
SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Date 16.08.2021

Version 2.0

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

TUNICELL DILUTION KIT +M SAFETY DATA SHEET

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

NOTE: *This Safety Data Sheet is for informational purposes only, and represents a preliminary assessment for a new pre-commercial substance that has not yet 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 The information provided is based on the best available published and unpublished data for similar substances, as listed below.*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 dilution kit +M including Endotoxin-Free Ultra-Pure Water (Medical grade) + 4.6% D-mannitol (Medical grade)
Product Description:	Sterilized, certified cell grade, pyrogen free (< 0.5 EU/mL), Bioburden free water (< 10 CFU/mL), Resistivity at 25 °C 18.2 MΩ·cm, TOC ≤ 5 ppb (µg/L, with Mannitol Osmolarity Calc≈:253 mOsm/L))
Brand:	TUNICELL
Catalogue no	Dilution kit + M
REACH no.:	A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration, or the registration is envisaged for a later registration deadline
CAS no:	7732-18-5 (Water); 69-65-8 (Mannitol)
EC No:	231-791-2 (water) Mannitol (200-711-8)

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

Relevant identified uses:	Biochemical and Biomedical research and analysis; 3D printing, 3D cell culture, tissue engineering and regenerative medicine. Particularly recommended for dilution of Ocean TuniCell products, preparation and dilution of hydrogels, extracellular matrix scaffolds, bioinks, biomedical devices, drug delivery. For research use only.
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's identification

2.1 Classification of the substance or mixture

This substance is not classified as dangerous according to European Union legislation.

2.2 Label elements Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

	Water	Mannitol
Formula	H ₂ O	C ₆ H ₁₄ O ₆
Molecular weight	18.02 g/mol	182.172 g/mol
Approximate % by Weight	95.4%	4.6%
CAS-No.	7732-18-5	69-65-8

SECTION 4. First aid measures

4.1 Description of first aid measures

General advice No hazards which require special first aid measures.

4.2 Most important symptoms and effects, both acute and delayed

We have no description of any toxic symptoms.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Firefighting measures

Extinguishing media <i>Suitable extinguishing media</i> <i>Unsuitable extinguishing media</i>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. For this substance/mixture no limitations of extinguishing agents are given.
Special hazards arising from the substance or mixture	Not combustible
Advice for firefighters <i>Special protective equipment for firefighters</i>	None
Further information	None

SECTION 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	None
Environmental precautions	No special precautionary measures necessary.
Methods and materials for containment and cleaning up	Observe possible material restrictions (see sections 7 and 10). Pour into drain.
Reference to other sections	Indications about waste treatment see section 13.

SECTION 7. Handling and storage

Precautions for safe handling	For precautions see section 2.2.
Conditions for safe storage, including any incompatibilities	Storage conditions: Tightly closed Recommended storage temperature: see product label
Specific end use(s)	Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Engineering measures	Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See section 7.
Personal protective equipment	Individual protection measures Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.
Eye /face protection	Not required

Skin protection	Not required
Respiratory protection	Respiratory protection not required
Control of environmental exposure	No special precautionary measures necessary

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance Form	: Liquid
Colour:	: Colourless
b) Odour	: Odourless
c) Odour Threshold	: Not applicable
d) pH at 20 °C	: Neutral
e) Osmolarity calc.	: ≈:253 mOsm/L
f) Melting point/freezing point	: 0.0 °C
g) Initial boiling point and boiling range	: 100.0 °C at 1.013 hPa
h) Flash point	: Not applicable
i) Evaporation rate	: No data available
j) Flammability (solid, gas)	: No data available
k) Upper/lower flammability or explosive limits	: Not applicable
l) Vapour pressure	: 23 hPa at 20 °C
m) Vapor density	: No data available
n) Relative density	: 1.000 g/cm ³ at 3.98 °C
o) Water solubility	: Completely miscible
p) Partition coefficient	: n-octanol/water log Pow: -0.467
q) Autoignition temperature	: Not applicable
r) Decomposition temperature	: Distillable in an undecomposed state at normal pressure
s) Viscosity dynamic	: 0.952 mPa.s at 20 °C
t) Explosive properties	: Not classified as explosive
u) Oxidizing properties	: None

9.2 Other data

- Ignition temperature	: Not applicable
- Minimum ignition energy	: Not applicable

SECTION 10. Stability and reactivity

Reactivity	No data available
Chemical stability	The product is chemically stable under standard ambient conditions (room temperature).
Possibility of hazardous reactions Violent reactions possible with:	The generally known reaction partners of water
Conditions to avoid	None
Incompatible materials	No information available
Hazardous decomposition products	Non

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity:	No data available
Acute inhalation toxicity:	No data available
Acute dermal toxicity:	No data available
Skin irritation:	No data available
Eye irritation:	No data available
Sensitisation:	No data available
Germ cell mutagenicity:	No data available
Carcinogenicity:	No data available
Reproductive toxicity:	No data available
Teratogenicity:	No data available
Specific target organ toxicity- single exposure:	No data available
Specific target organ toxicity - repeated exposure:	No data available
Aspiration hazard:	No data available

11.2 Further information

No toxic effects are to be expected when the product is handled appropriately.

SECTION 12. Ecological information

Toxicity:	No data available
Persistence and degradability:	No data available
Bioaccumulative potential:	Not applicable
Mobility in soil:	No data available
Results of PBT and vPvB assessment PBT/vPvB assessment:	Not available as chemical safety assessment not required/not conducted
12.6 Other adverse effects Additional ecological information	No ecological problems are to be expected when the product is handled and used with due care and attention

SECTION 13. Disposal considerations

Waste treatment methods

Taking into account local regulations the product may be disposed of as waste water after neutralization.

SECTION 14. Transport information

Not classified as dangerous in the meaning of transport regulations.

UN number: ADR/RID: - IMDG: - IATA: -	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 MARPOL/73/78 and the IBC code:	Not applicable

SECTION 15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture	This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006. National legislation -Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances: Not applicable
Chemical safety assessment	For this product a chemical safety assessment was not carried out.

SECTION 16. Other information

Disclaimer

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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Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at www.wikipedia.org.