

Ropivacaine hydrochloride injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Ropivacaine hydrochloride injection
Other means of identification : NDC 55150-195-20 (40 mg/20mL Single Dose Vials)
NDC 55150-196-99 (200 mg/100 mL Single Dose Infusion Bottles)
NDC 55150-197-20 (100 mg/20 mL Single Dose Vials)
NDC 55150-198-30 (150 mg/30 mL Single Dose Vials)
NDC 55150-199-20 (150 mg/20 mL Single Dose Vials)
NDC 55150-200-10 (100 mg/10 mL Single Dose Vials)
NDC 55150-201-20 (200 mg/20 mL Single Dose Vials)

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: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Eye Irrit. 2A H319
STOT RE 2 H373

Full text of classification categories and H statements : see section 16

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS07

GHS08

Signal word (GHS-US) : Warning

Hazard statements (GHS-US) : H319 - Causes serious eye irritation
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements (GHS-US) : P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P314 - Get medical advice/attention if you feel unwell
P337+P313 - If eye irritation persists: Get medical advice/attention
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

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SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	GHS-US classification
(2S)-N-(2,6-Dimethylphenyl)-1-propylpiperidine-2-carboxamide	(CAS No) 132112-35-7	0.2 - 1	Eye Dam. 1, H318

Full text of classification categories and H statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
First-aid measures after skin contact	: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
First-aid measures after eye contact	: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
First-aid measures after ingestion	: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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

Symptoms/injuries after inhalation	: None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of this product.
Symptoms/injuries after skin contact	: None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.
Symptoms/injuries after eye contact	: Causes serious eye irritation. May produce numbness and blurred vision.
Symptoms/injuries after ingestion	: Ingestion may cause numbness of the tongue and anesthetic effects on the stomach.

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.
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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	: No special measures required.
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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	: Absorb any liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local 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 : No special handling required for hazard control under conditions of normal product use.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

(2S)-N-(2,6-Dimethylphenyl)-1-propylpiperidine-2-carboxamide (132112-35-7)

Not applicable

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection : Use protective goggles if eye contact is likely.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, wear NIOSH approved respirator when handling.

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 : 4.5 - 6 (1% solution)

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

Vapor pressure : No data available

Relative vapor density at 20 °C : No data available

Relative density : 1.002 - 1.005 (25°C)

Solubility : At 25°C ropivacaine HCl has a solubility of 53.8 mg/mL in water. It is freely soluble in methanol and soluble in isopropanol.

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

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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

Not determined.

10.5. Incompatible materials

Strongly alkaline conditions.

10.6. Hazardous decomposition products

During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO_x), nitrogen oxides (NO_x), and hydrogen chloride.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified. None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: Not classified. None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of this product.
Germ cell mutagenicity	: Not classified. Weak mutagenic activity was seen in the mouse lymphoma test. Mutagenicity was not noted in other assays.
Carcinogenicity	: Not classified. Long term studies in animals of most local anesthetics, including ropivacaine, to evaluate the carcinogenic potential have not been conducted.
Reproductive toxicity	: Not classified. Studies conducted with ropivacaine in rats did not demonstrate an effect on fertility or general reproductive performance over 2 generations. Ropivacaine was administered subcutaneously to rabbits on gestation days 6-18 at dosages of 1.3, 4.2, or 13 mg/kg/day. Similarly, ropivacaine was given subcutaneously to rats on gestation days 6-15 at dosages of 5.3, 11 and 26 mg/kg/day. No teratogenic effects were observed in rats or rabbits at the highest dosages tested. In two pre-natal and post-natal studies, female rats were treated daily from day 15 of gestation to day 20 postpartum with subcutaneous dosages of 5.3, 11 and 26 mg/kg/day. There were no treatment-related effects on late fetal development, parturition, lactation, neonatal viability, or growth of the offspring. In another study, male rats were dosed daily for 9 weeks before mating and during mating. Females were dosed daily for 2 weeks before mating and then during the mating, pregnancy, and lactation, up to day 42 post coitus. At a dosage of 23 mg/kg/day, an increased loss of pups was observed during the first 3 days postpartum. The finding was considered secondary to impaired maternal care due to maternal toxicity.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: May cause damage to organs through prolonged or repeated exposure. Based on clinical use, possible target organs include the nervous system, cardiovascular system, and skin.
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Not determined for product. Information for ropivacaine hydrochloride is as follows:

*LC50(96 hr) = 38 mg/L in fish.

*EC50(48 hr) = 34 mg/L in *Daphnia magna*

*EC50(72 hr) = 59 mg/L in green algae.

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12.2. Persistence and degradability

Not readily biodegradable.

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 effects from 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 applicable

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

Full text of H-phrases:

Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
H318	Causes serious eye damage
H319	Causes serious eye irritation
H373	May cause damage to organs through prolonged or repeated exposure

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