

Bupivacaine HCl Injection USP

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Bupivacaine HCl Injection USP
Other means of identification : 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

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
6 Wheelling Road
Dayton, NJ 08810
T 609-642-1136

1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

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. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Bupivacaine hydrochloride	(CAS No) 18010-40-7	0.25 - 0.75	Not classified

Full text of H-phrases: 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.
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 : Prolonged skin contact may cause irritation.
Symptoms/injuries after eye contact : Direct contact with eyes may cause temporary irritation.
Symptoms/injuries after ingestion : May cause discomfort if swallowed.

Bupivacaine HCl Injection USP

Safety Data Sheet

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

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)	
ACGIH	Not applicable
OSHA	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

Bupivacaine HCl Injection USP

Safety Data Sheet

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
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
Skin corrosion/irritation	: Not classified pH: 4 - 6.5
Serious eye damage/irritation	: Not classified pH: 4 - 6.5
Respiratory or skin sensitization	: Not classified

Bupivacaine HCl Injection USP

Safety Data Sheet

Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
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

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on the global warming : No known ecological damage caused by this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste 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 a dangerous good as defined in transport regulations

SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

15.2. US State regulations

No additional information available

SECTION 16: Other information

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