

SAFETY DATA SHEETS

This SDS packet was issued with item:

071450444

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071450436

SAFETY DATA SHEET



Revision date: 10-24-2018

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Sodium Chloride Irrigation (ICU Medical)

Trade Name: Not established

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

ICU Medical
600 North Field Drive
Lake Forest, Illinois 60045
1-800-654-7780

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: austin_ehs@icumed.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	0.45-0.9
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Due to the nature of this material first aid is not normally required.

Skin Contact: Due to the nature of this material first aid is not normally required.

Ingestion: Due to the nature of this material first aid is not normally required.

Inhalation: Not an expected route of exposure.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Not applicable

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

Not applicable

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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Not applicable

Environmental Precautions

None

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Wipe up with a damp cloth and place in container for disposal.

Additional Consideration for Large Spills: None

7. HANDLING AND STORAGE

Precautions for Safe Handling

No special handling requirements for normal use of this material.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: None

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

SODIUM CHLORIDE

Latvia OEL - TWA 5 mg/m³

Lithuania OEL - TWA 5 mg/m³

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit: 2 mg/m³

Australia PEAK 2 mg/m³

Austria OEL - MAKs 2 mg/m³

Bulgaria OEL - TWA 2.0 mg/m³

Czech Republic OEL - TWA 1 mg/m³

Estonia OEL - TWA 1 mg/m³

France OEL - TWA 2 mg/m³

Greece OEL - TWA 2 mg/m³

Hungary OEL - TWA 2 mg/m³

Japan - OELs - Ceilings 2 mg/m³

Latvia OEL - TWA 0.5 mg/m³

OSHA - Final PELs - TWAs: 2 mg/m³

Poland OEL - TWA 0.5 mg/m³

Slovakia OEL - TWA 2 mg/m³

Slovenia OEL - TWA 2 mg/m³

Sweden OEL - TWAs 1 mg/m³

Switzerland OEL - TWAs 2 mg/m³

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit: 2 ppm

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia PEAK	5 ppm 7.5 mg/m ³
Austria OEL - MAKs	5 ppm 8 mg/m ³
Belgium OEL - TWA	5 ppm 8 mg/m ³
Bulgaria OEL - TWA	5 ppm 8.0 mg/m ³
Cyprus OEL - TWA	5 ppm 8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	2 ppm 3.0 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm 8 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³
Switzerland OEL - TWAs	2 ppm 3.0 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

SODIUM CHLORIDE

ICU Medical Occupational
Exposure Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Exposure Controls

Engineering Controls:
Personal Protective
Equipment:

Engineering controls should be used as the primary means to control exposures.
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Not required for the normal use of this product.

Eyes:

Not required under normal conditions of use.

Skin:

Not required for the normal use of this product.

Respiratory protection:

None required under normal conditions of use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Liquid

Color:

Colorless

Odor:

None

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

pH:

4.5-7.0

Melting/Freezing Point (°C):

No data available

Boiling Point (°C):

No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

SODIUM HYDROXIDE

No data available

SODIUM CHLORIDE

No data available

Water for injection

No data available

HYDROCHLORIC ACID

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):

No data available

Vapor Pressure (kPa):

No data available

Vapor Density (g/ml):

No data available

Relative Density:

No data available

Viscosity:

No data available

Flammability:

Autoignition Temperature (Solid) (°C):

No data available

Flammability (Solids):

No data available

Flash Point (Liquid) (°C):

No data available

Upper Explosive Limits (Liquid) (% by Vol.):

No data available

Lower Explosive Limits (Liquid) (% by Vol.):

No data available

10. STABILITY AND REACTIVITY

Reactivity:

No data available

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10. STABILITY AND REACTIVITY

Chemical Stability: Stable
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: None
Incompatible Materials: None
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Mild eye irritant in experimental animals (based on components)

Acute Toxicity: (Species, Route, End Point, Dose)

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³
Rat Oral LD 50 3g/kg
Mouse Oral LD 50 4g/kg
Rabbit Dermal LD 50 > 10g/kg

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

HYDROCHLORIC ACID

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: No harmful effects to aquatic organisms are expected.

Toxicity: No data available

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Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SODIUM CHLORIDE

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

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15. REGULATORY INFORMATION

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources: Publicly available toxicity information.

Revision date: 10/24/2018

Prepared by: ICU Medical EHS

ICU Medical believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet