

This safety data sheet complies with the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Issuing Date: 18-May-2015

Revision Date: 27-Jun-2019

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product Identifier

SDS Number: 1256016
Product Name: Compound Sodium Lactate Intravenous Infusion BP (Hartmann's Solution)
Product Code(s): AHB2323, AHB2324, ME2324
Synonyms: None

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

Product Use: Pharmaceutical.
Product Type: Injectable solution
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
0044 1635 206345

E-mail address

medinfo_emea@baxter.com

1.4. Emergency telephone number

CHEMTREC
+1 703-741-5970 / 1-800-424-9300 CCN 2447

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

2.2. Label elements

Product Identifier

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

2.3. Other hazards

No information available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Chemical name	EU EINECS List	CAS No.	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Reg. No
Sodium Chloride 7647-14-5	231-598-3	7647-14-5	<1	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	01-2119485491-33

Potassium Chloride 7447-40-7	231-211-8	7447-40-7	<0.1	No data available	01-2119539416-36
Calcium Chloride 10043-52-4	233-140-8	10043-52-4	<0.1	Eye Irrit. 2 (H319)	01-2119991101-45
Sodium Lactate 72-17-3	200-772-0	72-17-3	<1	No data available	01-2119969948-09
Water 7732-18-5	231-791-2	7732-18-5	>98	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

General Advice	Treat symptomatically and supportively.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms occur.
Skin contact:	Wash contaminated skin with soap and water. Get medical attention if irritation develops.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

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

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

Use extinguishing media suitable for surrounding materials.

Extinguishing media which must not be used for safety reasons

No information available

5.2. Special hazards arising from the substance or mixture

No information available

5.3. Advice for firefighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

6.2. Environmental precautions

Do not allow material to contaminate ground water system.

6.3. Methods and material for containment and cleaning up

Methods for Containment:

If emergency personnel are unavailable, contain spilled material.

Methods for cleaning up:

For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

6.4. Reference to other sections

See Section 12 for more information

Section 7: HANDLING AND STORAGE**7.1. Precautions for safe handling**

Technical measures/precautions: Wash thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions: Keep in a cool, well-ventilated place. Store at or below 30°C (86°F). Do not freeze. Avoid excessive heat.

Incompatible materials: No special restrictions on storage with other products.

7.3. Specific end use(s)

Other Guidelines None.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters**

Exposure Limits: This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical name	European Union	Uk oes/mel:	France	Spain	Germany
Sodium Chloride 7647-14-5	None	None	None	None	None
Potassium Chloride 7447-40-7	None	None	None	None	None
Calcium Chloride 10043-52-4	None	None	None	None	None
Sodium Lactate 72-17-3	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None
Chemical name	Italy	Portugal	Netherlands	Finland	Denmark
Sodium Chloride 7647-14-5	None	None	None	None	None
Potassium Chloride 7447-40-7	None	None	None	None	None
Calcium Chloride 10043-52-4	None	None	None	None	None
Sodium Lactate 72-17-3	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Sodium Chloride 7647-14-5	None	None	None	None	None
Potassium Chloride 7447-40-7	None	None	None	None	None
Calcium Chloride 10043-52-4	None	None	None	None	None
Sodium Lactate 72-17-3	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None
Chemical name	Sweden				

Sodium Chloride 7647-14-5	None
Potassium Chloride 7447-40-7	None
Calcium Chloride 10043-52-4	None
Sodium Lactate 72-17-3	None
Water 7732-18-5	None

8.2. Exposure controls

Engineering Measures No special containment is required.

Personal protective equipment

Eye protection Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

Respiratory protection No personal respiratory protective equipment normally required.

Hand protection Not required.

Skin and body protection Not required.

Environmental exposure controls Do not allow material to contaminate ground water system.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state:	Liquid.
Appearance:	Aqueous solution.
Color:	Not available
Odor:	Not available
Odor Threshold:	No information available
pH:	5.0 - 7.0
Melting point / melting range:	Not available
Boiling point / boiling range:	Not available
Flash point:	Not determined
Flammability (solid, gas):	No information available
Evaporation rate:	Not available
Flammable limits	Not available.
in air-upper (%):	
Flammable limits	Not available.
in air-lower (%):	
Vapor pressure:	Not available
Vapor density	No information available
Density:	Not available
Solubility:	Soluble in water.
Partition coefficient	Not available
(n-octanol/water):	
Autoignition temperature:	Not available.
Decomposition temperature	No information available
Viscosity:	Not available
Explosive Properties:	No information available
Oxidizing Properties:	No information available

9.2. Other information**Section 10: STABILITY AND REACTIVITY**

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended storage conditions

10.3. Possibility of hazardous reactions

Polymerization No information available
Hazardous Reactions None under normal use conditions

10.4. Conditions to avoid

Do not freeze.

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

No data available

Section 11: TOXICOLOGICAL INFORMATION
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Chemical name	Inhalation LC50	Dermal LD50	Oral LD50
Sodium Chloride 7647-14-5	42 g/m ³ 1 h (Rat)	> 10 g/kg (Rabbit)	= 3 g/kg (Rat)
Potassium Chloride 7447-40-7	-	-	= 2600 mg/kg (Rat)
Calcium Chloride 10043-52-4	-	= 2630 mg/kg (Rat)	= 1000 mg/kg (Rat)
Sodium Lactate 72-17-3	-	-	-
Water 7732-18-5	-	-	> 90 mL/kg (Rat)

11.1. Information on toxicological effects**Acute Toxicity****Inhalation:** Inhalation not likely under normal use conditions.**Eye contact:** Not expected to cause eye irritation.**Skin contact:** Not expected to cause skin irritation.**Ingestion:** Not expected to be hazardous by ingestion. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.**Unknown Acute Toxicity****Unknown Acute Toxicity** 1.19 % of the mixture consists of ingredient(s) of unknown toxicity.**Acute Oral Toxicity**

0.53 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

Acute dermal toxicity

0.57 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

Acute inhalation toxicity - gas

1.19 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

Acute inhalation toxicity - Vapor

1.19 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

Acute inhalation toxicity - dust/mist

1.19 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information**Irritation:** Not classified.**Corrosivity:** Not classified.**Sensitization:** Not classified.

Mutagenic effects: Not classified.
Carcinogenic effects: Not classified.

Chemical name	ACGIH	IARC	NTP	OSHA	EU Annex I Carcinogen Information	UK
Sodium Chloride 7647-14-5	-	-	-	-	-	-
Potassium Chloride 7447-40-7	-	-	-	-	-	-
Calcium Chloride 10043-52-4	-	-	-	-	-	-
Sodium Lactate 72-17-3	-	-	-	-	-	-
Water 7732-18-5	-	-	-	-	-	-

Reproductive toxicity: Not classified.
STOT - single exposure: Not classified.
STOT - repeated exposure: Not classified.
Aspiration Hazard: Not classified.

Section 12: ECOLOGICAL INFORMATION

Chemical name	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Sodium Chloride 7647-14-5	1000 mg/L EC50 48 h 340.7 - 469.2 mg/L EC50 48 h	4747 - 7824 mg/L LC50 Oncorhynchus mykiss 96 h 12946 mg/L LC50 Lepomis macrochirus 96 h 6020 - 7070 mg/L LC50 Pimephales promelas 96 h 6420 - 6700 mg/L LC50 Pimephales promelas 96 h 5560 - 6080 mg/L LC50 Lepomis macrochirus 96 h 7050 mg/L LC50 Pimephales promelas 96 h	None.	None.
Potassium Chloride 7447-40-7	83 mg/L EC50 48 h 825 mg/L EC50 48 h	750 - 1020 mg/L LC50 Pimephales promelas 96 h 1060 mg/L LC50 Lepomis macrochirus 96 h	2500 mg/L 72 h	None.
Calcium Chloride 10043-52-4	2400 mg/L LC50 48 h	10650 mg/L LC50 Lepomis macrochirus 96 h	None.	None.

Sodium Lactate 72-17-3	None.	None.	None.	None.
Water 7732-18-5	None.	None.	None.	None.

12.1. Toxicity

No information available

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available

12.4. Mobility in soil

No information available

12.5. Results of PBT and vPvB assessment

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

In accordance with local and national regulations

Contaminated Packaging

In accordance with local and national regulations.

Section 14: TRANSPORT INFORMATION

IMDG

- 14.1 UN number Not regulated
- 14.2 Proper Shipping Name Not regulated.
- 14.3 Transport hazard class(es) Not regulated
- 14.4 Packing Group Not regulated.
- 14.5 Marine Pollutant Not applicable
- 14.6 Special Provisions None
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available

RID

- 14.1 UN-No Not regulated
- 14.2 Proper Shipping Name Not regulated
- 14.3 Hazard Class Not regulated
- 14.4 Packing Group Not regulated
- 14.5 Environmental hazard Not applicable
- 14.6 Special Provisions None

ADR Road Transport

- 14.1 UN-No Not regulated

14.2 Proper Shipping Name	Not regulated
14.3 Hazard Class	Not regulated
14.4 Packing Group:	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

IATA

14.1 UN number	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

Section 15: REGULATORY INFORMATION

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

International Inventories

EU EINECS List This product complies with EINECS

Legend

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

15.2. Chemical safety assessment

No information available

Section 16: OTHER INFORMATION

Full text of H-Statements referred to under section 3

H319 - Causes serious eye irritation

H315 - Causes skin irritation

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Additional information:

Not Available.

Key literature references and sources for data

www.ChemADVISOR.com/

Prepared by: Baxter Research & Development

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This data sheet contains changes from the previous version in section(s):

New GHS format. Changes to Section 1. Additional product codes.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of Safety Data Sheet