

**Heparin Sodium Injection, USP
Safety Data Sheet**

**Heparin Sodium Injection, USP
Preservative Free
Safety Data Sheet**



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Heparin Sodium Injection USP Safety Data Sheet	SDS Number: SDS-000013	Page Number: Page 1 of 9
Function: Regulatory Affairs	Effective Date: April 23, 2019	Version Number: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Heparin Sodium Injection, USP

Synonyms: 1,000 USP units per mL, 10,000 USP units per 10mL, 30,000 units per 30mL, 5,000 USP units per mL, 50,000 USP units per 10mL, 10,000 USP units per mL, 40,000 USP units per 4mL

1.2. Intended Use of the Product

Use of the Substance/Mixture: Heparin Sodium Injection is indicated for: Prophylaxis and treatment of venous thrombosis and pulmonary embolism; Prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing major abdominothoracic surgery or who, for other reasons, are at risk of developing thromboembolic disease; Atrial fibrillation with embolization; Treatment of acute and chronic consumptive coagulopathies (disseminated intravascular coagulation); Prevention of clotting in arterial and cardiac surgery; Prophylaxis and treatment of peripheral arterial embolism; Use as an anticoagulant in blood transfusions, extracorporeal circulation, and dialysis procedures.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Meitheal Pharmaceuticals Inc.

8700 W. Bryn Mawr, Suite 600S

Chicago, IL 60631

Tel: 224-443-4617

www.meithealpharma.com

1.4. Emergency Telephone Number

Emergency Number : 844-824-8426

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

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

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
Water	AQUA / Aqua	(CAS-No.) 7732-18-5	>= 93.64	Not classified

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Heparin, sodium salt	Heparin sodium / Sodium heparin / Dalteparin sodium / SODIUM HEPARIN / Ardeparin sodium / Logiparin / Tinzaparin sodium / Heparin, sodium salt	(CAS-No.) 9041-08-1	<= 4.98	Comb. Dust
Benzyl alcohol	Benzenecarbinol / Benzenemethanol / Methanol, phenyl- / Phenylmethanol / Phenylmethyl alcohol / BENZYL ALCOHOL / .alpha.-Hydroxytoluene	(CAS-No.) 100-51-6	0.88 - 0.99	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Sodium chloride	Sea salt / Sodium chloride (NaCl) / SODIUM CHLORIDE / Sodium salt of hydrochloric acid / Salt / SEA SALT	(CAS-No.) 7647-14-5	0.42 - 0.82	Not classified
Sodium hydroxide	Caustic soda / Sodium hydroxide (Na(OH)) / SODIUM HYDROXIDE / LYE	(CAS-No.) 1310-73-2	*Used to adjust pH	Met. Corr. 1, H290 Acute Tox. 3 (Oral), H301 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402 Aquatic Chronic 3, H412
Hydrochloric acid	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous	(CAS-No.) 7647-01-0	*Used to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401

Full text of H-phrases: 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).

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 5 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

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.

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Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

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: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

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: Will not support combustion unless the water has evaporated.

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.

Hazardous Combustion Products: Sodium oxides, Chlorine, Carbon oxides (CO, CO₂), Sulfur compounds.

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 protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: 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.

Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials 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 Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.



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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

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: Store in a dry, cool place. Keep container closed when not in use. 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)

Heparin Sodium Injection is indicated for: Prophylaxis and treatment of venous thrombosis and pulmonary embolism; Prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing major abdominothoracic surgery or who, for other reasons, are at risk of developing thromboembolic disease; Atrial fibrillation with embolization; Treatment of acute and chronic consumptive coagulopathies (disseminated intravascular coagulation); Prevention of clotting in arterial and cardiac surgery; Prophylaxis and treatment of peripheral arterial embolism; Use as an anticoagulant in blood transfusions, extracorporeal circulation, and dialysis procedures.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Benzyl alcohol (100-51-6)		
USA AIHA	WEEL TWA (ppm)	10 ppm
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

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Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face 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
Appearance	: Clear, colorless to slightly yellow color solution
Odor	: No data available
Odor Threshold	: No data available
pH	: 5.0 - 7.5
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
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Density	: 1.0085 - 1.0258 g/ml
Solubility	: Soluble in water
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: 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.

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10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

10.6. **Hazardous Decomposition Products:** Not expected to decompose under ambient conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 g/m ³ (Exposure time: 1 h)
Benzyl alcohol (100-51-6)	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
ATE (Dust/Mist)	1.50 mg/l/4h
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	140 - 340 mg/kg
ATE (Oral)	140.00 mg/kg body weight
Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg

Skin Corrosion/Irritation: Not classified (pH: 5.0 - 7.5)

Serious Eye Damage/Irritation: Not classified (pH: 5.0 - 7.5)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

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.

Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Sodium chloride (7647-14-5)

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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])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)
Benzyl alcohol (100-51-6)	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 Fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
ErC50 (Algae)	770 mg/l
Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l
Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)

12.2. Persistence and Degradability

Heparin Sodium Injection, USP	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Heparin Sodium Injection, USP	
Bioaccumulative Potential	Not established.
Sodium chloride (7647-14-5)	
BCF Fish 1	(no bioaccumulation)
Benzyl alcohol (100-51-6)	
Log Pow	1.1

12.4. Mobility in Soil No additional information available**12.5. 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.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

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- 14.1. In Accordance with DOT Not regulated for transport
14.2. In Accordance with IMDG Not regulated for transport
14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION**15.1. US Federal Regulations**

Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1% (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Heparin, sodium salt (9041-08-1)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

15.2. US State Regulations

Benzyl alcohol (100-51-6)	
U.S. - Massachusetts - Right To Know List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Sodium hydroxide (1310-73-2)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Hydrochloric acid (7647-01-0)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	

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SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 04/22/2019
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H227	Combustible liquid
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

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.

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SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Heparin Sodium Injection, USP (Preservative-free)

Synonyms: 2,000 USP units per 2mL

1.2. Intended Use of the Product

Use of the Substance/Mixture: Heparin Sodium Injection is indicated for: Anticoagulant therapy in prophylaxis and treatment of venous thrombosis and its extension; Low-dose regimen for prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing major abdominothoracic surgery or who, for other reasons, are at risk of developing thromboembolic disease; Prophylaxis and treatment of pulmonary embolism; Atrial fibrillation with embolization; Treatment of acute and chronic consumptive coagulopathies (disseminated intravascular coagulation); Prevention of clotting in arterial and cardiac surgery; Prophylaxis and treatment of peripheral arterial embolism. Heparin may also be employed as an anticoagulant in blood transfusions, extracorporeal circulation, and dialysis procedures.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Meitheal Pharmaceuticals Inc.

8700 W. Bryn Mawr, Suite 600S

Chicago, IL 60631

Tel: 224-443-4617

www.meithealpharma.com

1.4. Emergency Telephone Number

Emergency Number : 844-824-8426

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

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

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
Water	AQUA / Aqua	(CAS-No.) 7732-18-5	>= 98.69	Not classified

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Sodium chloride	Sea salt / Sodium chloride (NaCl) / SODIUM CHLORIDE / Sodium salt of hydrochloric acid / Salt / SEA SALT	(CAS-No.) 7647-14-5	0.81	Not classified
Heparin, sodium salt	Heparin sodium / Sodium heparin / Dalteparin sodium / SODIUM HEPARIN / Ardeparin sodium / Logiparin / Tinzaparin sodium / Heparin, sodium salt	(CAS-No.) 9041-08-1	<= 0.5	Comb. Dust
Sodium hydroxide	Caustic soda / Sodium hydroxide (NaOH) / SODIUM HYDROXIDE / LYE	(CAS-No.) 1310-73-2	*Used to adjust pH	Met. Corr. 1, H290 Acute Tox. 3 (Oral), H301 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402 Aquatic Chronic 3, H412
Hydrochloric acid	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous	(CAS-No.) 7647-01-0	*Used to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401

Full text of H-phrases: 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).

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 5 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

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.

Chronic Symptoms: None known.

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.



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SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

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: Will not support combustion unless the water has evaporated.

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.

Hazardous Combustion Products: Sodium oxides. Chlorine. Carbon oxides (CO, CO₂). Sulfur compounds.

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 protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: 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.

Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials 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 Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

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: Store in a dry, cool place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

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Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Heparin Sodium Injection is indicated for: Anticoagulant therapy in prophylaxis and treatment of venous thrombosis and its extension; Low-dose regimen for prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing major abdominothoracic surgery or who, for other reasons, are at risk of developing thromboembolic disease; Prophylaxis and treatment of pulmonary embolism; Atrial fibrillation with embolization; Treatment of acute and chronic consumptive coagulopathies (disseminated intravascular coagulation); Prevention of clotting in arterial and cardiac surgery; Prophylaxis and treatment of peripheral arterial embolism. Heparin may also be employed as an anticoagulant in blood transfusions, extracorporeal circulation, and dialysis procedures.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the 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 and Face 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.

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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
Appearance	: Clear, colorless to slightly yellow color solution
Odor	: No data available
Odor Threshold	: No data available
pH	: 5.0 - 7.5
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
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Density	: 1.0085 g/ml
Solubility	: Soluble in water
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: 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:** Not expected to decompose under ambient conditions.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on Toxicological Effects**

Acute Toxicity: Not classified

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 g/m ³ (Exposure time: 1 h)
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	140 - 340 mg/kg

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Hydrochloric acid (7647-01-0)

LD50 Dermal Rabbit > 5010 mg/kg

Skin Corrosion/Irritation: Not classified (pH: 5.0 - 7.5)

Serious Eye Damage/Irritation: Not classified (pH: 5.0 - 7.5)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Hydrochloric acid (7647-01-0)

IARC group 3

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

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.

Chronic Symptoms: None known.

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])

NOEC Chronic Fish 252 mg/l (Species: Pimephales promelas)

Sodium hydroxide (1310-73-2)

LC50 Fish 1 45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

EC50 Daphnia 1 40 mg/l

Hydrochloric acid (7647-01-0)

LC50 Fish 1 7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)

12.2. Persistence and Degradability

Heparin Sodium Injection, USP (preservative free)

Persistence and Degradability Not established.

12.3. Bioaccumulative Potential

Heparin Sodium Injection, USP (preservative free)

Bioaccumulative Potential Not established.

Sodium chloride (7647-14-5)

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BCF Fish 1	(no bioaccumulation)
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12.4. Mobility in Soil No additional information available

12.5. 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.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Heparin, sodium salt (9041-08-1)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

15.2. US State Regulations

Sodium hydroxide (1310-73-2)

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U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List

Hydrochloric acid (7647-01-0)

U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 04/22/2019
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H290	May be corrosive to metals
H301	Toxic if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

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.

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