

SALINE, ADENINE, GLUCOSE - MANNITOL (SAG-M) RED BLOOD CELL PRESERVATIVE SOLUTION

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Revision date: 16/01/2019

Date of issue: 16/01/2019

Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product Name : SALINE, ADENINE, GLUCOSE - MANNITOL (SAG-M) RED BLOOD CELL PRESERVATIVE SOLUTION

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : The product is indicated for use only with apheresis procedures using automated apheresis machines for the preservation of red blood cells.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Haemonetics Corporation
400 Wood Road
Braintree, MA 02184

1.4. Emergency telephone number

Emergency number : Contact the Health, Safety and Environment Department – (781) 848-7100

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

Other hazards not contributing to the classification : Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Water for injection	(CAS No) 7732-18-5 (EC no) 231-791-2	97,7	Not classified
Glucose	(CAS No) 50-99-7 (EC no) 200-075-1	0,9	Not classified
Sodium chloride	(CAS No) 7647-14-5 (EC no) 231-598-3	0,877	Not classified
Mannitol	(CAS No) 69-65-8 (EC no) 200-711-8	0,525	Not classified
Adenine	(CAS No) 73-24-5 (EC no) 200-796-1	0,0169	Acute Tox. 3 (Oral), H301

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

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).

SALINE, ADENINE, GLUCOSE - MANNITOL (SAG-M) RED BLOOD CELL PRESERVATIVE SOLUTION

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

- First-aid measures after inhalation : When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
- First-aid measures after skin contact : Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.
- First-aid measures after eye contact : Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.
- 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.

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: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray, dry chemical, foam, carbon dioxide.
- 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.

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).

6.1.1. For non-emergency personnel

- Protective equipment : Use appropriate personal protection equipment (PPE).
- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- 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 material 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 Heading 8. Exposure controls and personal protection. See Section 13, Disposal Considerations.

SALINE, ADENINE, GLUCOSE - MANNITOL (SAG-M) RED BLOOD CELL PRESERVATIVE SOLUTION

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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.

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 acids, strong bases, strong oxidizers.

7.3. Specific end use(s)

The product is indicated for use only with apheresis procedures using automated apheresis machines and is designed to be used with disposable accessories which are never re-used.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium chloride (7647-14-5)

Latvia	OEL TWA (mg/m ³)	5 mg/m ³
Lithuania	IPRV (mg/m ³)	5 mg/m ³

8.2. Exposure controls

Appropriate engineering controls : Emergency eye wash fountains and safety showers should be available in the immediate 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.



Materials for protective clothing : Chemically resistant materials and fabrics.

Hand protection : Wear protective gloves.

Eye 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
Colour	: Clear, colorless solution
Odour	: Odorless
Odour threshold	: No data available
pH	: 5.0 – 6.0
Evaporation rate	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available

SALINE, ADENINE, GLUCOSE - MANNITOL (SAG-M) RED BLOOD CELL PRESERVATIVE SOLUTION

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Flammability (solid, gas)	: Not flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information 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

Upon thermal decomposition: carbon oxides (CO, CO₂), chlorine, sodium oxides

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Sodium chloride (7647-14-5) LD50 oral rat LC50 inhalation rat (mg/l)	3 g/kg > 42 g/m ³ (Exposure time: 1 h)
Adenine (73-24-5) LD50 oral rat	227 mg/kg
Glucose (50-99-7) LD50 oral rat	25800 mg/kg
Mannitol (69-65-8) LD50 oral rat	13,500 – 22000 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

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Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Not classified.

Sodium chloride (7647-14-5)

LC50 fish 1	5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 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 Daphnia 2	340,7 (340,7 - 469,2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

12.2. Persistence and degradability

SALINE, ADENINE, GLUCOSE - MANNITOL (SAG-M) RED BLOOD CELL PRESERVATIVE SOLUTION

Persistence and degradability : Not established.

12.3. Bioaccumulative potential

SALINE, ADENINE, GLUCOSE - MANNITOL (SAG-M) RED BLOOD CELL PRESERVATIVE SOLUTION

Bioaccumulative potential : Not established.

Sodium chloride (7647-14-5)

BCF fish 1 : (no bioaccumulation)

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional information : Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Other information : No supplementary information available.

14.6. Special precautions for user

14.6.1. Overland transport

No additional information available

14.6.2. Transport by sea

No additional information available

14.6.3. Air transport

No additional information available

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

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Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3.b. Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10

Adenine

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

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Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
H301	Toxic if swallowed

EU GHS SDS

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.