

# SAFETY DATA SHEET

## 1. PRODUCT

### 1.1 Product identifiers

Name: Ropivacaine hydrochloride monohydrate

CAS-No.: 132112-35-7

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

Identified uses : Laboratory chemicals, Manufacture of substances

## 2. HAZARDS IDENTIFICATION


### 2.1 Classification of the substance or mixture

#### GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Serious eye damage (Category 1), H318

For the full text of the H-Statements mentioned in this Section, see Section 16.

### 2.2 GHS Label elements, including precautionary statements

|                            |   |
|----------------------------|---|
| Pictogram                  |   |
| Signal word                | Danger  |
| Hazard statement(s)        | H318 Causes serious eye damage.   |
| Precautionary statement(s) | P280 Wear protective gloves/ eye protection/ face protection.<br>P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P310 Immediately call a POISON CENTER or doctor/ physician. |

### 2.3 Hazards not otherwise classified (HNOC) or not covered by GHS

No data available

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Synonyms: Naropin  
(S)-N-(2,6-dimethylphenyl)-1-propylpiperidine-2-carboxamide hydrochloride monohydrate  
(2S)-N-(2,6-dimethylphenyl)-1-propyl-2-piperidinecarboxamide hydrochloride monohydrate

Formula:  $C_{17}H_{26}N_2O \cdot HCl \cdot H_2O$

CAS-No.: 132112-35-7

#### Hazardous components

| Component                                    | Classification   | Concentration |
|--|------------------|---------------|
| <b>ROPIVACAINE HYDROCHLORIDE MONOHYDRATE</b> |                  |               |
|  | Eye Dam. 1; H318 | -             |

For the full text of the H-Statements mentioned in this Section, see Section 16.

## 4. FIRST AID MEASURES

#### 4.1 Description of first aid measures

|   |
|---|
| <b>General advice</b>   |
| Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.       |
| <b>If inhaled</b>   |
| If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician. |
| <b>In case of skin contact</b>  |
| Wash off with soap and plenty of water. Consult a physician.  |
| <b>In case of eye contact</b>   |
| Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.                          |
| <b>If swallowed</b>   |
| Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.             |

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

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

#### 4.2 Indication of any immediate medical attention and special treatment needed

no data available

---

### 5. FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

##### Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

#### 5.2 Special hazards arising from the substance or mixture

no data available

#### 5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

#### 5.4 Further information

no data available

---

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For personal protection see section 8.

#### 6.2 Environmental precautions

Do not let product enter drains.

#### 6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

#### 6.4 Reference to other sections

For disposal see section 13.

---

### 7. HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

## 7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: 2 - 8 °C

## 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

---

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### Components with workplace control parameters

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### Personal protective equipment

|                                   |   |
|-----------------------------------|---|
| Eye/face protection               | Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).  |
| Skin protection                   | Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.  |
| Body Protection                   | Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.   |
| Respiratory protection            | Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). |
| Control of environmental exposure | Do not let product enter drains.  |

---

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

|  |                   |
|--|-------------------|
| Appearance                                   | Form: solid       |
| Odour  | no data available |
| Odour Threshold                              | no data available |
| pH   | no data available |
| Melting point/freezing point                 | no data available |
| Initial boiling point and boiling range      | no data available |
| Flash point                                  | no data available |
| Evaporation rate                             | no data available |
| Flammability (solid, gas)                    | no data available |
| Upper/lower flammability or explosive limits | no data available |
| Vapour pressure                              | no data available |
| Vapour density                               | no data available |
| Relative density                             | no data available |
| Water solubility                             | no data available |
| Partition coefficient: n-octanol/water       | log Pow: 3.169    |

|                           |                   |
|---------------------------|-------------------|
| Auto-ignition temperature | no data available |
| Decomposition temperature | no data available |
| Viscosity                 | no data available |
| Explosive properties      | no data available |
| Oxidizing properties      | no data available |

## 9.2 Other safety information

no data available

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

no data available

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

no data available

### 10.4 Conditions to avoid

no data available

### 10.5 Incompatible materials

Strong oxidizing agents

### 10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NO<sub>x</sub>), Hydrogen chloride gas

Other decomposition products - no data available

In the event of fire: see section 5

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

|   |
|---|
| <b>Acute toxicity</b>   |
| no data available<br>Inhalation: no data available<br>Dermal: no data available<br>no data available  |
| <b>Skin corrosion/irritation</b>  |
| no data available   |
| <b>Serious eye damage/eye irritation</b>  |
| no data available   |
| <b>Respiratory or skin sensitisation</b>  |
| no data available   |
| <b>Germ cell mutagenicity</b>   |
| no data available   |
| <b>Carcinogenicity</b>  |
| IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.<br>ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.<br>NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.<br>OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA. |

|   |
|---|
| <b>Reproductive toxicity</b>  |
| no data available<br>no data available  |
| <b>Specific target organ toxicity -single exposure</b>  |
| no data available   |
| <b>Specific target organ toxicity -repeated exposure</b>  |
| no data available   |
| <b>Aspiration hazard</b>  |
| no data available   |
| <b>Additional Information</b>   |
| RTECS: Not available<br>To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. |

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

no data available

### 12.2 Persistence and degradability

no data available

### 12.3 Bioaccumulative potential

no data available

### 12.4 Mobility in soil

no data available

### 12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

### 12.6 Other adverse effects

no data available

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

|  |
|--|
| <b>Product</b>   |
| Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. |
| <b>Contaminated packaging</b>  |
| Dispose of as unused product.  |

## 14. TRANSPORT INFORMATION

### DOT (US)

Not dangerous goods

### IMDG

Not dangerous goods

### IATA

Not dangerous goods

## 15. REGULATORY INFORMATION

### SARA 302 Components

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

### SARA 313 Components

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### SARA 311/312 Hazards

Acute Health Hazard

### Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

### Pennsylvania Right To Know Components

| Component                             | CAS-No.     | Revision Date |
|---------------------------------------|-------------|---------------|
| ROPIVACAINE HYDROCHLORIDE MONOHYDRATE | 132112-35-7 |               |

### New Jersey Right To Know Components

| Component                             | CAS-No.     | Revision Date |
|---------------------------------------|-------------|---------------|
| ROPIVACAINE HYDROCHLORIDE MONOHYDRATE | 132112-35-7 |               |

### California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

---

## 16. OTHER INFORMATION

### Full text of H-Statements referred to under sections 2 and 3.

Eye Dam. Serious eye damage

H318 Causes serious eye damage.

### HMIS Rating

Health hazard: 2

Chronic Health Hazard:

Flammability: 0

Physical Hazard 0

### NFPA Rating

Health hazard: 2

Fire Hazard: 0

Reactivity Hazard: 0

---