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### Section 1 - Identification

- (a) **Product Identifier:** Ropivacaine Hydrochloride Injection, USP
- (b) **Product Code:** 25021-652, 25021-653, 25021-671.
- Common/Trade Name:** Naropin
- Chemical Name:** (S)-(-)-1-Propylpiperidine-2-carboxylic acid (2,6-dimethylphenyl)-amide hydrochloride monohydrate
- Chemical Family:** Amino Amide
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Infusion Bags.
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

### Section 2 - Hazards Identification


- (a) **Classification:** GHS:  
Skin Sensitization (Category 1)  
Respiratory Sensitization (Category 1)


**HMIS Rating**

Health Hazard	2
Flammability	0
Physical Hazard	0


**NFPA Rating**

Health Hazard	2
Fire Hazard	0
Reactivity Hazard	0

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<b>(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):</b>	<b>(c) Description of Hazards:</b>
<u>Signal Word:</u> <u>Symbols:</u>	DANGER 
<u>Hazard Statements:</u> H317 H334	<ul style="list-style-type: none"> <li>- May cause an allergic skin reaction.</li> <li>- May cause allergy or asthma symptoms or breathing difficulties if inhaled.</li> </ul>
<u>Precautionary Statements:</u> P261 P272  P280  P284  P302+353 P304+340  P332+313 P342+311  P362+364 P501	<ul style="list-style-type: none"> <li>- Avoid breathing dust/fumes/gas/mist/vapors/spray.</li> <li>- Contaminated work clothing should not be allowed out of the workplace.</li> <li>- Wear protective gloves/protective clothing/eye protection/face protection</li> <li>- In case of inadequate ventilation] wear respiratory protection</li> <li>- IF ON SKIN: Wash with plenty of water</li> <li>- IF INHALED: Removed victim to fresh air and keep at rest in a position comfortable for breathing</li> <li>- If skin irritation occurs: Get medical advice/attention.</li> <li>- If experiencing respiratory symptoms: Call a POISON CENTER/doctor</li> <li>- Take of contaminated clothing and wash it before reuse</li> <li>- Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.</li> </ul>


**(d) Unknown Acute Toxicity: N/A**

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### Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(S)-(-)-1-Propylpiperidine-2-carboxylic acid (2,6-dimethylphenyl)-amide hydrochloride monohydrate	Ropivacaine Hydrochloride	2 mg/mL and 5mg/mL	132112-35-7	N/A
Sodium Chloride	Sodium Chloride	8.0mg/mL and 8.6 mg/mL	7647-14-5	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s. to pH	1310-73-2	N/A
Hydrochloric acid	Hydrochloric acid	q.s. to adjust pH	7647-01-0	N/A
Water for Injection	Water for Injection	q.s. to 1 mL	7732-18-5	N/A

(a) Common Name / Synonym	Content (mg/bag)		
	Content (mg/mL)	100 mL	200 mL
Ropivacaine Hydrochloride	2	200	400
Sodium Chloride	8.6	860	1720
Hydrochloric acid	q.s. to adjust pH	q.s. to adjust pH	q.s. to adjust pH
Sodium Hydroxide	q.s. to adjust pH	q.s. to pH	q.s. to pH
Water for Injection	q.s. to 1 mL	q.s. to 100 mL	q.s. to 200 mL

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(a) Common Name / Synonym	Content (mg/bag)		
	Content (mg/mL)	100 mL	200 mL
Ropivacaine Hydrochloride	5	500	1000
Sodium Chloride	8.0	800	1600
Hydrochloric acid	q.s. to adjust pH	q.s. to adjust pH	q.s. to adjust pH
Sodium Hydroxide	q.s. to adjust pH	q.s. to pH	q.s. to pH
Water for Injection	q.s. to 1 mL	q.s. to 100 mL	q.s. to 200 mL

(a) Common Name / Synonym	Quantity per mL	
	0.2% w/v	0.5% w/v
Ropivacaine Hydrochloride	2 mg	5mg
Sodium Chloride	8.6 mg	8 mg
Hydrochloric acid	q.s. to adjust pH	q.s. to adjust pH
Sodium Hydroxide	q.s. to pH	q.s. to pH
Water for Injection	q.s. to 1 mL	q.s. to 1 mL

#### Section 4 - First Aid Measures

- Eye Exposure:** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
- Skin Exposure:** Wash off with soap and plenty of water. Consult a physician.
- Ingestion:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Do not induce vomiting. Consult a physician.
- Injection:** Cardiac arrhythmia or arrest may occur. Prolonged efforts may be required to improve the probability of a successful resuscitation.
- Inhalation:** If Inhaled, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

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**Section 5 –Fire-fighting Measures**

- (a) **Extinguishing Media**      Water spray, foam, dry chemical, or CO2.
- (b) **Hazardous Combustion Products:**      Not flammable or combustible.
- (c) **Special Protective Equipment / Precautions:**      Wear self contained breathing apparatus for firefighting if necessary.

**Section 6 - Accidental Release Measures**


- Spill:**      Clear up spillages. Transfer to a container for disposal. Wash the spillage area with water.
- Release to Air:**      If aerosolized, reduce exposures by ventilating area.
- Release to Water:**      Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

**Section 7 - Handling and Storage**

- General Handling:**      Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
- Storage Conditions:**      Store at 20° to 25°C (68° to 77°F); excursions permitted between 15°C and 30°C (between 59°F and 86°F). Discard unused portion promptly

**Section 8 - Exposure Controls / Personal Protection**


- (a) **Exposure Limits**  
  
No ACGIH TLV or OSHA PEL assigned.
- (b) **Engineering Controls**  
  
Ventilation:      Good general ventilation should be sufficient to control airborne levels.
- (c) **Individual Protection Measures**

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Respiratory Protection:	Use a negative pressure air purifying respirator (half face mask) with filter class A if the risk assessment does not support the selection of other protection.
Eye Protection:	Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection
Hand Protection	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Skin Protection:	Avoid contact with the skin. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions
Other Protective Equipment:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.
Additional Exposure Precautions:	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

### Section 9 - Physical and Chemical Properties

(a)	<b>Appearance</b>	Clear, colorless aqueous solution
(b)	<b>Odor</b>	No Odor
(c)	<b>Odor Threshold</b>	None
(d)	<b>pH</b>	4.0 to 6.0
(e)	<b>Melting Point:</b>	Not applicable
(f)	<b>Initial Boiling Point:</b>	Not available
(g)	<b>Flash Point</b>	Not available
(h)	<b>Evaporation Rate:</b>	Not available
(i)	<b>Flammability</b>	Not available
(j)	<b>Upper Lower Flammability or Explosion Limits</b>	Not available
(k)	<b>Vapor Pressure:</b>	Not available
(l)	<b>Vapor Density:</b>	Not available
(m)	<b>Relative Density</b>	1.002 to 1.005 at 25°C

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<b>(n)</b>	<b>Solubility(ies)</b>	53.8 mg/mL in water at 25°C. Solubility is limited at pH above 6
<b>(o)</b>	<b>Partition Coefficient: n-octanol/water</b>	14:1 between n-octanol and phosphate buffer
<b>(p)</b>	<b>Auto-ignition Temperature</b>	Not available
<b>(q)</b>	<b>Decomposition Temperature</b>	Not available
<b>(r)</b>	<b>Viscosity</b>	Not available

### Section 10 - Stability and Reactivity

<b>(a)</b>	<b>Reactivity</b>	No known reactivity hazard under normal conditions
<b>(b)</b>	<b>Chemical Stability</b>	Stable under recommended storage conditions.
<b>(c)</b>	<b>Possibility of Hazardous Reactions</b>	no data available
<b>(d)</b>	<b>Conditions to Avoid</b>	no data available
<b>(e)</b>	<b>Incompatible Materials</b>	Strong oxidizing agents and alkalis
<b>(f)</b>	<b>Hazardous Decomposition Products</b>	Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Hydrogen chloride gas

### Section 11 - Toxicological Information

<b>(a)</b>	<b>Likely Routes of Exposure</b>	Ingestion, Inhalation, skin, eye
<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	May cause tingling/numbness in exposed areas (paresthesia). High atmospheric concentrations may lead to anesthetic effects. May produce numbness of the tongue and anesthetic effects on the stomach.
<b>(c)</b>	<b>Delayed and immediate effects and also chronic effects from short and long term exposure</b>	Chronic effects are unlikely. Repeated and/or prolonged contact may cause irritation.

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**(d) Acute Toxicity**

Component	Type	Route	Species	Dosage
Ropivacaine Hydrochloride	LD <sub>50</sub>	Parenteral	Rat	56 mg/Kg

**(e) Hazardous Chemical Listings**

NTP: No                  IARC: No                  OSHA: No                  ACGIH: No

**Section 12 - Ecological Information**

<b>(a) Ecotoxicity</b>	EC50 green algae 72 H 59 mg/l EC50 Daphnia magna 48 H 34 mg/l EC50 (microtox test) 15 MIN > 1 000 mg/l LC50 Zebra Fish 96 H 38 mg/l
<b>(b) Persistence and degradability</b>	Not rapidly degradable
<b>(c) Bioaccumulative potential</b>	The substance has low potential for bioaccumulation
<b>(d) Mobility in soil</b>	Soluble in water
<b>(e) Other Adverse Effects</b>	No data available

**Section 13 - Disposal Considerations**


**Waste Treatment Methods:** Disposal should be in accordance with local, state, or national legislation.

**Contaminated Packaging:** Empty container will retain product residue. Observe all hazard precautions

**Section 14 - Transport Information**

<b>(a) UN Number</b>	Not dangerous goods
<b>(b) UN Proper Shipping Name</b>	Not dangerous goods
<b>(c) Transport Hazard Class(es)</b>	Not dangerous goods
<b>(d) Packing Group</b>	Not dangerous goods
<b>(e) Environmental Hazards</b>	Not dangerous goods



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<b>(f)</b>	<b>Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</b>	Not dangerous goods
<b>(g)</b>	<b>Special Precautions</b>	Not dangerous goods

**Section 15 - Regulatory Information**

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations:**

TSCA: This product is a drug and is exempt from TSCA regulation

CERCLA: Not on this list

SARA 302: Not on this list

SARA 313: No chemicals subject to SARA Section 313 reporting requirements

SARA 311/312 Hazards: Acute Health Hazards

California Proposition 65: No warnings are necessary

**Section 16 - Other Information**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.

1901 N. Roselle Rd, Suite 700


Schaumburg, IL 60195

847-908-1600

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)

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CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)