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

Safety Data Sheet
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

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

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).

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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 after inhalation: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries after skin contact: Prolonged exposure may cause irritation.
Symptoms/injuries after eye contact: Prolonged exposure may cause skin irritation.
Symptoms/injuries after ingestion: May cause slight irritation to eyes.
Symptoms/injuries after skin contact: 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.
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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

<table>
<thead>
<tr>
<th>Sodium chloride (7647-14-5)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Latvia</td>
<td>OEL TWA (mg/m³)</td>
</tr>
<tr>
<td>Lithuania</td>
<td>IPRV (mg/m³)</td>
</tr>
</tbody>
</table>

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.


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

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Clear, colorless solution</td>
</tr>
<tr>
<td>Odour</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>5.0 – 6.0</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not flammable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effect</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride (7647-14-5)</td>
<td>LD50 oral rat</td>
<td>3 g/kg</td>
</tr>
<tr>
<td></td>
<td>LC50 inhalation rat (mg/l)</td>
<td>&gt; 42 g/m³ (Exposure time: 1 h)</td>
</tr>
<tr>
<td>Adenine (73-24-5)</td>
<td>LD50 oral rat</td>
<td>227 mg/kg</td>
</tr>
<tr>
<td>Glucose (50-99-7)</td>
<td>LD50 oral rat</td>
<td>25800 mg/kg</td>
</tr>
<tr>
<td>Mannitol (69-65-8)</td>
<td>LD50 oral rat</td>
<td>13,500 – 22000 mg/kg</td>
</tr>
</tbody>
</table>

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.
SECTION 12: Ecological information

12.1. Toxicity
Ecology - general : Not classified.

<table>
<thead>
<tr>
<th>Sodium chloride (7647-14-5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fish 1</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
</tr>
<tr>
<td>LC50 fish 2</td>
</tr>
<tr>
<td>EC50 Daphnia 2</td>
</tr>
</tbody>
</table>

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. |

<table>
<thead>
<tr>
<th>Sodium chloride (7647-14-5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCF fish 1</td>
</tr>
</tbody>
</table>

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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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:

<table>
<thead>
<tr>
<th>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</th>
<th>Adenine</th>
</tr>
</thead>
</table>

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

Revision date: 16/01/2019

Full text of H- and EUH-statements:

<table>
<thead>
<tr>
<th>Acute Tox. 3 (Oral)</th>
<th>Acute toxicity (oral), Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>H301</td>
<td>Toxic if swallowed</td>
</tr>
</tbody>
</table>

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.