

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Glycerolyte 57 Solution

1.2. Intended Use of the Product

Cryopreservative processing solution. For professional use only.

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

Manufactured for:

Fresenius Kabi AG

61346 Bad Homburg / Germany

Tel: +49 (0) 6172 686 0

For U.S.: +1-800-933-6025

www.fresenius-kabi.com/us/

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS

+1 (800) 255-3924 (North America)

+1 (813)248-0585 (International)

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 data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Glycerin	Glycerine / Glycerol / 1,2,3-Trihydroxypropane / Propane-1,2,3-triol	(CAS-No.) 56-81-5	30 - 60	Not classified
Water	AQUA	(CAS-No.) 7732-18-5	15 - 40	Not classified
Propanoic acid, 2-hydroxy-, monosodium salt, (2S)- / Sodium (S)-lactate / Sodium L-lactate / Propanoic acid, 2-hydroxy-, sodium salt (1:1), (2S)- / Sodium L-(+)-lactate / Sodium lactate / Sodium (S)-2-hydroxypropionate		(CAS-No.) 867-56-1	1 – 5	Not classified
Potassium chloride	Potassium chloride (KCl) / POTASSIUM CHLORIDE / Hydrochloric acid, potassium salt	(CAS-No.) 7447-40-7	0.1 - 1	Not classified
Phosphoric acid, disodium salt	Sodium phosphate dibasic / Disodium hydrogen phosphate / Disodium hydrogenorthophosphate / Disodium hydrogenphosphate / Disodium phosphate, anhydrous / Disodium phosphate / Sodium phosphate, dibasic / Phosphoric acid, sodium salt (1:2) / DISODIUM PHOSPHATE /	(CAS-No.) 7558-79-4	0.1 - 1	Not classified

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	Disodium hydrogen orthophosphate / Disodium orthophosphate			
Phosphoric acid, monosodium salt	Sodium acid phosphate / Monosodium phosphate / Sodium dihydrogen phosphate / Sodium dihydrogen phosphate (1:2:1) / Sodium dihydrogenorthophosphate / Sodium phosphate, monobasic / Sodium dihydrogenphosphate / Sodium phosphate monobasic / Phosphoric acid, sodium salt (1:1) / SODIUM PHOSPHATE / Sodium dihydrogen orthophosphate / Monosodium orthophosphate / Monobasic sodium phosphate	(CAS-No.) 7558-80-7	0.1 - 1	Not classified

Full text of H-phrases: 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%).

** The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the Hazardous Products Regulations (HPR) SOR/2015-17 and 29 CFR 1910.1200.

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).

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.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

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: Acrolein. Sodium oxides. Phosphorus oxides. Chlorine.

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).

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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: 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.

Ventilate area.

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. Transfer spilled material to a suitable container for disposal. 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

Precautions for Safe Handling: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

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: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong oxidizers.

7.3. Specific End Use(s)

Cryopreservative processing solution. For professional use only.

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.

Glycerin (56-81-5)		
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (mist, total particulate) 5 mg/m ³ (mist, respirable fraction)
Alberta	OEL TWA (mg/m ³)	10 mg/m ³ (mist)
British Columbia	OEL TWA (mg/m ³)	10 mg/m ³ (mist, total) 3 mg/m ³ (mist-respirable)
New Brunswick	OEL TWA (mg/m ³)	10 mg/m ³ (mist)
Nunavut	OEL STEL (mg/m ³)	20 mg/m ³ (mist)
Nunavut	OEL TWA (mg/m ³)	10 mg/m ³ (mist)
Northwest Territories	OEL STEL (mg/m ³)	20 mg/m ³ (mist)
Northwest Territories	OEL TWA (mg/m ³)	10 mg/m ³ (mist)
Québec	VEMP (mg/m ³)	10 mg/m ³ (mist)
Saskatchewan	OEL STEL (mg/m ³)	20 mg/m ³ (mist)
Saskatchewan	OEL TWA (mg/m ³)	10 mg/m ³ (mist)
Yukon	OEL TWA (mg/m ³)	30 mppcf (mist) 10 mg/m ³ (mist)

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.

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



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

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	: Aqueous solution, clear, colorless
Odor	: Not available
Odor Threshold	: Not available
pH	: 6.8 (Approximately)
Evaporation Rate	: Not available
Melting Point	: Not available
Freezing Point	: Not available
Boiling Point	: 100 °C (212 °F) (water)
Flash Point	: Not available
Auto-ignition Temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: Not available
Upper Flammable Limit	: Not available
Vapor Pressure	: Not available
Relative Vapor Density at 20°C	: Not available
Relative Density	: Not available
Specific Gravity	: 1.14
Solubility	: Water: Soluble
Partition Coefficient: N-Octanol/Water	: Not available
Viscosity	: Not 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 oxidizers.
- 10.6. **Hazardous Decomposition Products:** Not expected to decompose under ambient conditions. Thermal decomposition generates: Glycerin decomposes to produce corrosive fumes of Acrolein.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified [pH: 6.8 (Approximately)]

Eye Damage/Irritation: Not classified [pH: 6.8 (Approximately)]

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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:

Potassium chloride (7447-40-7)	
LD50 Oral Rat	3020 mg/kg (Species: Wistar)
Glycerin (56-81-5)	
LD50 Oral Rat	12600 mg/kg
LD50 Dermal Rabbit	> 10 g/kg
LC50 Inhalation Rat	> 570 mg/m ³ (Exposure time: 1 h)
Phosphoric acid, monosodium salt (7558-80-7)	
LD50 Oral Rat	8290 mg/kg
LD50 Dermal Rabbit	> 7940 mg/kg
Phosphoric acid, disodium salt (7558-79-4)	
LD50 Oral Rat	17 g/kg
LD50 Dermal Rat	> 5000 mg/kg (50% solution)

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Potassium chloride (7447-40-7)	
LC50 Fish 1	1060 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 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])
Glycerin (56-81-5)	
LC50 Fish 1	54000 (51000 – 57000) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

12.2. Persistence and Degradability

Glycerolyte 57 Solution	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Glycerolyte 57 Solution	
Bioaccumulative Potential	Not established.
Glycerin (56-81-5)	
BCF Fish 1	(no bioaccumulation)
Partition coefficient n-octanol/water (Log Pow)	-1.76

12.4. Mobility in Soil Not available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

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SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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

Ecology - Waste Materials: Avoid 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

Potassium chloride (7447-40-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Glycerin (56-81-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Phosphoric acid, monosodium salt (7558-80-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Propanoic acid, 2-hydroxy-, monosodium salt, (S)- (867-56-1)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Phosphoric acid, disodium salt (7558-79-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	5000 lb
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Glycerin (56-81-5)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Phosphoric acid, disodium salt (7558-79-4)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	

15.3. Canadian Regulations

Potassium chloride (7447-40-7)	
Listed on the Canadian DSL (Domestic Substances List)	
Glycerin (56-81-5)	
Listed on the Canadian DSL (Domestic Substances List)	
Phosphoric acid, monosodium salt (7558-80-7)	
Listed on the Canadian DSL (Domestic Substances List)	
Propanoic acid, 2-hydroxy-, monosodium salt, (S)- (867-56-1)	
Listed on the Canadian DSL (Domestic Substances List)	
Phosphoric acid, disodium salt (7558-79-4)	
Listed on the Canadian DSL (Domestic Substances List)	

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Water (7732-18-5)

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 : 04/01/2024

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.

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)