

MATERIAL SAFETY DATA SHEET

Celsior®

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1. Product and Company Identification

Product Name: Celsior®

Synonym(s): Cold Storage Solution

Product Use: Celsior® is intended for flushing and cold storage of organs at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.

Description: Celsior® is a clear to slightly yellow, sterile, non-pyrogenic, extracellular solution. The solution is slightly acidic, slightly hypertonic with low viscosity, and has a high buffering capacity.

Manufactured for:

WATERS MEDICAL SYSTEMS LLC.
2112 15th Street NW Phone: 1-507-288-7777
Rochester, MN 55901 Fax: 1-507-252-3700 fax
UNITED STATES Email: info@wtrs.com

2. Hazards identification

Emergency Overview:

The chemical, physical and toxicological properties of this preparation, pertaining directly to occupational exposures, have not been thoroughly characterized.

Precautionary Statements:

Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear to slightly yellow solution.

Routes of Exposure:

Typical occupational exposure routes are eye and skin contact.

Potential Health Effects:

- **Inhalation:** Inhalation is not an expected route of exposure during normal use and is unlikely to produce adverse health effects.
- **Eye:** Eye exposure is not expected to cause irritation.
- **Skin:** Skin contact is not expected to cause irritation.
- **Ingestion:** Effects of ingestion are unknown, but may include digestive system irritation nausea,

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vomiting or diarrhea.

- **Chronic Effects:** Chronic effects are not expected based on the concentration of components in this preparation.
- **Target Organs:** None expected.

Regulatory Status:

This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIPS 2002 No. 1689; or U.N. GHS ST/SG/AC10/30.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

3. Composition / Information on Ingredients

| Ingredient Name | EC R-Phrases | CAS # | EC Hazard Class | EC # | % (w/w) |
|--------------------|--------------|------------|-----------------|-----------|---------|
| Sterile water | None | 7732-18-5 | None | 231-791-2 | > 99 |
| Lactobionic acid | None | 96-82-2 | None | 202-538-3 | < 0.1 |
| D-Mannitol | None | 69-65-8 | None | 200-711-8 | < 0.1 |
| Histidine | None | 71-00-1 | None | 200-745-3 | < 0.01 |
| Sodium hydroxide | R35 | 1310-73-2 | C | 215-185-5 | < 0.01 |
| Glutamic acid | None | 56-86-0 | None | 200-293-7 | < 0.01 |
| Magnesium chloride | R15, R17 | 7786-30-3 | F | 232-094-6 | < 0.01 |
| Potassium chloride | R36 | 7447-40-7 | Xi | 231-211-8 | < 0.01 |
| Glutathione | None | 70-18-8 | None | 200-725-4 | < 0.01 |
| Calcium chloride | R36 | 10043-52-4 | Xi | 233-140-8 | < 0.01 |

4. First Aids Measures

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Immediately flush eyes with plenty of tepid water while separating eyelids with fingers, removing contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation

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persist.

Skin Contact:

Wash material from skin with soap and water and rinse thoroughly with clean water. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, drink 4 to 8 ounces (120 to 240 mL) of water to dilute. Seek medical attention if symptoms of digestive irritation or discomfort occur.

5. Fire Fighting Measures

Flammable Properties:

Aqueous solutions with these components are typically non-flammable.

Suitable Extinguishing Media:

Carbon dioxide, chemical foam, dry chemical or water spray.

Specific Hazards Arising from the Chemical:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

As in any fire, firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. Accidental Release Measures

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Methods and Materials for Containment and Clean-Up:

Carefully soak up spill with paper towels or a non-combustible absorbent material. After material pickup is complete, wash spill site to remove any residual material and dry completely. Dispose of spilled material and contaminated waste in accordance with all applicable federal, state, local and provincial

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environmental regulations, per Section XIII.

7. Handling and Storage

Handling:

Follow good laboratory hygiene practices. Wear proper Personal Protective Equipment (PPE) and employ exposure controls as indicated in Section 8. Avoid physical contact. Wash hands thoroughly after handling.

Storage:

Refer to product label and/or literature for specific storage conditions. The recommended storage temperature(s) at the time of MSDS preparation/revision is: Store product at refrigerated temperatures 2° - 8°C (36° - 46°F) until use. Avoid excessive heat. Do not freeze. Do not store with incompatible substances or under avoidable conditions identified in Section X.

8. Exposure Controls / Personal Protection

Exposure Guidelines:

ACGIH - Occupational Exposure Limits - Ceilings

Sodium hydroxide 1310-73-2 2 mg/m³ Ceiling

ACGIH - Occupational Exposure Limits - TLV Basis - Critical Effects

Sodium hydroxide 1310-73-2 irritation

Belgium - Occupational Exposure Limits - STELs

Sodium hydroxide 1310-73-2 2 mg/m³ VLE

Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium hydroxide 1310-73-2 2 mg/m³ Ceiling

Denmark - Occupational Exposure Limits - Ceilings

Sodium hydroxide 1310-73-2 2 mg/m³ Ceiling

France - Occupational Exposure Limits - TWAs (VMEs)

Sodium hydroxide 1310-73-2 2 mg/m³ VME

Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium hydroxide 1310-73-2 2 mg/m³ TWA (inhalable fraction)

Greece - Occupational Exposure Limits - STELs

Sodium hydroxide 1310-73-2 2 mg/m³ STEL

Greece - Occupational Exposure Limits - TWAs

Sodium hydroxide 1310-73-2 2 mg/m³ TWA

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Ireland - Occupational Exposure Limits - STELs

Sodium hydroxide 1310-73-2 2 mg/m³ STEL

Japan - Recommended Exposure Limits - Ceiling Limits

Sodium hydroxide 1310-73-2 2 mg/m³ Ceiling

Korea - Occupational Exposure Limits - Ceilings

Sodium hydroxide 1310-73-2 2 mg/m³ Ceiling

Netherlands - Occupational Exposure Limits - Ceilings

Sodium hydroxide 1310-73-2 2 mg/m³ Ceiling

NIOSH - Pocket Guide - Ceiling Limits

Sodium hydroxide 1310-73-2 2 mg/m³ Ceiling

NIOSH - Pocket Guide - IDLHs (Immediately Dangerous to Life or Health)

Sodium hydroxide 1310-73-2 10 mg/m³

IDLH Norway - Occupational Exposure Limits - Ceilings

Sodium hydroxide 1310-73-2 2 mg/m³ Ceiling

OSHA - Final PELs - Time Weighted Averages (TWAs)

Sodium hydroxide 1310-73-2 2 mg/m³ TWA

Spain - Occupational Exposure Limits - STELs (VLA-EC)

Sodium hydroxide 1310-73-2 2 mg/m³ VLA-EC

Sweden - Occupational Exposure Limits - Ceilings (CLVs)

Sodium hydroxide 1310-73-2 2 mg/m³ Ceiling

Switzerland - Occupational Exposure Limits - STELs

Sodium hydroxide 1310-73-2 2 mg/m³ STEL (inhalable)

Switzerland - Occupational Exposure Limits - TWAs

Sodium hydroxide 1310-73-2 2 mg/m³ MAK (inhalable)

Engineering Controls:

This preparation is aqueous and non-volatile and is not expected to necessitate special ventilation measures. Facilities storing or utilizing this preparation should be equipped with an eyewash fountain and a safety shower.

Personal Protective Equipment (PPE):

- **Respiratory:** A respirator is not required under normal conditions of use.
- **Eye/Face:** If splashes are likely to occur, wear appropriate protective safety eye wear as described in the ANSI standard 787.1-2003.
- **Skin:** Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over your clothes, to minimize contact and contamination of clothing.
- **Gloves:** Prevent skin exposure by wearing protective gloves impermeable to this

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material/preparation. Nitrile gloves are recommended for incidental handling

Personal Protective Equipment (PPE):

- **General:** Consult your company's safety manager/industrial hygienist or your safety equipment manufacturer/supplier for assistance with your selection of appropriate PPE

9. Physical and Chemical Properties

Appearance: Clear to slightly yellow solution

Odor: Unknown

Specific Gravity: Not available

Boiling Point: 100 - 105 °C (212 - 221 °F) @ 760 mm Hg (approx.; that of water)

Melting Point: Not applicable

Freezing Point: -1 - 0 °C (30.2 - 32 °F) (approx.; that of water)

Viscosity: 1.15 cST

pH: 7.20 - 7.40 (@ 20°C)

Solubility: Water-soluble

Vapor Pressure: 24 mm Hg @ 25°C (approx.; that of water)

Partition Coefficient (n-octanol/water): Not available

Vapor Density: 23 g/m³ @ 25°C (approx.; that of water)

10. Stability and Reactivity

Chemical Stability:

Stable under ordinary conditions of use and storage; (see handling and storage information in Section 7).

Conditions to Avoid:

Excessive heat and freezing temperatures may damage the product.

Incompatible Materials:

Unknown.

Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

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Hazardous polymerization will not occur.

11. Toxicological Information

Acute Effects:

Acute effects are not expected based on the concentration of components in this preparation.

NIOSH - Selected LD50s and LC50s

| | | |
|--------------------|------------|--|
| Calcium chloride | 10043-52-4 | Oral LD50 Rat: 1 g/kg; Oral LD50 Mouse: 1940 mg/kg |
| D-Mannitol | 69-65-8 | Oral LD50 Rat: 13500 mg/kg; Oral LD50 Mouse: 22 g/kg |
| Glutamic acid | 56-86-0 | Oral LD50 Rat: >30 g/kg |
| Glutathione | 70-18-8 | Oral LD50 Mouse: 5 g/kg |
| Histidine | 71-00-1 | Oral LD50 Rat: >15 g/kg; Oral LD50 Mouse: >15 g/kg |
| Magnesium chloride | 7786-30-3 | Oral LD50 Rat: 2800 mg/kg; Oral LD50 Mouse: 4700 mg/kg |
| Potassium chloride | 7447-40-7 | Oral LD50 Rat: 2600 mg/kg; Oral LD50 Mouse: 1500 mg/kg |

Chronic Effects:

Chronic effects are not expected based on the concentration of components in this preparation

12. Ecological Information

Ecotoxicity:

No information available for product

13. Disposal Considerations

Methods of Disposal:

Unused, expired, and waste product, as well as contaminated waste, should be disposed of as with any other prescription pharmaceutical product. Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Packaging:

Containers of this material may retain product residues. Handle contaminated packaging in the same way as the substance itself and dispose according to instructions. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

Waste Classification:

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Chemical waste generators must refer to the relevant hazardous waste regulations to ensure complete and accurate classification. Disposal regulations may vary according to geographic location.

14. Transport Information

Basic Shipping Description:

Not classified as dangerous goods at the time of MSDS preparation. Not regulated per IATA and DOT regulations.

15. Regulatory Information

US Federal Regulations:

This preparation is an FDA-regulated material or medical device

CERCLA/SARA - Hazardous Substances and their Reportable Quantities

| | | |
|------------------|-----------|------------------------------------|
| Sodium hydroxide | 1310-73-2 | 1000 lb. final RQ; 454 kg final RQ |
|------------------|-----------|------------------------------------|

CWA (Clean Water Act) - Reportable Quantities of Designated Hazardous Substances

| | | |
|------------------|-----------|--------------|
| Sodium hydroxide | 1310-73-2 | 1,000 lb. RQ |
|------------------|-----------|--------------|

Inventory - United States - Section 8(b) Inventory (TSCA)

| | | |
|--------------------|------------|---------|
| Calcium chloride | 10043-52-4 | XU |
| D-Mannitol | 69-65-8 | Present |
| Glutamic acid | 56-86-0 | Present |
| Glutathione | 70-18-8 | Present |
| Histidine | 71-00-1 | Present |
| Magnesium chloride | 7786-30-3 | XU |
| Potassium chloride | 7447-40-7 | XU |
| Sodium hydroxide | 1310-73-2 | XU |

US State Regulations:

California - Directors List of Hazardous Substances (8 CCR 339)

| | | |
|--------------------|-----------|-----------|
| Magnesium chloride | 7786-30-3 | [present] |
| Sodium hydroxide | 1310-73-2 | Present |

Massachusetts - Right To Know List

| | | |
|--------------------|-----------|-----------|
| Magnesium chloride | 7786-30-3 | [present] |
| Sodium hydroxide | 1310-73-2 | Present |

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Massachusetts - Toxics Use Reduction Act

Sodium hydroxide 1310-73-2 CERCLA Only chemical

New Jersey - Department of Health RTK List

Magnesium chloride 7786-30-3 sn 1136

Sodium hydroxide 1310-73-2 sn 1706

Pennsylvania - RTK (Right to Know) List

Magnesium chloride 7786-30-3 [present]

Sodium hydroxide 1310-73-2 Environmental hazard

International Regulations:

This preparation is intended for use as a medicinal device. If approved for use in the EU it is regulated under the Medical Devices Directive (93/42/EC) and is exempt from classification under the Dangerous Substances Directive (67/548/EC).

Canada - WHMIS - Classifications of Substances

Calcium chloride 10043-52-4 D2B

D-Mannitol 69-65-8 (Uncontrolled product according to WHMIS classification criteria)

Glutamic acid 56-86-0 (Uncontrolled product according to WHMIS classification criteria)

Glutathione 70-18-8 D2A

Histidine 71-00-1 (Uncontrolled product according to WHMIS classification criteria)

Magnesium chloride 7786-30-3 (Uncontrolled product according to WHMIS classification criteria)

Potassium chloride 7447-40-7 (Uncontrolled product according to WHMIS classification criteria)

Sodium hydroxide 1310-73-2 E

Canada - WHMIS - Ingredient Disclosure List

Sodium hydroxide 1310-73-2 1 % (English Item 1442, French Item 998)

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Calcium chloride 10043-52-4 Xi; R-36

Magnesium chloride 7786-30-3 F; R-15 R-17

Sodium hydroxide 1310-73-2 C; R-35

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Concentration Limits

Sodium hydroxide 1310-73-2 5%; C; R-35< 2%; C; R-34< 0.5%; Xi; R-36/38

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Calcium chloride 10043-52-4 S-2 S-22 S-24

Magnesium chloride 7786-30-3 S-2 S-7/8 S-43

Sodium hydroxide 1310-73-2 S-1/2 S-26 S-37/39 S-45

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Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

| | | |
|--------------------|------------|--|
| Calcium chloride | 10043-52-4 | hazard class 1, low hazard to waters (footnote 14) |
| Magnesium chloride | 7786-30-3 | hazard class 1, low hazard to waters (footnote 14) |
| Potassium chloride | 7447-40-7 | hazard class 1, low hazard to waters |
| Sodium hydroxide | 1310-73-2 | hazard class 1, low hazard to waters (footnote 8) |

Inventory - Australia - Inventory of Chemical Substances (AICS)

| | | |
|--------------------|------------|---------|
| Calcium chloride | 10043-52-4 | Present |
| D-Mannitol | 69-65-8 | Present |
| Glutamic acid | 56-86-0 | Present |
| Glutathione | 70-18-8 | Present |
| Histidine | 71-00-1 | Present |
| Magnesium chloride | 7786-30-3 | Present |
| Potassium chloride | 7447-40-7 | Present |
| Sodium hydroxide | 1310-73-2 | Present |

Inventory - Canada - Domestic Substances List (DSL)

| | | |
|--------------------|------------|---------|
| Calcium chloride | 10043-52-4 | Present |
| D-Mannitol | 69-65-8 | Present |
| Glutamic acid | 56-86-0 | Present |
| Glutathione | 70-18-8 | Present |
| Histidine | 71-00-1 | Present |
| Magnesium chloride | 7786-30-3 | Present |
| Potassium chloride | 7447-40-7 | Present |
| Sodium hydroxide | 1310-73-2 | Present |

Inventory - China

| | | |
|------------------|------------|---------|
| Calcium chloride | 10043-52-4 | Present |
| D-Mannitol | 69-65-8 | Present |
| Glutamic acid | 56-86-0 | Present |
| Glutathione | 70-18-8 | Present |

Inventory - China

| | | |
|--------------------|-----------|---------|
| Histidine | 71-00-1 | Present |
| Magnesium chloride | 7786-30-3 | Present |
| Potassium chloride | 7447-40-7 | Present |
| Sodium hydroxide | 1310-73-2 | Present |

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

| | | |
|------------------|------------|-----------|
| Calcium chloride | 10043-52-4 | 233-140-8 |
| D-Mannitol | 69-65-8 | 200-711-8 |

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| | | |
|--------------------|-----------|-----------|
| Glutamic acid | 56-86-0 | 200-293-7 |
| Glutathione | 70-18-8 | 200-725-4 |
| Histidine | 71-00-1 | 200-745-3 |
| Lactobionic acid | 96-82-2 | 202-538-3 |
| Magnesium chloride | 7786-30-3 | 232-094-6 |
| Potassium chloride | 7447-40-7 | 231-211-8 |
| Sodium hydroxide | 1310-73-2 | 215-185-5 |

Inventory - Japan Existing and New Chemical Substances (ENCS)

| | | |
|--------------------|------------|---------------|
| Calcium chloride | 10043-52-4 | 1-176 |
| D-Mannitol | 69-65-8 | 8-49; 9-1375 |
| Glutamic acid | 56-86-0 | 9-1573 |
| Glutathione | 70-18-8 | 9-404; 9-1571 |
| Histidine | 71-00-1 | 9-1607 |
| Magnesium chloride | 7786-30-3 | 1-233; 1-244 |
| Potassium chloride | 7447-40-7 | 1-228 |
| Sodium hydroxide | 1310-73-2 | 1-410; 2-1972 |

Inventory - Korea - Existing and Evaluated Chemical Substances

| | | |
|--------------------|------------|----------|
| Calcium chloride | 10043-52-4 | KE-04496 |
| D-Mannitol | 69-65-8 | KE-23061 |
| Glutamic acid | 56-86-0 | KE-01563 |
| Glutathione | 70-18-8 | KE-17781 |
| Histidine | 71-00-1 | KE-19948 |
| Lactobionic acid | 96-82-2 | KE-17413 |
| Magnesium chloride | 7786-30-3 | KE-22691 |
| Potassium chloride | 7447-40-7 | KE-29086 |
| Sodium hydroxide | 1310-73-2 | KE-31487 |

Switzerland - Toxic Substances Classification

| | | |
|--------------------|-----------|--|
| Magnesium chloride | 7786-30-3 | Giftklasse 4 |
| Potassium chloride | 7447-40-7 | Class 5 |
| Sodium hydroxide | 1310-73-2 | Class 2 (>5%, G-4490); Class 3 (1-5%, G-4491); Class 4 (<1%, G-4492) |

Canadian Hazardous Products:

- WHMIS Status: Exempt

European Communities Dangerous Substances/Preparations:

- EC Hazard Class: Exempt

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- Risk Phrases: None
- Safety Phrases: None

16. Other Information

Further Information:

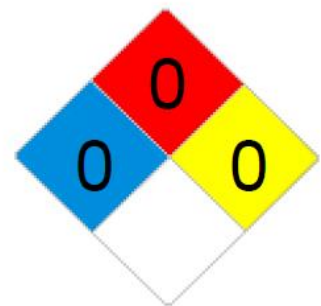
This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard Information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labelling of Chemicals.

The hazard ratings on this MSDS are for appropriately trained workers using a Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks. Chronic (long-term) health effects are indicated in the HMIS® by an asterisk (*). HMIS® is a registered trade and service mark of the NPCA. For details on HMIS® ratings visit www.paint.org/hmis. For details on NFPA 704 visit www.nfpa.org.

HMIS® RATINGS

| | |
|-----------------|---|
| HEALTH | 0 |
| FLAMMABILITY | 0 |
| PHYSICAL HAZARD | 0 |

NFPA RATINGS



MSDS Origination Date: August 4th, 2015

Version: 1

Revision Date: Not Applicable

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