

Esmolol Hydrochloride in Sodium Chloride Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Esmolol Hydrochloride in Sodium Chloride Injection
Other means of identification : 2,500 mg per 250 mL (10 mg/mL), NDC 55150-420-10
2,000 mg per 100 mL (20 mg/mL), NDC 55150-421-10

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics
279 Princeton Highstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. Label elements

GHS US labeling

No labeling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Water	(CAS-No.) 7732-18-5	> 90	Not classified
Benzenepropanoic acid, 4-[2-hydroxy-3-[(1-methylethyl)amino]propoxy]-, methyl ester, hydrochloride	(CAS-No.) 81161-17-3	1 – 5	Not classified
Sodium chloride	(CAS-No.) 7647-14-5	< 1	Not classified
Hydrochloric acid	(CAS-No.) 7647-01-0	≤ 1	Skin Corr. 1, H314 Eye Dam. 1, H318
Sodium hydroxide	(CAS-No.) 1310-73-2	≤ 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Sodium acetate trihydrate	(CAS-No.) 6131-90-4	≤ 1	Not classified
Acetic acid	(CAS-No.) 64-19-7	≤ 0.1	Flam. Liq. 3, H226 Acute Tox. 4 (Dermal), H312

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

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First-aid measures after eye contact	: In case of contact with eyes, rinse immediately with plenty of water. Seek immediate medical attention.
First-aid measures after ingestion	: Wash mouth with water. Do not induce vomiting unless directed by medical personnel. Seek immediate medical attention.

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

Symptoms/effects after inhalation	: May cause irritation if inhaled.
Symptoms/effects after skin contact	: May cause skin irritation.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: May be harmful if swallowed.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Dry chemical, carbon dioxide, water spray or alcohol-resistant foam.
Unsuitable extinguishing media	: None.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: May form toxic gases during a fire.
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5.3. Advice for firefighters

Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.
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6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
Methods for cleaning up	: Collect spill with suitable absorbent. Dispose in accordance with local, state, and federal requirements.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep container tightly closed.
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Water (7732-18-5)

Not applicable

Sodium chloride (7647-14-5)

Not applicable

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Hydrochloric acid (7647-01-0)		
ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
OSHA	OSHA PEL (Ceiling)	7 mg/m ³
OSHA	OSHA PEL C [ppm]	5 ppm
IDLH	IDLH [ppm]	50 ppm
NIOSH	NIOSH REL (Ceiling)	7 mg/m ³
NIOSH	NIOSH REL C [ppm]	5 ppm
Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m ³
OSHA	OSHA PEL (TWA) [1]	2 mg/m ³
IDLH	IDLH	10 mg/m ³
NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
Acetic acid (64-19-7)		
ACGIH	ACGIH OEL TWA [ppm]	10 ppm
ACGIH	ACGIH OEL STEL [ppm]	15 ppm
OSHA	OSHA PEL (TWA) [1]	25 mg/m ³
OSHA	OSHA PEL (TWA) [2]	10 ppm
IDLH	IDLH [ppm]	50 ppm
NIOSH	NIOSH REL (TWA)	25 mg/m ³
NIOSH	NIOSH REL TWA [ppm]	10 ppm
NIOSH	NIOSH REL (STEL)	37 mg/m ³
NIOSH	NIOSH REL STEL [ppm]	15 ppm
Sodium acetate trihydrate (6131-90-4)		
Not applicable		
Benzenepropanoic acid, 4-[2-hydroxy-3-[(1-methylethyl)amino]propoxy]-, methyl ester, hydrochloride (81161-17-3)		
Not applicable		

8.2. Exposure controls

Appropriate engineering controls	: Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection	: Use suitable protective gloves to minimize skin contact.
Eye protection	: Wear safety glasses or goggles.
Skin and body protection	: Wear suitable working clothes.
Respiratory protection	: Wear NIOSH approved respirator if workplace exposure limits may be exceeded.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Color	: Colorless
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available

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Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: completely soluble.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Do not freeze.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg
Sodium chloride (7647-14-5)	
LD50 oral rat	3 g/kg
LD50 dermal rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation - Rat	> 42 g/m ³ (Exposure time: 1 h)
ATE US (oral)	3000000 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 oral rat	238 – 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 Inhalation - Rat	1.68 mg/l (Exposure time: 1 h)
ATE US (oral)	238 mg/kg body weight
ATE US (vapors)	1.68 mg/l/4h
ATE US (dust, mist)	1.68 mg/l/4h
Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg

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Acetic acid (64-19-7)	
LD50 oral rat	3310 mg/kg
LD50 dermal rabbit	1060 mg/kg
LC50 Inhalation - Rat	11.4 mg/l/4h
ATE US (oral)	3310 mg/kg
ATE US (dermal)	1060 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3 - Not classifiable

Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Sodium chloride (7647-14-5)	
LC50 - Fish [1]	5560 – 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [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 - Crustacea [2]	340.7 – 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Sodium hydroxide (1310-73-2)	
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

Acetic acid (64-19-7)	
LC50 - Fish [1]	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 - Fish [2]	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Sodium chloride (7647-14-5)	
BCF - Fish [1]	(no bioaccumulation)

Acetic acid (64-19-7)	
Partition coefficient n-octanol/water (Log Pow)	-0.31 (at 20 °C)

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
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)
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Acetic acid (64-19-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	5000 lb

15.2. US State regulations

Hydrochloric acid (7647-01-0)	
U.S. - Massachusetts - Right To Know List	
U.S. - Minnesota - Hazardous Substance List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Sodium hydroxide (1310-73-2)	
U.S. - Massachusetts - Right To Know List	
U.S. - Minnesota - Hazardous Substance List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Acetic acid (64-19-7)	
U.S. - Massachusetts - Right To Know List	
U.S. - Minnesota - Hazardous Substance List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1

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Skin Corr. 1	Skin corrosion/irritation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage

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.