



# 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: Prilocaine Hydrochloride** Revision Date: **22 FEB 2026**

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

#### 1.1 Product Identifiers

- Product Name: Prilocaine Hydrochloride
- Product Number: PH-20260222
- Brand: SIGALD
- CAS-No.: 4360-75-4
- Synonyms: (S)-N-(2-Methylphenyl)-2-propylaminopropanamide hydrochloride; Propitocaine hydrochloride

#### 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 amide local anesthetic drugs; raw material for injectable/topical local anesthetic formulations (infiltration, nerve block, surface anesthesia); veterinary drug raw material for animal local anesthesia; pharmaceutical R&D reference reagent.
- Uses Advised Against: Not for direct human consumption/injection in raw form; no non-pharmaceutical industrial use; avoid use in food/cosmetic products without professional formulation.

### 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, 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 system) 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 and handling conditions. No hazardous polymerization will occur.

#### 2.4 Health Hazards



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- Acute: Swallowing causes dizziness, nausea, and nervous system numbness; skin contact leads to mild redness and itching; eye contact causes conjunctival redness and tearing; dust inhalation may cause cough and headache.
- Chronic: Prolonged exposure may cause mild neurological numbness in sensitive individuals; no significant organ damage with proper protection.
- Not classified as a hazardous environmental substance; low acute toxicity to aquatic organisms (96h LC<sub>50</sub> > 350 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: Prilocaine Hydrochloride (100%)
- CAS-No.: 4360-75-4
- EC-No.: N/A
- Hazardous components: 100% (Prilocaine Hydrochloride, GHS Category 4/2/2/3)

## SECTION 4: First Aid Measures

### 4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air and keep at rest in a position comfortable for breathing. Call a doctor if cough or dizziness persists for more than 1 hour.
- In Case of Skin Contact: Immediately remove all contaminated clothing and shoes. Rinse skin with plenty of running water and mild soap for 10-15 minutes. Apply mild emollient if irritation occurs.
- In Case of Eye Contact: Hold eyelids open and rinse thoroughly with plenty of running water for at least 15 minutes. Remove contact lenses if present. Seek medical advice if redness lasts more than 24 hours.
- If Swallowed: Do not induce vomiting. Rinse mouth with water. Call a poison center or doctor immediately if large amounts are swallowed or abdominal pain occurs.

### 4.2 Most Important Symptoms and Effects

- Acute: Gastrointestinal discomfort, limb numbness (swallowed); skin erythema (contact); eye irritation, tearing (contact); respiratory tract discomfort (inhalation).
- Delayed: Mild neurological numbness may occur 1-2 hours after excessive exposure; no other known delayed toxic effects.

## 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.

### 5.2 Special Hazards Arising from the Substance

- Non-combustible; slight decomposition at high temperature (>210°C) produces low-toxic amine and aromatic hydrocarbon fumes; no toxic or explosive gases released under normal fire conditions.

### 5.3 Advice for Firefighters

- Wear self-contained breathing apparatus (SCBA) and full fire-fighting protective gear only if large-scale decomposition fumes occur during fire.
- Prevent fire-extinguishing water from entering municipal sewers or natural water bodies to avoid minor environmental contamination.

## 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 the spill site and evacuate non-essential personnel.
- Avoid inhaling dust and direct contact with skin and eyes during cleanup.

### 6.2 Environmental Precautions

- Prevent spilled powder from entering sewers, rivers, lakes or soil. Cover the spill with inert material (sand/vermiculite) to avoid dust spreading.

### 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 or vacuum the powder.

- Large Spill: Contain the spill with sandbags, transfer to a sealed HDPE drum with a hazard label, and hand over to a licensed hazardous waste treatment company. Do not wash the spill into drains.

## SECTION 7: Handling and Storage

### 7.1 Precautions for Safe Handling

- Operate in a well-ventilated dust-free area or fume hood; avoid generating and inhaling dust during weighing and mixing.
- Wear the specified personal protective equipment (PPE) for all handling operations.
- Do not eat, drink or smoke in the work area; wash hands and face thoroughly with soap and water after handling.
- Avoid contact with strong acids, strong bases, oxidizing agents and high-temperature environments to prevent decomposition.

- Storage Conditions: Store in a cool, dry, dark and well-ventilated pharmaceutical warehouse. Temperature  $\leq 25^{\circ}\text{C}$ , relative humidity  $\leq 60\%$ . Keep the container tightly sealed to prevent hygroscopy and 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, strong reducing agents.
- Storage Class (TRGS 510): 10 (Non-Hazardous Solids with irritant properties)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from food, feed, cosmetic raw materials and other pharmaceutical intermediates with different properties; store locked up.

## SECTION 8: Exposure Controls/Personal Protection

### 8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal control limit:  $0.25 \text{ mg/m}^3$  (8-hour TWA).
  - Biological Limit Value (BLV): N/A.
- ### 8.2 Exposure Controls
- Engineering Controls: Local exhaust ventilation (LEV) for dust-generating operations; install a dust collection and 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 for routine operations; powered air-purifying respirator (PAPR) for high-dust operations.
    - Hand Protection: Replace gloves immediately if damaged, punctured or contaminated.

## SECTION 9: Physical and Chemical Properties

9.1 Basic Physical and Chemical Properties

a) Physical State: Solid (white crystalline powder)  
b) Color: White to off-white  
c) Odor: Practically odorless  
d) Melting Point/Freezing Point:  $167\text{-}171^{\circ}\text{C}$   
e) Boiling Point: Not applicable (decomposes before boiling)  
f) Flammability: Non-combustible  
g) Flammability Limits: Not applicable  
h) Flash Point: Not applicable  
i) Autoignition Temperature:  $> 450^{\circ}\text{C}$   
j) Decomposition Temperature:  $\geq 210^{\circ}\text{C}$  (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 ( $\approx 75 \text{ g/L}$ ,  $25^{\circ}\text{C}$ ); soluble in ethanol, methanol; slightly soluble in acetone, ethern  
n) Partition Coefficient (log P, n-octanol/water): 2.2 ( $25^{\circ}\text{C}$ )  
o) Vapor Pressure ( $25^{\circ}\text{C}$ ):  $< 0.0001 \text{ hPa}$   
p) Density ( $25^{\circ}\text{C}$ ):  $1.28\text{-}1.32 \text{ g/cm}^3$  (bulk density)  
q) Particle Size: 95% passing 80 mesh  
r) Explosive Properties: Not explosives  
s) Oxidizing Properties: None  
t) Hygroscopy: Slightly hygroscopic

## SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the 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 Hazardous Reactions: No hazardous reactions under normal use; no decomposition under routine formulation and production conditions.

10.3 Conditions to Avoid: High temperature ( $> 210^{\circ}\text{C}$ ), direct sunlight, high humidity, contact with incompatible materials, strong mechanical shock.

10.4 Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts, strong reducing agents, alkaline pharmaceutical excipients.

10.5 Hazardous

Decomposition Products: Carbon dioxide, water vapor, low-toxic amine fumes (at high temperature complete combustion/decomposition); no highly toxic decomposition products.

## SECTION 11: Toxicological Information

### 11.1 Toxicological Effects

- Acute Toxicity:
  - Oral (Rat, LD<sub>50</sub>): 600 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 closed patch test - mild redness and edema (Category 2), reversible within 72 hours.
- Eye Irritation: Rabbit eye test - severe conjunctival redness and mild corneal opacity (Category 2), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild respiratory tract 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 in animals.
- Specific Target Organ Toxicity: Nervous system is the main target organ; high dose causes dizziness, numbness and local anesthetic effects; no cardiac toxicity at clinical relevant doses.

## SECTION 12: Ecological Information

### 12.1 Toxicity

- Fish (Zebrafish, 96h LC<sub>50</sub>): 360 mg/L
  - Daphnia (48h EC<sub>50</sub>): 340 mg/L
  - Freshwater Algae (72h EC<sub>50</sub>): 380 mg/L
- 12.2 Persistence and Degradability: Biodegradable (BOD<sub>5</sub>/COD = 0.62); degraded by microorganisms in aquatic and soil environments within 21-28 days, no persistent residues.
- 12.3 Bioaccumulative Potential: Low (log P = 2.2); no significant bioaccumulation in aquatic organisms and food chain.
- 12.4 Mobility in Soil: Low mobility; adsorbs to soil organic matter (K<sub>oc</sub> = 490), 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 and terrestrial plants at low concentrations.

## SECTION 13: Disposal Considerations

### 13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is classified as hazardous waste; must be disposed of by licensed hazardous waste treatment facilities via incineration (combustion products are non-toxic CO<sub>2</sub>, H<sub>2</sub>O and small amount of amine fumes).
- Packaging Waste: Rinse packaging with ethanol and water to remove residual powder, then dispose of as hazardous waste; do not recycle or reuse contaminated packaging.
- Unused Product: Do not discharge to the environment; incinerate with professional waste treatment companies in accordance with local national and international regulations.
- Disposal Compliance: Comply with national and local hazardous waste disposal 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. (Prilocaine 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 inner plastic lining or aluminum foil vacuum bags; affix standard Class 9 hazard labels and product identification labels.
- Transport temperature ≤ 30°C; avoid direct sunlight, rain, collision, extrusion and rough handling during transport.
- Do not transport with food, feed, cosmetics, aquatic products and oral pharmaceutical finished products.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations for Class 9 hazardous substances; transport by specialized hazardous chemical vehicles for bulk shipment.

### SECTION 15: Regulatory Information

#### 15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 9 hazardous chemical); Pharmaceutical Raw Material Registration Requirements for medical intermediates; Chinese Pharmacopoeia (CP) 2025 edition compliance.
  - EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Warning); European Pharmacopoeia (EP) 10.0 compliance; IMDG Code (Class 9).
  - US: TSCA (listed on the TSCA Inventory); DOT (Class 9 hazardous material); FDA (compliant with pharmaceutical intermediate quality standards); United States Pharmacopoeia (USP) 47 compliance.
  - Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law.
  - Other: Comply with local pharmaceutical raw material import/export registration and hazardous chemical transport regulations of the destination country.
- #### 15.2 Additional Regulatory Requirements
- Provide English MSDS and COA for customs clearance; apply for a hazardous chemical transport document for bulk shipment; provide product quality test reports and pharmacopoeia compliance certificates for pharmaceutical production use.

### SECTION 16: Other Information

- Further Information: This MSDS is based on current scientific and regulatory knowledge, complying with GB/T 16483, GB/T 17519 and GHS Rev.9 standards. It is for occupational health and safety use only for professional operators and transport personnel.
- Revision Date: 22 FEB 2026
- Disclaimer: The supplier is not liable for any damage caused by improper use, storage, transport or disposal of this product beyond the scope of the specified standards and national/international regulations.