Cardioplegic Solution for Cardiac Perfusion 1,000 mL Freeflex Bag

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: 01/20/2023 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Cardioplegic Solution for Cardiac Perfusion 1,000 mL Freeflex Bag

1.2. Intended Use of the Product

Induction of cardiac arrest during open-heart surgery.

1.3. Name, Address, and Telephone of the Responsible Party

Manufacturer

Fresenius Kabi Deutschland GmbH
Freseniusstraße 1
Friedberg, Hesse 61169
Germany
General Phone Number: +49 6172 686 0
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
Technical Product Information: +49 6172 686 8599
Emergency Phone Number: 8475502300
Email: logistik.friedberg@fresenius-kabi.com

Distributor

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, Illinois 60047
USA
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
Email: NACommunications@fresenius-kabi.com

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
Domestic: 1-800-255-3924
International: +1-813-248-0585

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Not classified

2.2. Label Elements

GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS Ingredient Classification
Water	water / AQUA	(CAS-No.) 7732-18-5	98-100	Not classified
Sodium chloride	Salt / SEA SALT / Sodium salt of hydrochloric acid / SODIUM CHLORIDE / Sodium chloride (NaCl) / Sea salt	(CAS-No.) 7647-14-5	<1.0	Not classified
Magnesium chloride	Magnesium chloride (MgCl2) / MAGNESIUM CHLORIDE / Magnesium chloride, anhydrous / Magnesium dichloride / Magnesium chloride anhydrous / magnesium chloride anhydrous	(CAS-No.) 7786-30-3	<1.0	Not classified
Potassium chloride	Potassium chloride (KCl) / POTASSIUM CHLORIDE / Hydrochloric acid, potassium salt / potassium chloride	(CAS-No.) 7447-40-7	<1.0	Not classified
Calcium chloride	Calcium chloride (CaCl2) / Calcium chloride, anhydrous / CALCIUM CHLORIDE / Calcium dichloride / Calcium chloride anhydrous	(CAS-No.) 10043-52-4	<0.1	Eye Irrit. 2A, H319

Full text of H-statements: see section 16. Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Pain and swelling may occur if accidentally injected, with the potential for damage to surrounding tissues. Injection of large amounts of solution may result in cardiac dysrhythmia or cardiac arrest. Treat accidental injections of material as a medical emergency,

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand. Pain and swelling may occur if accidentally injected, with the potential for damage to surrounding tissues. Injection of large amounts of solution may result in cardiac dysrhythmia or cardiac arrest. Treat accidental injections of material as a medical emergency,

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO_2), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: None expected under normal conditions of use.

Other Information: No additional information available.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material, then place in suitable container. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropiately to minimize risk of accidents.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with applicable protocols.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Do not remove solution container from its overwrap until immediately before use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 20 – 25 °C (68 – 77 °F). Do not freeze.

7.3. Specific End Use(s)

Induction of cardiac arrest during open-heart surgery.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Calcium chloride (10043-52-4)		
Ontario	OEL TWA	5 mg/m³

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles or glasses.

Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles or safety glasses with side shields.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	:	Liquid
Appearance	:	Clear/colourless liquid
Odor	:	None
Odor Threshold	:	No data available
pH	:	3.8
Evaporation Rate	:	No data available
Melting Point	:	0 °C (32 °F)
Freezing Point	:	0 °C (32 °F)
Boiling Point	:	100 °C (212 °F)
Flash Point	:	No data available
Auto-ignition Temperature	:	No data available
Decomposition Temperature	:	No data available
Flammability (solid, gas)	:	Not applicable
Lower Flammable Limit	:	No data available
Upper Flammable Limit	:	No data available
Vapor Pressure	:	No data available
Relative Vapor Density at 20°C	:	No data available
Relative Density	:	No data available
Density	:	~1.0 g/ml
Specific Gravity	:	No data available
Solubility	:	Miscible.
Partition Coefficient: N-Octanol/Water	:	No data available
Viscosity	:	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Dermal, Eye Contact, Inhalation, Oral.

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified

pH: 3.8

Eye Damage/Irritation: Not classified

pH: 3.8

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h)

Magnesium chloride (7786-30-3)	
LD50 Oral Rat	2800 mg/kg
LD50 Dermal Rat	> 2000 mg/kg (No deaths)

Potassium chloride (7447-40-7)	
LD50 Oral Rat	3020 mg/kg (Species: Wistar)

Calcium chloride (10043-52-4)	
LD50 Oral Rat	2301 mg/kg
LD50 Dermal Rabbit	> 5000 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Expected to be readily biodegradable.

Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)

Magnesium chloride (7786-30-3)	
LC50 Fish 1	1970 – 3880 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	140 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Potassium chloride (7447-40-7)	
LC50 Fish 1	1060 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [1]	825 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	750 (750 – 1020) mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])

Calcium chloride (10043-52-4)	
LC50 Fish 1	10650 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [1]	2280000 – 3948000 µg/l (Exposure time: 48 h - Species: Daphnia magna)

12.2. Persistence and Degradability

Cardioplegic Solution for Cardiac Perfusion 1,000 mL Freeflex Bag	
Persistence and Degradability	Expected to be biodegradable.

12.3. Bioaccumulative Potential

Cardioplegic Solution for Cardiac Perfusion 1,000 mL Freeflex Bag	
Bioaccumulative Potential	Not expected to bioaccumulate.

Sodium chloride (7647-14-5)	
BCF Fish 1	(no bioaccumulation)

Calcium chloride (10043-52-4)	
BCF Fish 1	(no bioaccumulation)

12.4. Mobility in Soil

Cardioplegic Solution for Cardiac Perfusion 1,000 mL Freeflex Bag	
Ecology - Soil	Leaches into groundwater.

12.5. Other Adverse Effects

Other Adverse Effects: None known.

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional Legislation (Waste): Disposal must be done according to official regulations.

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product.

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid unintended release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Sodium chloride (7647-14-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Water (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Magnesium chloride (7786-30-3)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Potassium chloride (7447-40-7)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Calcium chloride (10043-52-4)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. US State Regulations

Cardioplegic Solution for Cardiac Perfusion 1,000 mL Freeflex Bag()
State or local regulations

15.3. Canadian Regulations

Sodium chloride (7647-14-5)
Listed on the Canadian DSL (Domestic Substances List)

Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)

Magnesium chloride (7786-30-3)
Listed on the Canadian DSL (Domestic Substances List)

Potassium chloride (7447-40-7)
Listed on the Canadian DSL (Domestic Substances List)

Calcium chloride (10043-52-4)
Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 01/20/2023

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

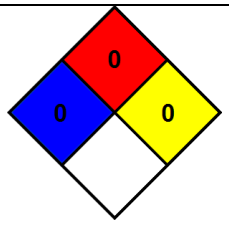
GHS Full Text Phrases:

H319	Causes serious eye irritation

NFPA Health Hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA Fire Hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 0 Minimal Hazard - No significant risk to health

Flammability : 0 Minimal Hazard

Physical : 0 Minimal Hazard

Personal protection : B

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)