



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

## Safety Data Sheet (MSDS)

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

**Product Name: Dyclonine Hydrochloride** **Revision Date: 28 FEB 2026**

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

#### 1.1 Product Identifiers

- Product Name: Dyclonine Hydrochloride
- Product Number: DH-20260228
- Brand: SIGALD
- CAS-No.: 536-43-6
- Synonyms: 4-(2-Dimethylaminoethoxy)benzophenone hydrochloride; Dyclone 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
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#### 1.3 Emergency telephone

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

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

- Identified Uses: Pharmaceutical intermediate for surface local anesthetic; raw material for topical anesthetic formulations (oral, mucosal, skin); raw material for medical device coating anesthetic; pharmaceutical R&D reference reagent.
- Uses Advised Against: Not for direct injection/human internal use; no non-pharmaceutical industrial use; avoid use in cosmetics/food products; do not use for injectable anesthesia formulations.

### SECTION 2: Hazards Identification

#### 2.1 GHS Classification

- Acute toxicity, oral (Category 4); Skin irritation (Category 2); Serious eye irritation (Category 2); Skin sensitization (Category 1)

#### 2.2 GHS Label Elements

- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H315: Causes skin irritation
  - H317: May cause an allergic skin reaction
  - H319: Causes serious eye irritation
  - H335: May cause respiratory irritation
- 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/physician if you feel unwell
  - P302+P352: If on skin: Wash with plenty of water and soap
  - P305+P351+P338+P313: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Get medical advice/attention
  - P333+P313: If skin irritation or rash occurs: Get medical advice/attention
  - P362+P364: Take off contaminated clothing and wash it before reuse
  - P405: Store locked up
  - P501: Dispose of contents/container to an approved waste disposal plant

#### 2.3 Physical and Chemical Hazards



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- Non-combustible; no explosive/oxidizing properties under normal storage and handling conditions. No hazardous polymerization will occur.2.4 Health Hazards
- Acute: Swallowing causes mild gastrointestinal discomfort, dizziness; skin contact leads to redness, itching, rash (allergic reaction in sensitive people); eye contact causes severe conjunctival redness, corneal irritation; dust inhalation causes cough, throat dryness.
- Chronic: Prolonged skin contact may cause persistent allergic dermatitis in sensitized individuals; no significant organ toxicity with strict protective measures.2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC<sub>50</sub> = 350 mg/L for zebrafish); low bioaccumulation potential; biodegradable in natural environment with no persistent residues.2.6 Other Hazards
- No additional hazards identified under normal pharmaceutical use conditions with strict PPE.

## SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance**
- Active Ingredient: Dyclonine Hydrochloride (100%)
- CAS-No.: 536-43-6
- EC-No.: N/A
- Hazardous components: 100% (Dyclonine Hydrochloride, GHS Category 4/2/2/1)

## SECTION 4: First Aid Measures

### 4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately, keep at rest in a comfortable breathing position. If coughing or discomfort occurs, call a POISON CENTER/doctor.
- In Case of Skin Contact: Immediately remove all contaminated clothing and shoes. Rinse skin with plenty of running water and mild soap for 15-20 minutes. If rash/irritation occurs, seek medical advice immediately.
- In Case of Eye Contact: **IMMEDIATE MEDICAL ADVICE REQUIRED.** Hold eyelids open and rinse thoroughly with plenty of running water for at least 20 minutes. Remove contact lenses if present. Do not rub eyes.
- 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 if unwell or symptoms appear.4.2 Most Important Symptoms and Effects

- Acute: Nausea, mild dizziness (swallowed); skin erythema, pruritus, allergic rash (contact); severe eye irritation, blurred vision (contact); cough, throat irritation (inhalation).
- Delayed: Allergic skin reaction may occur 24-48 hours after skin contact in sensitized individuals.4.3 Indication of Immediate Medical Attention

- Allergic skin reaction, severe eye contact and persistent gastrointestinal discomfort after swallowing require professional medical attention.

## 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 (>220°C) produces low-toxic amine, aromatic hydrocarbon and hydrochloride fumes; no toxic/explosive gases released under normal fire conditions.5.3 Advice for Firefighters

- Wear self-contained breathing apparatus (SCBA) and full chemical-resistant fire-fighting protective gear if decomposition fumes occur during fire.
- Keep a safe distance from the fire scene; prevent fire-extinguishing water from entering municipal sewers or natural water bodies.



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## SECTION 6: Accidental Release Measures

### 6.1 Personal Precautions

- Wear N95 dust mask, chemical-resistant nitrile gloves, full face shield and impermeable lab coat. Ensure good ventilation at the spill site and evacuate all non-essential personnel.
- Do not touch the spilled powder with bare hands; avoid inhaling dust during the cleanup process.

### 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 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 HDPE plastic container for professional hazardous waste disposal. Do not blow or vacuum the powder.
- Large Spill: Contain the spill with sandbags/dikes, transfer to a sealed HDPE drum with clear hazard labels, and hand over to a licensed hazardous waste treatment company. Do not wash the spill into drains or water bodies.

### 6.4 Reference to Other Sections

For waste disposal, see Section 13.

## SECTION 7: Handling and Storage

### 7.1 Precautions for Safe Handling

- Operate in a well-ventilated dust-free fume hood; use dust-free operation tools to avoid generating dust during weighing and mixing.
- Wear the specified full PPE for all handling operations; no eating, drinking, smoking or phone use in the work area.
- Wash hands, face and exposed skin thoroughly with soap and water after handling; take a shower if necessary.
- Avoid contact with strong acids, strong bases, oxidizing agents, heavy metal salts and high-temperature environments; do not mix with other pharmaceutical raw materials without professional guidance.

### 7.2 Conditions for Safe Storage

- Storage Conditions: Store in a **cool, dry, dark and locked** pharmaceutical warehouse. Temperature  $\leq 25^{\circ}\text{C}$ , relative humidity  $\leq 60\%$ . Keep the container tightly sealed with aluminum foil to prevent hygroscopy, light degradation 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, alkaline pharmaceutical excipients.
- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from all other pharmaceutical raw materials, food, feed and cosmetics; place in a dedicated toxic substance storage area with warning signs.

## SECTION 8: Exposure Controls/Personal Protection

### 8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal strict control limit:  $0.15 \text{ mg/m}^3$  (8-hour TWA, dust).

### 8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency particulate air (HEPA) filter for all dust-generating operations; dust collection system with emission concentration  $\leq 0.05 \text{ mg/m}^3$ .
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical-resistant full face shield (mandatory for all operations); safety goggles as secondary protection.

- Skin Protection: Chemical-resistant nitrile rubber gloves (thickness  $\geq 0.20$  mm), impermeable anti-chemical lab coat, protective shoe covers and disposable arm covers (prevent skin contact).
- Respiratory Protection: N95 dust mask for routine small-scale operations; powered air-purifying respirator (PAPR) for large-scale weighing/mixing.
- Hand Protection: Replace gloves immediately if damaged, punctured or contaminated; change gloves every 2 hours for continuous operation.

## 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: Slightly aromatic, practically odorless  
d) Melting Point/Freezing Point: 175-179°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:  $\geq 220^{\circ}\text{C}$  (mild decomposition, produces low-toxic fumes)  
k) pH Value: 4.0-6.0 (1% aqueous solution, 25°C)  
l) Viscosity: Not applicable (solid)  
m) Solubility: Soluble in water ( $\approx 10$  g/L, 25°C); freely soluble in ethanol, methanol, chloroform; slightly soluble in acetone, ethern)  
n) Partition Coefficient (log P, n-octanol/water): 3.2 (25°C)  
o) Vapor Pressure (25°C):  $< 0.0001$  hPa  
p) Density (25°C): 1.22-1.26 g/cm<sup>3</sup> (bulk density)  
q) Particle Size: 95% passing 80 mesh  
r) Explosive Properties: Not explosives  
s) Oxidizing Properties: None  
t) Hygroscopy: Slightly hygroscopic, sensitive to light

## SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions ( $\leq 25^{\circ}\text{C}$ , dry, dark, sealed); stable under standard pharmaceutical processing temperature ( $\leq 60^{\circ}\text{C}$ ) with light protection.  
10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; mild hydrolysis may occur in moist and alkaline environment to produce non-toxic metabolites.  
10.3 Conditions to Avoid: High temperature ( $> 220^{\circ}\text{C}$ ), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock, alkaline environment, repeated skin contact.  
10.4 Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts, reducing agents, alkaline pharmaceutical excipients, water with high pH value.  
10.5 Hazardous Decomposition Products: Carbon dioxide, water vapor, low-toxic amine fumes, aromatic hydrocarbon and hydrochloride fumes (at high temperature complete combustion/decomposition); non-toxic phenolic derivatives produced by alkaline hydrolysis.

## SECTION 11: Toxicological Information

### 11.1 Toxicological Effects

- Acute Toxicity (low systemic toxicity, topical use safe):
  - Oral (Rat, LD<sub>50</sub>): 340 mg/kg (Harmful)
  - Dermal (Rabbit, LD<sub>50</sub>):  $> 2000$  mg/kg (Not harmful)
  - Inhalation (Rat, LC<sub>50</sub>): 12 mg/m<sup>3</sup> (4-hour exposure, Harmful)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - moderate redness and edema (Category 2), reversible within 7 days with treatment.
- Skin Sensitization: Guinea pig test - positive (Category 1), may cause allergic skin reaction in sensitive humans.
- Eye Irritation/Damage: Rabbit eye test - severe conjunctival redness and mild corneal opacity (Category 2), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild bronchial irritation and cough at high dust concentrations ( $\geq 1.0$  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 clinical relevant doses; safe for topical use in pregnant women (no systemic absorption).
- Specific Target Organ Toxicity: No significant target organ toxicity with topical use; nervous system mild depression only after massive oral ingestion.

## SECTION 12: Ecological Information

### 12.1 Toxicity

- Fish (Zebrafish, 96h LC<sub>50</sub>): 350 mg/L
- Daphnia (48h EC<sub>50</sub>): 330 mg/L
- Freshwater Algae (72h EC<sub>50</sub>): 370 mg/L
- 12.2 Persistence and Degradability: Biodegradable (BOD<sub>5</sub>/COD = 0.60); degraded by microorganisms in aquatic and soil environments within 15-20 days, no persistent residues.
- 12.3 Bioaccumulative Potential: Low (log P = 3.2); no significant bioaccumulation in aquatic organisms and food chain.
- 12.4 Mobility in Soil: Low mobility; strongly adsorbs to soil organic matter (K<sub>oc</sub> = 620), 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; high concentration may cause mild inhibition of aquatic algae growth.

## SECTION 13: Disposal Considerations

### 13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is classified as **toxic hazardous waste**; must be disposed of by licensed hazardous waste treatment facilities via high-temperature incineration (≥800°C) with flue gas treatment.
- Packaging Waste: Rinse packaging with ethanol and acidified water to remove residual powder, then dispose of as toxic hazardous waste; do not recycle or reuse any contaminated packaging.
- Unused Product: Do not discharge to the environment; incinerate with professional waste treatment companies in accordance with local national and international toxic waste regulations.
- Disposal Compliance: Comply with national and local hazardous waste disposal regulations (e.g., China HW02, EU EWC 080102, US RCRA Subtitle C).

## SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 2811  
14.2 UN Proper Shipping Name: Toxic solid, organic, n.o.s. (Dyclonine Hydrochloride)  
14.3 Transport Hazard Class: 6.1 (Toxic substances)  
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 and locked cover; affix standard Class 6.1 toxic 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 other pharmaceutical raw materials; transport in a dedicated compartment of specialized hazardous chemical vehicles.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations for Class 6.1 toxic substances; provide MSDS and transport approval documents for customs clearance.

## SECTION 15: Regulatory Information

### 15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 6.1 toxic chemical); Pharmaceutical Raw Material Registration Requirements for medical intermediates; Chinese Pharmacopoeia (CP) 2025 edition compliance; Special Control of Toxic Chemicals Regulations.



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- EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Warning); European Pharmacopoeia (EP) 10.0 compliance; ADR/RID Class 6.1 transport regulations.
- US: TSCA (listed on the TSCA Inventory); DOT Class 6.1 toxic material; FDA (compliant with pharmaceutical intermediate quality standards); United States Pharmacopoeia (USP) 47 compliance; RCRA toxic waste regulations.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Japanese Poisonous and Deleterious Substances Control Law.
- Other: Comply with local pharmaceutical raw material import/export registration, toxic chemical control and hazardous chemical transport regulations of the destination country.15.2 Additional Regulatory Requirements
- Provide English MSDS, COA and toxic chemical transport approval documents for customs clearance; apply for a special hazardous chemical storage license for on-site storage; 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 professional occupational health and safety use only for trained operators, transport personnel and storage managers. Key characteristic: **topical anesthetic with low systemic toxicity, only for external/mucosal use, not for injection.**
- Revision Date: 28 FEB 2026
- Disclaimer: The supplier is not liable for any damage, injury or environmental pollution caused by improper use, storage, transport or disposal of this product beyond the scope of the specified standards and national/international regulations. All operations must be conducted by trained professional personnel with strict compliance with relevant safety regulations.

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