



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
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## Safety Data Sheet (MSDS)

(According to GB/T 16483 and GB/T 17519; Adapts to GHS, IMDG, IATA Standards)

**Product Name: Ropivacaine Hydrochloride** **Revision Date: 20 FEB 2026**

### SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

#### 1.1 Product Identifiers

- Product Name: Ropivacaine Hydrochloride
- Product Number: RH-20260220
- Brand: SIGALD
- CAS-No.: 84057-95-4
- Synonyms: (S)-N-(2,6-Dimethylphenyl)-1-propylpiperidine-2-carboxamide hydrochloride; Ropivacaine HCl

#### 1.2 Details of the supplier of the safety data sheet

- Company: NEWAY SINOPHC TECH. LIMITED
- Address: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
- Telephone: +86-021-50350029
- Fax: +86-021-50350029

#### 1.3 Emergency telephone

- Emergency Phone #: +86-021-50350029 (CHEMTREC)

#### 1.4 Relevant Identified Uses and Uses Advised Against

- Identified Uses: Pharmaceutical intermediate for long-acting local anesthetic drugs; raw material for injectable local anesthetic formulations (spinal, epidural, peripheral nerve block); veterinary drug raw material for large animal surgical local anesthesia; pharmaceutical R&D reference reagent.
- Uses Advised Against: Not for direct human consumption; no non-pharmaceutical industrial use; avoid use in cosmetics/food products; do not use in unformulated injectable preparations.

### SECTION 2: Hazards Identification

#### 2.1 GHS Classification

- Acute toxicity, oral (Category 4); Skin irritation (Category 2); Serious eye irritation (Category 2); Specific target organ toxicity - single exposure (Nervous system/Cardiovascular system, Category 3)

#### 2.2 GHS Label Elements

- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H315: Causes skin irritation
  - H319: Causes serious eye irritation
  - H335: May cause respiratory irritation
  - H373: May cause damage to organs (Nervous/Cardiovascular) through prolonged or repeated exposure
- Precautionary Statements:
  - P264: Wash skin thoroughly after handling
  - P270: Do not eat, drink or smoke when using this product
  - P280: Wear protective gloves/eye protection/face protection
  - P301+P312: If swallowed: Call a POISON CENTER or doctor if you feel unwell
  - P302+P352: If on skin: Wash with plenty of water and soap
  - P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing
  - P330: Rinse mouth
  - P332+P313: If skin irritation occurs: Get medical advice/attention
  - P337+P313: If eye irritation persists: Get medical advice/attention
  - P362: Take off contaminated clothing and wash before reuse
  - P405: Store locked up
  - P501: Dispose of contents/container to an approved waste disposal plant

## 2.3 Physical and Chemical Hazards

- Non-combustible; no explosive/oxidizing properties under normal storage/handling. No hazardous polymerization will occur.
- Acute: Swallowing causes dizziness, nausea, cardiovascular/neurological disturbance; skin contact leads to redness/itching; eye contact causes severe conjunctival redness/tearing; dust inhalation causes cough/headache/numbness.
- Chronic: Prolonged exposure may cause mild neurological symptoms (numbness) or cardiac conduction slight abnormality in sensitive individuals.
- Not classified as hazardous environmental substance; low acute toxicity to aquatic organisms (96h LC<sub>50</sub> > 250 mg/L for zebrafish); low bioaccumulation potential.
- No additional hazards identified under normal pharmaceutical use conditions.

## SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance**
- Active Ingredient: Ropivacaine Hydrochloride (100%)
- CAS-No.: 84057-95-4
- EC-No.: N/A
- Hazardous components: 100% (Ropivacaine Hydrochloride, GHS Category 4/2/2/3)

## SECTION 4: First Aid Measures

### 4.1 Description of First-Aid Measures

- If Inhaled: Move victim to fresh air, keep at rest in a comfortable breathing position. Call a doctor if cough/numbness/headache persists.
- In Case of Skin Contact: Remove contaminated clothing/shoes, rinse skin with plenty of running water/ mild soap for 10-15 minutes. Seek medical advice if irritation/rash occurs.
- In Case of Eye Contact: Hold eyelids open, rinse thoroughly with running water for **at least 15 minutes**. Remove contact lenses if present. Seek **immediate** medical advice.
- If Swallowed: Do not induce vomiting. Rinse mouth with water. Do not give anything by mouth to an unconscious person. Call a poison center/doctor immediately, even if no symptoms appear.
- Acute: Gastrointestinal discomfort, dizziness, neurological numbness (swallowed); skin redness (contact); eye severe irritation (contact); respiratory irritation/headache (inhalation).
- Delayed: Mild cardiac conduction abnormality or persistent numbness may occur 1-3 hours after excessive exposure.
- Seek urgent medical help for large amount swallowing, persistent eye irritation, inhalation-induced dizziness/numbness, or skin severe rash.

## SECTION 5: Firefighting Measures

### 5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO<sub>2</sub>), dry chemical powder.
- Unsuitable Extinguishing Media: No limitations of extinguishing agents.
- Non-combustible; slight decomposition at high temperature (>220°C) produces low-toxic amine/aromatic hydrocarbon fumes; no toxic/explosive gases released under normal fire conditions.
- Wear self-contained breathing apparatus (SCBA) and full fire-fighting gear only if large-scale decomposition fumes occur.
- Prevent fire-extinguishing water from entering municipal sewers/natural water bodies (minimal aquatic impact).

## SECTION 6: Accidental Release Measures

### 6.1 Personal Precautions

- Wear N95 dust mask, nitrile protective gloves, chemical splash goggles and disposable lab coat. Ensure good ventilation at spill site; evacuate non-essential personnel.

- Prevent spilled powder from entering sewers/rivers/soil. Cover with inert material to avoid dust spreading and environmental contamination.6.3 Methods and Materials for Containment and Cleaning Up
- Small Spill: Gently sweep up with a clean dry brush, collect into a sealed plastic container for professional disposal. Do not blow/vacuum powder to avoid inhalation.
- Large Spill: Contain with sand/vermiculite, transfer to a sealed HDPE drum with label, hand over to licensed hazardous waste treatment company. Do not wash spill into drains.6.4 Reference to Other SectionsFor waste disposal, see Section 13.

## SECTION 7: Handling and Storage

### 7.1 Precautions for Safe Handling

- Operate in a well-ventilated dust-free area/fume hood; avoid dust generation during weighing/mixing.
- Wear specified PPE for all handling operations; no eating/drinking/smoking in work area.
- Wash hands/face thoroughly with soap and water after handling; avoid contact with strong acids/bases/oxidizing agents.7.2 Conditions for Safe Storage

- Storage Conditions: Store in a cool/dry/dark pharmaceutical warehouse, temperature  $\leq 25^{\circ}\text{C}$ , relative humidity  $\leq 60\%$ . Keep container tightly sealed to prevent hygroscopy/contamination.
- Incompatibilities: Strong acids ( $\text{HCl}/\text{H}_2\text{SO}_4$ ), strong bases ( $\text{NaOH}/\text{KOH}$ ), oxidizing agents ( $\text{H}_2\text{O}_2/\text{KMnO}_4$ ), heavy metal salts, alkaline pharmaceutical excipients.
- Storage Class (TRGS 510): 10 (Non-Hazardous Solids with irritant properties)
- Shelf Life: 36 months (unopened, under specified conditions).
- Segregation: Store separately from food/feed/cosmetics; store locked up, away from unauthorized access.

## SECTION 8: Exposure Controls/Personal Protection

### 8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal control limit:  $0.2 \text{ mg}/\text{m}^3$  (8-hour TWA, dust).
- Biological Limit Value (BLV): N/A.8.2 Exposure Controls
- Engineering Controls: Local exhaust ventilation (LEV) for dust-generating operations; install dust collection/filtration system to reduce air dust concentration.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical splash goggles (routine handling); goggles + face shield (large-scale weighing/mixing).
  - Skin Protection: Nitrile rubber gloves (thickness  $\geq 0.18 \text{ mm}$ ), impermeable lab coat, protective shoe covers.
  - Respiratory Protection: N95 dust mask (routine); powered air-purifying respirator (PAPR) (high-dust operations).
  - Hand Protection: Replace gloves immediately if damaged/contaminated.

## SECTION 9: Physical and Chemical Properties

9.1 Basic Physical and Chemical Propertiesa) Physical State: Solid (white crystalline powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point:  $144\text{-}148^{\circ}\text{C}$ e) Boiling Point: Not applicable (decomposes before boiling)f) Flammability: Non-combustibleg) Flammability Limits: Not applicableh) Flash Point: Not applicablei) Autoignition Temperature:  $> 450^{\circ}\text{C}$ j) Decomposition Temperature:  $\geq 220^{\circ}\text{C}$  (mild decomposition, no hazardous byproducts)k) pH Value: 4.0-6.0 (1% aqueous solution,  $25^{\circ}\text{C}$ )l) Viscosity: Not applicable (solid)m) Water Solubility: Freely soluble in water ( $\approx 70 \text{ g}/\text{L}$ ,  $25^{\circ}\text{C}$ ); soluble in ethanol/methanol; slightly soluble in acetone/ethern) Partition Coefficient (log P, n-octanol/water): 2.5 ( $25^{\circ}\text{C}$ )o) Vapor Pressure ( $25^{\circ}\text{C}$ ):  $< 0.0001 \text{ hPa}$ p) Density ( $25^{\circ}\text{C}$ ):  $1.31\text{-}1.35 \text{ g}/\text{cm}^3$  (bulk density)q) Particle Size: 95% passing 80 meshr) Explosive Properties: Not explosives) Oxidizing Properties: Nonet) Hygroscopy: Slightly hygroscopic

## SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions ( $\leq 25^{\circ}\text{C}$ , dry, sealed); stable under standard pharmaceutical processing temperature ( $\leq 60^{\circ}\text{C}$ ).10.2 Possibility of



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Hazardous Reactions: No hazardous reactions under normal use/formulation conditions.10.3 Conditions to Avoid: High temperature (>220°C), direct sunlight, high humidity, contact with incompatible materials, strong mechanical shock.10.4 Incompatible Materials: Strong acids/bases, oxidizing agents, heavy metal salts, alkaline excipients, strong reducing agents.10.5 Hazardous Decomposition Products: CO<sub>2</sub>, H<sub>2</sub>O, low-toxic amine fumes (high-temperature combustion/decomposition); no highly toxic products.

## SECTION 11: Toxicological Information

### 11.1 Toxicological Effects

- Acute Toxicity:
  - Oral (Rat, LD<sub>50</sub>): 760 mg/kg (harmful)
  - Dermal (Rabbit, LD<sub>50</sub>): >2000 mg/kg (low dermal toxicity)
  - Inhalation (Rat, LC<sub>50</sub>): >10 mg/m<sup>3</sup> (4-hour exposure, low inhalation toxicity)
- Skin Corrosion/Irritation: Rabbit 4-hour patch test - mild redness/edema (Category 2), reversible within 72 hours.
- Eye Irritation: Rabbit eye test - severe conjunctival redness (Category 2), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild irritation at high dust concentrations (≥5 mg/m<sup>3</sup>).
- Mutagenicity: Ames test/chromosome aberration test - negative; no mutagenic effects.
- Carcinogenicity: IARC Classification - Group 3 (not classifiable as to carcinogenicity to humans).
- Reproductive Toxicity: No adverse reproductive effects in animal tests at low doses (≤40 mg/kg); high doses may cause mild fetal developmental retardation.
- Specific Target Organ Toxicity: Nervous/Cardiovascular systems are main target organs; high dose causes dizziness/numbness/cardiac conduction slight abnormality.

## SECTION 12: Ecological Information

### 12.1 Toxicity

- Fish (Zebrafish, 96h LC<sub>50</sub>): 260 mg/L
- Daphnia (48h EC<sub>50</sub>): 240 mg/L
- Freshwater Algae (72h EC<sub>50</sub>): 290 mg/L
- 12.2 Persistence and Degradability: Biodegradable (BOD<sub>5</sub>/COD = 0.55); degraded by microorganisms in aquatic/soil environments within 28-35 days, no persistent residues.
- 12.3 Bioaccumulative Potential: Low (log P=2.5); no significant bioaccumulation in aquatic organisms/food chain.
- 12.4 Mobility in Soil: Low mobility; adsorbs to soil organic matter (Koc=580), no leaching risk to groundwater.
- 12.5 PBT/vPvB Assessment: Not classified as PBT/vPvB substances.
- 12.6 Other Adverse Effects: No known adverse effects on soil microorganisms/terrestrial plants at low concentrations.

## SECTION 13: Disposal Considerations

### 13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is hazardous waste; dispose by licensed facilities via incineration (combustion products: non-toxic CO<sub>2</sub>/H<sub>2</sub>O).
- Packaging Waste: Rinse with ethanol/water to remove residual powder, dispose as hazardous waste; do not recycle/reuse contaminated packaging.
- Unused Product: Do not discharge to environment; incinerate with professional waste treatment companies in accordance with local regulations.
- Disposal Compliance: Comply with national/local hazardous waste regulations (e.g., China HW02, EU EWC 080105).

## SECTION 14: Transport Information

- 14.1 UN Number: ADR/RID: 3077; IMDG: 3077; IATA-DGR: 3077
- 14.2 UN Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (Ropivacaine Hydrochloride)
- 14.3 Transport Hazard Class: 9 (Miscellaneous hazardous substances and articles)
- 14.4 Packaging Group: III (Minor hazard)
- 14.5 Environmental Hazards: IMDG Marine Pollutant: **No**
- 14.6 Special Precautions for Transport
  - Transport in sealed HDPE pharmaceutical-grade drums with aluminum foil inner lining; affix standard Class 9 hazard labels/product identification labels.

- Transport temperature  $\leq 30^{\circ}\text{C}$ ; avoid direct sunlight/rain/collision/extrusion during transport.
- Do not transport with food/feed/cosmetics/oral pharmaceutical finished products; bulk shipment via specialized hazardous chemical vehicles.
- Comply with ADR/RID, IMDG Code and IATA-DGR for Class 9 substances.

### **SECTION 15: Regulatory Information**

#### 15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 9); Pharmaceutical Raw Material Registration Requirements; Chinese Pharmacopoeia (CP) 2025 compliance.
- EU: REACH (Annex XVII compliant, no SVHC); CLP (GHS Warning); European Pharmacopoeia (EP) 10.0 compliance; IMDG Code (Class 9).
- US: TSCA (listed on Inventory); DOT (Class 9); FDA (pharmaceutical intermediate quality standards); United States Pharmacopoeia (USP) 47 compliance.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law.

#### 15.2 Additional Regulatory Requirements

- Provide English MSDS/COA for customs clearance; apply for hazardous chemical transport document for bulk shipment; provide pharmacopoeia compliance certificates for pharmaceutical production.

### **SECTION 16: Other Information**

- Further Information: This MSDS complies with GB/T 16483, GB/T 17519 and GHS Rev.9, based on current scientific/regulatory knowledge. For professional occupational health/safety use only.
- Revision Date: 20 FEB 2026
- Disclaimer: The supplier is not liable for damage caused by improper use/storage/transport/disposal beyond specified standards and national/international regulations.