

SAFETY DATA SHEET

acc. to Regulation (EC) No. 1907/2006

1. Identification of the substance or mixture and of the company

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 The information provided is based on the best available published and unpublished data for similar substances, as listed below.

Product identifier

Product name:	Re:ancel T-CNF Hydrogel
Product Description:	TEMPO-mediated oxidized, cellulose nanofibrils 2% in free water
Other common names or synonyms:	TEMPO cellulose nanofibrils (T-CNF), cellulose nanofibrils, microfibrillated cellulose, nanofibrils, microfibrils, nanofibrillated cellulose, cellulose nanofibers
REACH no.:	Not available
CAS no:	Cellulose (9004-34-6) (manufactured nanofibrillar form)
EC No:	Cellulose (232-674-9)
UFI Code:	Not available

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

Relevant identified uses:	Other (Feed materials, Intermediates)
Uses advised against:	For industrial and professional users

Details of the Supplier of the Safety Data Sheet

Company:	ANPOLY Inc.
Address:	66, Yunghapgisul-ro, Heunghae-eup, Buk-gu, Pohang-si, Gyeongsangbuk-do, 37563, Republic of Korea
Phone number:	+82-054-262-0222
Email:	info@anpolyinc.com
Homepage:	www.anpolyinc.com

Emergency phone number

Republic of Korea	+82-054-262-0222
International	Call your national poison center, or a doctor/physician

2. Hazard identification

Classification of the substance or mixture

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

Physical-chemical Hazards:	Not classified
Health Hazard:	Not classified
Environmental Hazard:	Not classified

Additional information: For full text of Hazard- and EU Hazard-statements: see SECTION 16

Label elements

Classification according to Regulation (EC) No. 1272/2008 [CLP]	
Hazard pictogram:	Not applicable
Signal word:	Not applicable
Hazard statements:	Not applicable
Precautionary statements:	<i>Prevention</i> - Not applicable <i>Response</i> - Not applicable <i>Storage</i> - Not applicable <i>Disposal</i> - Not applicable
Supplemental Hazard information (EU):	Not applicable
NFPA rating:	Health: 0 Fire: 0 Reactivity: 0

Other Hazards: Not available

According to Annex XIII, the substance does not meet PBT or vPvB criteria.
According to Regulation (EU) 2017/2100 and 2018/605, the substance does not affect to endocrine system.
The substance is not listed in Article 59
No other hazards have been identified

3. Composition/information on ingredients

Substances

Chemical name:	Cellulose
Other name:	TEMPO cellulose nanofibrils (T-CNF), cellulose nanofibrils, microfibrillated cellulose, nanofibrils, microfibrils, nanofibrillated cellulose, cellulose nanofibers
CAS-No.:	Cellulose (9004-34-6) (manufactured nanofibrillar form)
EC No:	Cellulose (232-674-9)
Composition:	Hydrogel – 2% CNF, 98% free water

4. Description of first aid measures

First aid measures

General Information :	Call 911 or emergency medical service.
Following inhalation:	- Move victim to fresh air if it can be done safely. - Give artificial respiration if victim is not breathing. - Administer oxygen if breathing is difficult.
Following skin contact:	- In case of contact with substance, immediately flush skin with running water for at least 20 minutes. - Remove and isolate contaminated clothing and shoes. - Wash contaminated clothing before reuse.
Following eye contact:	- In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. - Call 911 or emergency medical service.
Following ingestion:	- Never give anything by mouth to an unconscious person. - Seek medical attention.

Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms:	Not available
Potential acute health effects:	Not available

Indication of any immediate medical attention and special treatment needed

Note for the doctor:	Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves
Special treatment:	No specific treatment

5. Firefighting measures

Extinguishing media:	- Suitable extinguishing media : DRY sand, Dry chemical, Alcohol-resistant foam, Water spray, Regular foam , CO2 - Unsuitable extinguishing media : Not available
Special hazards arising from the substance or mixture:	- Containers may explode when heated. - May cause toxic effects if inhaled. - Vapors may cause dizziness or asphyxiation without warning. - May burn but does not ignite readily. - Fire may produce irritating and/or toxic gases. - Hazardous combustion products : Not available
Advice for fire fighters:	- Wear self-contained breathing apparatus for firefighting if necessary. - If it can be done safely, move undamaged containers away from the area around the fire. - Fire involving Tanks: Cool containers with flooding quantities of water until well after fire is out. - Fire involving Tanks: ALWAYS stay away from tanks engulfed in fire.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures:	For non-emergency personnel : All equipment used when handling the product must be ground. Keep unauthorized personnel away. 1) Protective equipment : Wear proper protective equipment and avoid contact with skin or inhalation of dust. 2) Emergency procedures : Evacuate personnel to safe areas. Ensure adequate ventilation. Use personal protective equipment.
Environmental precautions:	Prevent entry into waterways, sewers, basements or confined areas.
Methods and materials for containment and cleaning up:	For containment - With clean shovel place material into clean, dry container and cover loosely; move containers from spill area. - Small Spill: Absorb with earth, sand or other non-combustible material. For cleaning up - Remove residue with high-efficient cleaner - Flush area with large amounts of water. Other information : Wet down with water and dike for later disposal.
Reference to other sections:	- See Section 1 for emergency contact information. - See also sections 8 and 13 of the Safety Data Sheet.

7. Handling and storage

Precautions for safe handling:	Protective measures : Pay attention to incompatible materials and conditions. Advice on general occupational hygiene : - When using, do not eat, drink or smoke. - Wash thoroughly after handling.
Conditions for safe storage, including any compatibilities:	Store in refrigeration, well-ventilated area. Keep closed, tightly sealed containers to prevent evaporation of water and contamination 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.
Specific end use(s):	Recommendations : Avoid prolonged exposure. Wash thoroughly after handling.

8. Exposure controls/personal protection

Control parameters

Occupational exposure limits:	TWA - 10mg/m ³
Biological limit values:	Not applicable
Exposure limits at intended use:	Not applicable

Exposure controls

Appropriate engineering controls:	- Ensure adequate ventilation, especially in confined areas. - Ensure compliance with applicable exposure limits and operate local exhaust ventilation when working.
Personal protection equipment:	Eye and face protection - Tightly fitting safety goggles. - Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Skin protection - Hand protection : Handle with gloves. Gloves must be inspected prior to use. - Other skin protection : Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Respiratory protection - Wear positive pressure self-contained breathing apparatus (SCBA). - Wear suitable respiratory equipment in case of inadequate ventilation. Thermal hazards - Structural firefighters' protective clothing provides thermal protection but only limited chemical protection.
Environmental exposure controls:	- Substance/mixture related measures to prevent exposure : Prevent entry into waterways, sewers, basements or confined areas.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Gel, Optically transparent
Odor:	Odorless
Solids:	2 wt%
pH:	(25°C) 5 - 8
Conductivity:	(25°C) <3 mS/cm
Density	(25°C) 0.99 – 1.01 g/cm ³
Melting point/freezing point:	Not applicable
Initial boiling point and boiling range:	Not applicable
Flash point:	No data for Rheocellu T-CNF Hydrogel. Cellulose ca. 240 °C
Evaporation rate:	Not applicable
Flammability (solid, gas):	No data for Rheocellu T-CNF Hydrogel. Cellulose may be combustible at high temperature (240 °C)
Upper/lower flammability or explosive limits:	No data for Rheocellu T-CNF Hydrogel. Cellulose dust explosion class “St 2 – strong explosion”. Cellulose dust deflagration index K _{st} = 229. Note: nanomaterials may pose a greater explosion hazard than bulk material.
Vapor pressure/density:	Not applicable
Solubility(ies):	Insoluble in water; forms a gel
Partition coefficient: n-octanol/water:	Not applicable
Auto-ignition temperature:	No data for Rheocellu T-CNF Hydrogel. Cellulose may self-ignite at high temperatures (ca. 240 °C).
Decomposition temperature:	210 °C

10: Stability and reactivity

Reactivity:	This material is not reactive under normal ambient conditions.
Chemical stability:	Stable under normal temperatures and pressures.
Possibility of hazardous reactions:	- May cause toxic effects if inhaled. - Vapors may cause dizziness or asphyxiation without warning.
Conditions to avoid:	Ignition sources as heat, spark, flame, etc.
Incompatible materials:	Not available
Hazardous decomposition products:	Not available

11. Toxicological information

	CNF	Test Standard
Acute oral toxicity:	CNF(100%)’s acute oral toxicity result: - ALD >2,000 mg/kg Rat - GHS = ‘Category 5 or Unclassified’	ANPOLY tested OECD Guidelines for the Testing of Chemicals, Test No. 420: Acute Oral Toxicity - Fixed Dose Procedure
Acute dermal toxicity:	CNF(100%)’s acute dermal toxicity result: - ALD >2,000 mg/kg Rat - GHS = ‘Category 5 or Unclassified’	ANPOLY tested OECD Guidelines for the Testing of Chemicals, Test No. 402: Acute Dermal Toxicity
Skin sensitization:	CNF(100%)’s skin sensitization (by guinea pig) result: No sensitization with a final sensitization rate of 0%	ANPOLY tested ISO 10993-10 ‘Tests for irritation and skin sensitization’ (1 st August 2010) OECD Guideline for Testing of Chemicals No. 406 ‘Skin sensitization’ (17 th July 1992) Ministry Food and Drug Safety(Republic of Korea) Notice No. 2020-12 (25 th February, 2020) ‘Common Standards for Biological Safety of Medical Devices’
Intracutaneous(intradermal) reactivity:	CNF(100%)’s Intradermal reaction test (by rabbit) result: No intradermal reaction	ANPOLY tested ISO 10993-10 ‘Test for irritation and skin sensitization : ‘Animal intracutaneous(intradermal) reactivity test’ (1 st August 2010) Ministry Food and Drug Safety(Republic of Korea) Notice No. 2020-12 ((25 th February, 2020) ‘Common Standards for Biological Safety of Medical Devices’
Hemolyticity:	CNF(100%)’s Hemolytic test (by rabbit whole blood) result: Non hemolytic(Hemolysis index 0.02%)	ANPOLY tested ISO 10993-4 ‘Selection of tests for interactions with blood (April, 2017)’ ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials (01 st March 2017) Ministry Food and Drug Safety(Republic of Korea) Notice No. 2020-12 (25 th February, 2020) ‘Common Standards for Biological Safety of Medical Devices’
Pyrogenicity:	CNF(100%)’s Pyrogenicity test (by rabbit) result: No Pyrogenicity reaction to Material-mediated Pyrogen	ANPOLY tested ISO 10993-11 ‘Tests for systemic toxicity : Annex G Information in material-mediated pyrogens (September 2017)’ USP 43 NF 38 <151> Pyrogen Test (May 2020) Ministry Food and Drug Safety(Republic of Korea) Notice No. 2020-12 (25 th February, 2020) ‘Common Standards for Biological Safety of Medical Devices’

Genotoxicity:	Results of reversion mutation test of Cellulose Nanofiber using bacteria did not induce reversion	ANPOLY tested ISO 10993-3 Tests for genotoxicity : Bacterial reverse mutation test Ministry Food and Drug Safety (Republic of Korea) Notice No. 2020-12 (25th February, 2020) 'Common Standards for Biological Safety of Medical Devices'
Cytotoxicity:	CNF(100%)'s Cytotoxicity (by L-929 cell) result: No cytotoxicity with '0'	ANPOLY tested ISO 10993-5 'Tests for in vitro cytotoxicity' (01st Jun 2009)

12. Ecological information

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.

Toxicity

Data are for CNF produced by alternative processes except daphnia magna data. Surface properties/toxicology may be different for Rheocellu T-CNF Hydrogel.

Acute data

Daphnia magna	CNF-TEMPO(100% Foam)	EC50 >100 mg/L	ANPOLY tested ES 04704.1a (Test standard)
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 (<i>V. fischeri</i>)	1250 mg/L CNF (mechanically produced)	9% fluorescence inhibition	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 Rheocellu T-CNF Hydrogel. /other CNF.

Persistence and biodegradability	No data for Rheocellu T-CNF Hydrogel. 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).
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
PBT and vPvB assessment	No data available.
Other adverse effects	No data available.

13. Disposal considerations

Waste treatment methods

Product / Packaging disposal:	Waste codes / waste designations according to LoW : - Not classified as hazardous waste according to European Union regulations. - Dispose of contents/container to a facility in accordance with local and national regulations.
Waste treatment-relevant	- Waste must be disposed of in accordance with directive 2008/98/EC.

information:	- Waste must be disposed of in accordance with federal, state and local environmental control regulations
Sewage disposal-relevant information:	Release to the environment or sewage system is prohibited.
Other disposal recommendations:	Not available

14. Transport information

UN number or ID number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class:	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user:	Not applicable
Maritime transport in bulk according to IMO Instruments:	Not available

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

15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture:	<i>EU Regulation (EC) No. 1907/2006(REACH)/ Authorisations and/or restrictions on use :</i> -Authorisations(Annex XIV): Not applicable -Restrictions on use(Annex XVII): Not applicable <i>Other EU regulations:</i> EU - Seveso III Directive (2012/18/EU) - Qualifying Quantities of Dangerous Substances : Not applicable EU - Persistent Organic Pollutants (850/2004) : Not applicable EU - Paints, Varnishes, Vehicle Refinishing Products (2004/42/CE) – VOCs : Not applicable EU - Industrial Emissions (2010/75/EU) - Integrated Pollution Prevention and Control Directive – List of Polluting Substances : Not applicable EU - Fluorinated Gases (517/2014) - Global Warming Potential : Not applicable EU - Substances Depleting the Ozone layer (1005/2009) : Not applicable EU - Export and Import Restrictions (649/2012) - Chemicals and Articles Subject to Export Ban : Not applicable
Chemical safety assessment:	No chemical safety assessment has been carried out for this substance by the supplier.

16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Indication of changes / Date of issue:	- Date of issue : 03-07-2022 - Indication of changes : Rev. 0
Abbreviations and acronyms:	○ ECHA : European Chemicals Agency ○ EU CLP : EU Regulation 1272/2008 on the classification, labelling and packaging of chemicals and mixtures) ○ GLP : Good Laboratory Practice ○ EL50 : 50% Effect Loading dose ○ LC50 : Lethal Concentration 50% kill ○ LD50: Lethal Dose 50% kill ○ TWA : Time weight Average ○ EC Number = EINECS and ELINCS Number (see also EINECS and ELINCS) ○ EU = European Union

	○ SVHC = Substances of Very High Concern ○ vPvB = Very Persistent and Very Bioaccumulative
Key literature references and sources for data:	○ ACGIH ○ CAMEO Chemicals NOAA ○ ChemIDplus ○ ECHA ○ ECOSAR ○ Emergency response guide book ○ EPI Suite ○ HSDB ○ HPVIS ○ IARC ○ ICSC ○ INCHEM ○ IPCS ○ OECD SIDS ○ PubChem ○ Recommendations on the transport of dangerous goods ○ Single exposure oral administration toxicity test of cellulose nanofibers using rats. (GT 20-00169) ○ Single exposure dermal administration toxicity test of cellulose nanofibers using rats. (GT 20-00170) ○ Evaluation of acute toxic effects of cellulose nanofibers on daphnia (Test report no. NT20-00116K) ○ Bacterial reverse mutation assay of cellulose nanofiber (GM20-00763) ○ Cytotoxicity test of cellulose nanofibers using mouse fibroblasts(L-929) (Dissolution method) (GM20-00759) ○ Skin sensitization test of cellulose nanofibers using Hartley guinea pigs (GM20-00765)
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]: Not applicable	