

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING	
1.1 Product Identifiers	
Product Name	Reagent Urea 5x6 mL
Cat. No.	P000026
1.2 Relevant identified uses of the substance or mixture and uses advised against.	For <i>in vitro</i> diagnostic use Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice.
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)

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	Reagent Urea 5x6 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	The buffer contains <0.1% sodium azide. Avoid ingestion or contact with skin or mucous membranes. Sodium azide reacts with lead or copper plumbing to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS					
3.1 Substances – Not applicable					
3.2 Mixtures					
EC Classification No. 1272/2008					
Component Name	Hazardous Chemical	Concentration (% w/v)	CAS No.	REACH Reg. No.	Hazard Statement(s)
Urea Buffer	Sodium Azide	0 – 0.1%	26628-22-8	Not Applicable	EUH032, Acute Tox. 2: H300+H310+H330, STOT RE 2: H373, Aquatic Acute 1: H400, Aquatic Chronic 1: H410
Urea (Fast) Enzyme Reagent	None	Not applicable	Not applicable	Not applicable	Not applicable

SECTION 4. FIRST AID MEASURES	
4.1 Description of first aid measures	
Inhalation	If inhaled, move victim to fresh air, rest and maintain a half-upright position. Use artificial respiration if necessary. Immediately seek medical attention.
Skin Contact	If skin contact occurs, remove contaminated clothes, rinse skin with plenty of cold water or shower. Seek medical attention.
Eye Contact	If eye contact occurs, first rinse with plenty of cold water for several minutes, then immediately seek medical attention.
Ingestion	If ingested, rinse mouth. Do not induce vomiting. Give plenty of water to drink. Immediately seek medical attention.
Self-protection of the first aider	Wear appropriate personal protective equipment (see section 8.2.2)
4.2 Most important symptoms and effects, both acute and delayed	Not determined
4.3 Indication of any immediate medical attention and special treatment needed	Call an internal person trained in First Aid if available or contact a physician.

SECTION 5. FIREFIGHTING MEASURES	
5.1 Extinguishing media	As appropriate for surrounding fire
5.2 Special hazards arising from the substance or mixture	May emit toxic fumes under fire conditions.
5.3 Advice for firefighters	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6. ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	Ensure adequate ventilation. Wear appropriate Personal Protective Equipment e.g. laboratory coat, gloves, safety glasses and mask.
6.2 Environmental Precautions	Not determined
6.3 Methods and materials for containment and cleaning up	Use appropriate spill absorbent kit as instructed by the manufacturer. Alternatively mop up with an absorbent material and hold for waste disposal.
6.4 Reference to other sections	Refer to Section 8 & 13

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling	Wear personal protective equipment (see section 8.2.2). Wash thoroughly after handling. Do not use if skin is cut or scratched. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when using this product.
7.2 Conditions for safe storage, including any incompatibilities	Store at temperatures and conditions as indicated on the product label.
7.3 Specific end use (s)	For <i>in vitro</i> diagnostic use

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters	Not determined
8.2 Exposure Controls	
8.2.1 Appropriate engineering controls	Ensure adequate ventilation.
8.2.2 Personal protective equipment	
Eye/Face Protection	Approved safety glasses
Hand Protection	Standard laboratory rubber or latex gloves
Skin Protection	A laboratory coat is recommended
Respiratory Protection	Not required
8.2.3 Environmental Exposure Controls	Not determined

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties	
Appearance	Urea Buffer - Liquid Urea (Fast) Enzyme Reagent - Liquid
Colour	Urea Buffer - Colourless Urea (Fast) Enzyme Reagent - Pink
Odour	Not determined
Odour threshold (ppm)	Not determined
pH	7.6 (Urea Buffer) 7.8 (Urea (Fast) Enzyme Reagent)
Melting point / Freezing point	Not determined
Initial boiling point and boiling range	Liquid phase 100 °C
Flash point (°C)	Not determined
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	Not determined
Solubility(ies)	Not determined
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	Not determined

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity	Not determined
10.2 Chemical Stability	Stable under recommended storage conditions
10.3 Possibility of hazardous reactions	Not determined
10.4 Conditions to avoid	Not determined
10.5 Incompatible materials	Not determined
10.6 Hazardous decomposition products	Not determined

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects	
<u>Acute toxicity</u>	Not determined
Ingestion	Not determined
Inhalation	Not determined
Skin Contact	Not determined
Eye Contact	Not determined
Skin corrosion/irritation	Not determined
Serious eye damage/eye irritation	Not determined
Respiratory or skin sensitization	Not determined
Germ cell mutagenicity	Not determined
Carcinogenicity	Not determined
Reproductive toxicity	Not determined
Summary of evaluation of the CMR properties	Not determined
STOT – Single exposure	Not determined
STOT- Repeated exposure	Not determined
Aspiration hazard	Not determined
11.2 Other information	Not determined

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity	Not determined
12.2 Persistence and degradability	Not determined
12.3 Bioaccumulative potential	Not determined
12.4 Mobility in soil	Not determined
12.5 Results of PBT and vPvB assessment	Not determined
12.6 Other adverse effects	Not determined
12.7 Additional information	Not determined

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods	Each disposal facility must determine proper disposal methods of the substance or mixture and any contaminated packaging to comply with Local and National Environment Regulations. Refer to section 6.
13.2 Additional Information	Not determined

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)	Not applicable
14.4 Packing Group	Not applicable
14.5 Environmental Hazards	Not determined
14.6 Special Precautions for User	Refer to section 7
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

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

EUH032 – Contact with acids liberates very toxic gas
 Acute Tox. 2: H300+H310+H330 – Fatal if swallowed, in contact with skin or if inhaled
 STOT RE 2: H373 – May cause damage to organs through prolonged or repeated exposure
 Aquatic Acute 1: H400 – Very toxic to aquatic life
 Aquatic Chronic 1: H410 – Very toxic to aquatic life with long lasting effects

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 regards to appropriate safety precautions. The recipient of our products is responsible for observing any National Laws and guidelines applicable.