

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
1.1 Product Identifiers

Product Name	Perfusion Fluid T1 10x5 mL
Cat. No.	P000034
1.2 Relevant identified uses of the substance or mixture and uses advised against.	The Perfusion Fluid is intended for single use, to act as a carrier inside the M Dialysis microdialysis catheters.

1.3 Details of the supplier of the safety data sheet

Company	M Dialysis AB, Hammarby Fabriksväg 43, SE-120 30, Stockholm, Sweden
Telephone	+46 (0) 8 470 10 20
Fax	N/A
E-mail Address	info@mdialysis.com
Website	www.mdialysis.com

1.4 Emergency Telephone Number

Emergency Phone No.	+46 (0) 8 470 10 20 (CET or CEST, English spoken, Mon - Fri. 09.00-17.00)
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SECTION 2. HAZARDS IDENTIFICATION
2.1 Classification of the substance or mixture

2.1.1 Regulation (EC) No. 1272/2008 (CLP)	Not a hazardous mixture according to Regulation (EC) No 1272/2008 (CLP)
2.1.2 Additional Information	Not applicable

2.2 Label Elements
Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Product Name	Perfusion Fluid T1 10x5 mL
Hazard Pictogram (s)	None assigned
Signal Word (s)	None assigned
Hazard Statement (s)	None assigned
Precautionary Statement (s)	None assigned
Supplemental Hazard information (EU)	None assigned

2.3 Other Hazards None determined

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS
3.1 Substances – Not applicable

3.2 Mixtures – Not applicable

EC Classification No. 1272/2008

Component Name	Hazardous Chemical	Concentration (% w/v)	CAS No.	REACH Reg. No.	Hazard Statement(s)
N/A	N/A	N/A	N/A	N/A	N/A

SECTION 4. FIRST AID MEASURES	
4.1 Description of first aid measures	
Inhalation	N/A
Skin Contact	N/A
Eye Contact	N/A
Ingestion	N/A
Self-protection of the first aider	N/A
4.2 Most important symptoms and effects, both acute and delayed	N/A
4.3 Indication of any immediate medical attention and special treatment needed	N/A

SECTION 5. FIREFIGHTING MEASURES	
5.1 Extinguishing media	N/A
5.2 Special hazards arising from the substance or mixture	N/A
5.3 Advice for firefighters	N/A

SECTION 6. ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	N/A
6.2 Environmental Precautions	N/A
6.3 Methods and materials for containment and cleaning up	N/A
6.4 Reference to other sections	N/A

SECTION 7. HANDLING AND STORAGE	
7.1 Precautions for safe handling	N/A
7.2 Conditions for safe storage, including any incompatibilities	N/A
7.3 Specific end use (s)	The Perfusion Fluid is intended for single use, to act as a carrier inside the M Dialysis microdialysis catheters.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION	
8.1 Control Parameters	N/A
8.2 Exposure Controls	
8.2.1 Appropriate engineering controls	N/A
8.2.2 Personal protective equipment	
Eye/Face Protection	N/A
Hand Protection	N/A
Skin Protection	N/A
Respiratory Protection	N/A
8.2.3 Environmental Exposure Controls	N/A

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES	
9.1 Information on basic physical and chemical properties	
Appearance	Liquid
Colour	Colourless
Odour	ODourless
Odour threshold (ppm)	Not determined
pH	Not determined
Melting point / Freezing point	Not determined
Initial boiling point and boiling range	Not determined
Flash point (°C)	> 200 °C
Evaporation rate	Not determined
Flammability (solid, gas)	Not determined
Upper/lower flammability or explosive limits	Not determined
Vapour pressure	Not determined
Vapour Density	Not determined
Relative Density	~ 1
Solubility(ies)	Water soluble
Partition coefficient: (n-octanol/water)	Not determined
Auto ignition temperature (°C)	Not determined
Decomposition temperature (°C)	Not determined
Viscosity (mPa.s)	Not determined
Explosive properties	Not determined
Oxidising properties	Not determined
9.2 Other information	None

SECTION 10. STABILITY AND REACTIVITY	
10.1 Reactivity	Not determined
10.2 Chemical Stability	Stable
10.3 Possibility of hazardous reactions	N/A
10.4 Conditions to avoid	N/A
10.5 Incompatible materials	N/A
10.6 Hazardous decomposition products	Will not occur

SECTION 11. TOXICOLOGICAL INFORMATION
11.1 Information on toxicological effects

<u>Acute toxicity</u>	
Ingestion	N/A
Inhalation	N/A
Skin Contact	N/A
Eye Contact	N/A
Skin corrosion/irritation	N/A
Serious eye damage/eye irritation	N/A
Respiratory or skin sensitization	N/A
Germ cell mutagenicity	N/A
Carcinogenicity	N/A
Reproductive toxicity	N/A
Summary of evaluation of the CMR properties	N/A
STOT – Single exposure	N/A
STOT- Repeated exposure	N/A
Aspiration hazard	N/A
11.2 Other information	

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity	N/A
12.2 Persistence and degradability	N/A
12.3 Bioaccumulative potential	N/A
12.4 Mobility in soil	N/A
12.5 Results of PBT and vPvB assessment	N/A
12.6 Other adverse effects	None
12.7 Additional information	N/A

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods	N/A
13.2 Additional Information	None

SECTION 14. TRANSPORT INFORMATION

14.1 UN Number	Not classified as hazardous for transport
14.2 UN Proper Shipping Name	Not determined
14.3 Transport hazard class (es)	N/A
14.4 Packing Group	N/A
14.5 Environmental Hazards	Not determined
14.6 Special Precautions for User	N/A
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/A

SECTION 15. REGULATORY INFORMATION

This safety data sheet complies with the requirements of Regulation (EU) 2015/830

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

Not determined

15.2 Chemical Safety Assessments

A CSA has not been carried out

SECTION 16. OTHER INFORMATION

Text of Hazard Statements in Section 3

N/A

The information provided herein is believed to be correct as of the date hereof but does not purport to be all-inclusive and shall be used only as a guide. The information present in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. The recipient of our products is responsible for observing any National Laws and guidelines applicable.