

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: 04/12/2015 Date of issue: 04/12/2015

Version: 1.0

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

1.1. Product identifier Product form Product Name

- : Mixture
- : 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 and is designed to be used with disposable accessories which are never re-used.

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

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
Adenine	(CAS No) 73-24-5 (EC no) 200-796-1	0,5419	Acute Tox. 3 (Oral), H301

Full text of H-statements: see section 16

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SECTION 4: First aid measures

4.1. Description of first aid m	easures
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).
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	
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 symptom	ns 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 immed	iate medical attention and special treatment needed
If exposed or concerned, get medica	l advice and attention. If medical advice is needed, have product container or label at hand.
SECTION 5: Firefighting m	easures
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.
	om 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 rel	ease measures
6.1. Personal precautions, pr	otective 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 person	nel
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 precaution	
Prevent entry to sewers and public v	vaters.
6.3. Methods and material fo	r 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 section	
See Heading 8. Exposure controls an	d personal protection. See Section 13, Disposal Considerations.

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SECTION 7: Handling and storage Precautions for safe handling 7.1. 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. : Handle in accordance with good industrial hygiene and safety procedures. Hygiene measures 7.2. Conditions for safe storage, including any incompatibilities **Technical measures** : Comply with applicable regulations. : Keep container closed when not in use. Store in a dry, cool place. Keep/Store away Storage conditions from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible materials

: Strong acids, strong bases, strong oxidizers.

Specific end use(s) 7.3.

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

Control parameters 8.1.

Sodium chloride (7647-14-5)		
Latvia	OEL TWA (mg/m³)	5 mg/m ³
Lithuania	IPRV (mg/m ³)	5 mg/m³

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

Other information

When using, do not eat, drink or smoke. **SECTION 9: Physical and chemical properties**

protection.

9.1. Information on basic physical and o	chemical properties
Physical state	: Liquid
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
рН	: No data available
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

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Flammability (solid, gas)	: No data available
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 reactiv	vitv
10.1. Reactivity	Vity
Hazardous reactions will not occur under norn	nal conditions
10.2. Chemical stability	
Stable under recommended handling and stor	age 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 tempera	atures, and incompatible materials.
10.5. Incompatible materials	
Strong acids, strong bases, strong oxidizers.	
	cts
10.6. Hazardous decomposition produc	
10.6. Hazardous decomposition produc Upon thermal decomposition: carbon oxides (CO, CO ₂).
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12.1. Toxicity Ecology - general

: Not classified.

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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	
	SAG-M) RED BLOOD CELL PRESERVATIVE SOLUTION
Persistence and degradability	Not established.
12.3. Bioaccumulative potential	
	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 assess	ment
No additional information available	
12.6. Other adverse effects	
Other information	: Avoid release to the environment.
SECTION 13: Disposal consider	ations
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	A / 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	
•	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:

3.b. Substances or mixtures fulfilling the criteria for any of	Adenine
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	

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	: 04/12/2015
Data sources	: According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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.