

Bupivacaine HCl Injection USP

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Bupivacaine HCl Injection USP
Other means of identification : Preservative-Free
0.25% 10 mL 25s NDC 55150-167-10, 30 mL 25s NDC 55150-168-30, 0.5% 10 mL 25s NDC 55150-169-10, 30 mL 25s NDC 55150-170-30, 0.75% 10 mL 25s NDC 55150-171-10, 30 mL 25s NDC 55150-172-30

Multi-Dose
0.25% 50 mL 25s NDC 55150-249-50, 0.5% 50 mL 25s NDC 55150-250-50

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-Hightstown Rd.
E. Windsor, NJ 088520
T 888-238-7880

1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Skin Irrit. 2 H315
Eye Irrit. 2 H319

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

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS07

Signal word (GHS-US) : Warning
Hazard statements (GHS-US) : H315 - Causes skin irritation
H319 - Causes serious eye irritation
Precautionary statements (GHS-US) : P264 - Wash thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302+P352 - If on skin: Wash with plenty of water
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P332+P313 - If skin irritation occurs: Get medical advice/attention
P337+P313 - If eye irritation persists: Get medical advice/attention
P362+P364 - Take off contaminated clothing and wash it before reuse

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

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3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Bupivacaine hydrochloride	(CAS No) 18010-40-7	0.25 - 0.75	Not classified
Excipients:			
Sodium chloride (adjust tonicity)	(CAS No) 7647-14-5	< 1	Not classified
Sodium hydroxide (adjust pH)	(CAS No) 1310-73-2	< 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Hydrochloric acid (adjust pH)	(CAS No) 7647-01-0	< 1	Acute Tox. 3 (Inhalation:gas), H331 Skin Corr. 1A, H314
Methylparaben (preservative - Multi-Dose only)	(CAS No) 99-76-3	0.1	Aquatic Chronic 3, H412

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 : Under normal conditions of intended use, this material is not expected to be an inhalation hazard. No special first aid needed.
- First-aid measures after skin contact : Wash contact areas with soap and water. Get medical attention if irritation develops and persists.
- First-aid measures after eye contact : Rinse with water. Get medical attention if irritation develops and persists.
- First-aid measures after ingestion : Rinse mouth thoroughly. No harmful effects expected in amounts likely to be ingested by accident.

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

- Symptoms/injuries after inhalation : Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
- Symptoms/injuries after skin contact : Causes skin irritation.
- Symptoms/injuries after eye contact : Causes serious eye irritation.
- Symptoms/injuries after ingestion : May cause discomfort 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 : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.

5.3. Advice for firefighters

- Protection during firefighting : Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : No special measures required.

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 : Absorb spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations.

6.4. Reference to other sections

No additional information available

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged and repeated contact. Wear appropriate personal protective equipment.
Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Bupivacaine hydrochloride (18010-40-7)

Not applicable

Sodium chloride (7647-14-5)

Not applicable

Sodium hydroxide (1310-73-2)

ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
IDLH	US IDLH (mg/m ³)	10 mg/m ³
NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³

Hydrochloric acid (7647-01-0)

ACGIH	ACGIH Ceiling (ppm)	2 ppm
OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm
IDLH	US IDLH (ppm)	50 ppm
NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm

Methylparaben (99-76-3) (Multi-Dose only)

Not applicable

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : No protection is ordinarily required under normal conditions of use.
Eye protection : No protection is ordinarily required under normal conditions of use.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : No protection is ordinarily required under normal conditions of use.

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 : 4 - 6.5
Melting point : No data available
Freezing point : No data available
Boiling point : 100 °C (212 °F)
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : No data available

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Flammability (solid, gas)	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Vapor pressure	: No data available
Relative density	: 1.004 @ 20 °C (68 °F)
Relative vapor density at 20 °C	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: 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

Excessive heat. Freezing. Sunlight.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Carbon oxides. Carbon dioxide. Nitrogen oxides. Hydrochloric acid.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Sodium chloride (7647-14-5)	
LD50 oral rat	3 g/kg
LC50 inhalation rat (mg/l)	> 42 g/m ³ (Exposure time: 1 h)
ATE US (oral)	3000000 mg/kg
Sodium hydroxide (1310-73-2)	
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 oral rat	238 - 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 inhalation rat (mg/l)	1.68 mg/l (Exposure time: 1 h)
ATE US (gases)	781 ppmV/4h
Methylparaben (99-76-3) (Multi-Dose only)	
ATE US (oral)	2100 mg/kg

Skin corrosion/irritation : Causes skin irritation.
pH: 4 - 6.5

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Serious eye damage/irritation	: Causes serious eye irritation. pH: 4 - 6.5
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Hydrochloric acid (7647-01-0)

IARC group	3 - Not classifiable
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Reproductive toxicity	: Not classified
Specific target organ toxicity – single exposure	: Not classified
Specific target organ toxicity – 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 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 - 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])
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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Sodium chloride (7647-14-5)

BCF fish 1	(no bioaccumulation)
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12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on the global warming	: No known effects from this product.
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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.
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SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not a dangerous good as defined in transport regulations

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
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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)

Methylparaben (99-76-3) (Multi-Dose only)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

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

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

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
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