</b>	Data are limited; dust may be harmful if inhaled. A study in mice reported acute immune response in the lung following exposure to CNF, however also potential exposure to biocide (Vartiainen 2011).	May be harmful if inhaled. An <i>in vivo</i> 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).
<b>Ingestion</b>	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).
<b>Dermal contact</b>	No data available.	One study reported no dermal irritation after acute exposure up to 2000 mg/kg of microcrystalline cellulose (WHO 1998).
<b>Eye contact</b>	No data available.	One study with MCC reported minimal irritation after acute ocular instillation in rabbit (WHO 1998).

**LONG TERM EXPOSURE**

	<b>CNF (Nanocellulose)</b>	<b>Cellulose</b>
<b>Inhalation</b>	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).
<b>Ingestion</b>	No data available.	No adverse effects in rats consuming a 30% MCC diet for 72 days (unpublished report, WHO 1998). 0-20% cellulose diet 4 weeks in rat - no death nor growth effects (Hove 1978). 5, 10, 20% cellulose diet 21-days in rats - no death (Sundaravelli 1971). 10% MCC fed to rats for 35 weeks - no effects (Lupton 1988).
<b>Dermal contact</b>	No data available.	No data available.
<b>Eye contact</b>	No data available.	No data available.

### 11.1.3 Other measures of toxicity

	<b>CNF (Nanocellulose)</b>	<b>Cellulose</b>
<b>Immunotoxicity</b>	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).
<b>Neurotoxicity</b>	No data available.	No data available.
<b>Genotoxicity</b>	Highest tolerated dose >240 mg/L in bacterial Ames test; no mutagenicity (Pitkänen 2010). After pharyngeal aspiration of 200 µg/mouse, no effects after 24h nor 28d on marrow polychromatic erythrocytes (as determined by micronucleus assay) (Aimonen 2015). <i>in vitro</i> Beas2B human bronchial epithelial cells: no DNA strand breakage (>950 mg/L) nor chromosomal damage (1250 mg/L) Lindberg (2014)	Highest tolerated dose >2000 mg/L in bacterial Ames test (OECD 471); no mutagenicity (Pitkänen 2010). <i>in vitro</i> Beas2B human bronchial epithelial cells: no DNA strand breakage (>950 mg/L) nor chromosomal damage (1250 mg/L) (Lindberg 2014). <i>in vitro</i> BEAS2B human bronchial epithelial cells (48h) - no micronucleus induction >100 mg/L (Catalán 2014).
<b>Carcinogenicity</b>	No data available.	Rats fed a 30% MCC diet for 72 weeks - no increase in tumorigenicity (unpublished report, WHO 1998).
<b>Reproductive toxicity</b>	No egg-laying effects in nematodes ( <i>C.elegans</i> ) up to 500 mg/L (Pitkänen 2014).	Rats fed MCC a 30% MCC diet for 72 weeks – no adverse reproductive effects (WHO 1998).
<b>Biodurability/ Biopersistence</b>	CNF (both TEMPO and homogenized) in artificial airway epithelial lining fluid using serum ultrafiltrate) did not degrade (as evidenced by unchanged crystalline structure) over 7 days (Stefaniak 2014).	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

### 12.1 Toxicity

#### Acute data

Zebrafish embryo	CNF-TEMPO (Forest Products Laboratory)	LOEC = ~ 2000 mg/L	Harper et al. 2015 (in press)
	CNF-homogenization (Forest Products Laboratory)	LOEC = 200 mg/L	Harper et al. 2015
	CNF-homogenization (Maine Pilot Plant)	No mortality up to 2000 mg/L	Harper et al. 2015
Bacteria ( <i>V. fischeri</i> )	1250 mg/L CNF (mechanically produced)	9% fluorescence inhibition ocular instillation in rabbit (WHO 1998).	Vartiainen et al. 2011
Algae ( <i>C. vulgaris</i> )	1-100 mg/L CNF (chemically produced)	Decreased viability after 96h	Pereira et al. 2014

### Chronic data

No data for CNF.

<b>12.2 Persistence and biodegradability</b>	No data for CNF. 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 (Vikman et al. 2014). 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).
<b>12.3 Bioaccumulative potential</b>	No data available.
<b>12.4 Mobility in soil</b>	No data available.
<b>12.5 PBT and vPvB assessment</b>	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
<b>12.6 Other adverse effects</b>	No data available.

## SECTION 13: Disposal considerations

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

**14.1 UN number:** None

**14.2 UN proper shipping name:** Not applicable

**14.3 Transport hazard class:** Not applicable

**14.4 Packing group:** Not applicable

**14.5 Environmental hazards:** Not classified as hazardous to the environment

**14.6 Special precautions for user:** No additional information available

**14.7 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

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

None for CNF. For related substances, **OSHA regulations:** See Section 8.

**15.1.1. EU-Regulations**

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Directive 2012/18/EU (SEVESO III)

**15.2 Chemical safety assessment:** No chemical safety assessment has been carried out for this substance by the supplier. This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

## SECTION 16: Other information

### Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
OECD	Organisation for Economic Co-operation and Development
NOEC	No-Observed Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LD50	Median lethal dose
LC50	Median lethal concentration
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
EC50	Median effective concentration
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
BCF	Bioconcentration factor
ATE	Acute Toxicity Estimate
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
PNEC	Predicted No-Effect Concentration
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
DNEL	Derived-No Effect Level

Other information: This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product. It is the user's responsibility to take mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product

SDS EU (REACH Annex II)

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