



MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name Glycerolyte 57 Solution
Version # 02
Revision date 01-14-2011
CAS # Mixture
MSDS Number 1087937
Product use Processing solution for cryoperservative of human red blood cells.
Manufacturer information Fenwal Inc
Three Corporate Drive
Lake Zurich
IL 60047
United States
General Assistance: 1-847 550-2300
Contact person: Arlene Farrar, Fenwal, Inc.,
Environmental Health & Safety

2. Hazards Identification

Physical state Liquid.
Appearance Aqueous solution.
Emergency overview CAUTION
May cause eye irritation.
OSHA regulatory status This product is hazardous according to OSHA 29 CFR 1910.1200.
Potential health effects
Routes of exposure Skin contact. Eye contact.
Eyes May cause eye irritation. May cause redness and pain.
Skin Prolonged contact may cause dryness of the skin.
Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Ingestion May cause discomfort if swallowed.
Target organs No specific target organs noted.
Chronic effects None known.
Potential environmental effects The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Water	7732-18-5	> 40
Glycerin	56-81-5	50-60
Sodium-L-lactate	867-56-1	1-5
Dibasic sodium phosphate	7558-79-4	< 1
Potassium chloride	7447-40-7	< 1
Monobasic Sodium Phosphate Monohydrate	7558-80-7	< 0.1

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First Aid Measures

First aid procedures

Eye contact Rinse with water. Get medical attention if irritation persists after washing.

Skin contact	Rinse skin with water/shower. Get medical attention if irritation persists after washing.
Inhalation	No specific first aid measures noted.
Ingestion	Rinse mouth. Large quantities: Get medical attention if symptoms occur.
Notes to physician	No specific indications.
General advice	No recommendation given.

5. Fire Fighting Measures

Flammable properties	The product is non-combustible. During fire, gases hazardous to health may be formed.
Extinguishing media	
Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None.
Protection of firefighters	
Specific hazards arising from the chemical	None known.
Protective equipment and precautions for firefighters	Self-contained breathing apparatus, operated in positive pressure mode and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
Hazardous combustion products	Carbon monoxide.

6. Accidental Release Measures

Personal precautions	Avoid prolonged or repeated contact with skin. See Section 8 of the MSDS for Personal Protective Equipment.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground unless allowed by local regulations.
Methods for containment	Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible.
Methods for cleaning up	Absorb spillage with suitable absorbent material. For waste disposal, see section 13 of the MSDS.

7. Handling and Storage

Handling	Avoid contact with eyes and prolonged skin contact. Wear approved safety goggles. Observe good industrial hygiene practices.
Storage	Store in closed original container at room temperature. Store in a cool, dry, well-ventilated place. Store away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Glycerin (56-81-5)	TWA	10 mg/m ³	Mist.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Glycerin (56-81-5)	PEL	15 mg/m ³ 5 mg/m ³	Total dust. Respirable fraction.

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Glycerin (56-81-5)	TWA	10 mg/m ³	Mist.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Glycerin (56-81-5)	TWA	3 mg/m ³ 10 mg/m ³	Respirable mist. Mist.

Canada. Ontario OELs. (Ministry of Labor - Control of Exposure to Biological or Chemical Agents)

Components	Type	Value	Form
Glycerin (56-81-5)	TWA	10 mg/m3	Mist.

Canada. Quebec OELS. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value	Form
Glycerin (56-81-5)	TWA	10 mg/m3	Mist.

Mexico. Occupational Exposure Limit Values

Components	Type	Value	Form
Glycerin (56-81-5)	TWA	10 mg/m3	Mist.

Engineering controls Provide adequate ventilation. Observe occupational exposure limits and minimize the risk of inhalation of vapors and mist.

Personal protective equipment

Eye / face protection Wear approved safety goggles.

Skin protection For prolonged or repeated skin contact use suitable protective gloves. Suitable gloves can be recommended by the glove supplier. Risk of splashes: Use skin protection.

Respiratory protection No personal respiratory protective equipment normally required. In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory equipment with combination filter.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical & Chemical Properties

Appearance Aqueous solution.

Color Clear, colorless.

Odor None.

Odor threshold Not available.

Physical state Liquid.

Form Liquid.

pH 6.7 - 7.2

Melting point Similar to water

Freezing point Similar to water

Boiling point Similar to water

Flash point Not flammable

Evaporation rate Similar to water

Flammability Not flammable

Flammability limits in air, upper, % by volume Not flammable

Flammability limits in air, lower, % by volume Not flammable

Vapor pressure Similar to water

Vapor density Similar to water

Specific gravity 1.14

Solubility (water) Not applicable

Partition coefficient (n-octanol/water) Not applicable

Auto-ignition temperature Not applicable

Decomposition temperature Not applicable

10. Chemical Stability & Reactivity Information

Chemical stability Material is stable under normal conditions.

Conditions to avoid Excessive heat. Freezing. Contact with incompatible materials.

Incompatible materials	None noted.
Hazardous decomposition products	Carbon monoxide. Chlorine. Sodium oxides.
Possibility of hazardous reactions	Will not occur.

11. Toxicological Information

Toxicological data

Components	Test Results
Potassium chloride (7447-40-7)	Acute Oral LD50 Rat: 2600 mg/kg
Dibasic sodium phosphate (7558-79-4)	Acute Oral LD50 Rat: 17 g/kg
Acute effects	May cause eye irritation. May cause redness and pain.
Sensitization	Not a skin sensitizer.
Chronic effects	No additional adverse health effects noted.
Carcinogenicity	Not classified.
Mutagenicity	Not classified.
Reproductive effects	Not classified.
Teratogenicity	Not classified.
Symptoms and target organs	May cause redness and pain.

12. Ecological Information

Ecotoxicological data

Components	Test Results
Potassium chloride (7447-40-7)	EC50 Water flea (<i>Daphnia magna</i>): 83 mg/l 48 hours LC50 Western mosquitofish (<i>Gambusia affinis</i>): 435 mg/l 96 hours
Sodium-L-lactate (867-56-1)	EC50 Water flea (<i>Daphnia magna</i>): > 2050 mg/l 48 hours
Ecotoxicity	The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data available.
Bioaccumulation / Accumulation	No data available.
Partition coefficient (n-octanol/water)	Not applicable
Mobility in environmental media	No data available.

13. Disposal Considerations

Disposal instructions	This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Disposal recommendations are based on material as supplied. Disposal must be in accordance with current applicable laws and regulations, and material characteristics at time of disposal.
Waste from residues / unused products	Dispose in accordance with all local, State and Federal regulations.

14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information**US federal regulations**

This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. This material is not listed on the US TSCA 8(b) Inventory, therefore it may only be used for TSCA exempt purposes such as R&D or drug use. Regulated by FDA under Compassionate Use regulations. CERCLA/SARA Hazardous Substances - Not applicable.

CERCLA (Superfund) reportable quantity (lbs)

Dibasic sodium phosphate 5000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
 Immediate Hazard - Yes
 Delayed Hazard - Yes
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

Section 302 extremely hazardous substance No

Section 311 hazardous chemical No

Drug Enforcement Agency (DEA) Not controlled

WHMIS status Non-controlled

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

State regulations

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Hazardous Substances (Director's): Listed substance

Dibasic sodium phosphate (CAS 7558-79-4) Listed.

US - Massachusetts RTK - Substance: Listed substance

Dibasic sodium phosphate (CAS 7558-79-4) Listed.

Glycerin (CAS 56-81-5) Listed.

US - New Jersey RTK - Substances: Listed substance

Dibasic sodium phosphate (CAS 7558-79-4) Listed.

US - Pennsylvania RTK - Hazardous Substances: Listed substance

Dibasic sodium phosphate (CAS 7558-79-4) Listed.

Glycerin (CAS 56-81-5) Listed.

16. Other Information**Further information**

HMIS® is a registered trade and service mark of the NPCA.

Other information	For approved drug use in countries where registered. Keep out of reach of children.
HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 0 Instability: 0
Disclaimer	The information in this MSDS was obtained for sources which we believe are reliable. However, the information is provided without any representation or warranty, express or implied, regarding its accuracy or correctness.
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This data sheet contains changes from the previous version in section(s):	This document has undergone significant changes and should be reviewed in its entirety.