Safety Data Sheet (MSDS)

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

Product Name: Bupivacaine HydrochlorideRevision Date: 25 FEB 2026

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

1.1 Product Identifiers

- Product Name: Bupivacaine Hydrochloride
- Product Number: BH-20260225
- Brand: SIGALD
- CAS-No.: 14252-80-3
- Synonyms: 1-Butyl-N-(2,6-dimethylphenyl)piperidine-2-carboxamide hydrochloride; Marcaine 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 long-acting amide local anesthetic drugs; raw material for injectable local anesthetic formulations (epidural, spinal, 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/injection in raw form; no non-pharmaceutical industrial use; avoid use in cosmetics/food products; do not use in unformulated injectable preparations for clinical use.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 3); Skin irritation (Category 2); Serious eye irritation (Category 2); Specific target organ toxicity - single exposure (Nervous system/Cardiovascular system, Category 2); Specific target organ toxicity - repeated exposure (Nervous system, Category 3)2.2 GHS Label Elements
- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Danger**
- Hazard Statements:
  - H301: Toxic if swallowed
  - H315: Causes skin irritation
  - H319: Causes serious eye irritation

- H370: Causes damage to organs (Nervous/Cardiovascular) through single exposure
- H372: Causes 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+P310: If swallowed: Immediately call a POISON CENTER or doctor/physician
- P302+P352: If on skin: Wash with plenty of water and soap
- P305+P351+P338+P310: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician
- P332+P313: If skin irritation occurs: Get medical advice/attention
- 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.2.4 Health Hazards
- Acute: Swallowing causes severe dizziness, cardiac arrhythmia, convulsions, nervous system depression; skin contact leads to redness/itching/rash; eye contact causes severe conjunctival redness/ corneal irritation; dust inhalation causes cough/headache/limb numbness.
- Chronic: Prolonged exposure may cause persistent neurological numbness, cardiac conduction abnormalities, and cognitive impairment in sensitive individuals.2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC_{50} = 220 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: Bupivacaine Hydrochloride (100%)
- CAS-No.: 14252-80-3
- EC-No.: N/A
- Hazardous components: 100% (Bupivacaine Hydrochloride, GHS Category 3/2/2/2/3)

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move victim to fresh air immediately, keep at rest in a comfortable breathing position. Administer oxygen if breathing is difficult. Call a POISON CENTER/doctor at once.

- In Case of Skin Contact: Remove all contaminated clothing/shoes, rinse skin with plenty of running water/mild soap for 15-20 minutes. Seek medical advice if irritation/rash persists.
- In Case of Eye Contact: **IMMEDIATE MEDICAL ATTENTION REQUIRED**. Hold eyelids open, rinse thoroughly with running water for **at least 20 minutes**. Remove contact lenses if present. Do not rub eyes. Call a POISON CENTER/ophthalmologist immediately.
- 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 and provide product information.4.2 Most Important Symptoms and Effects
- Acute: Severe gastrointestinal discomfort, cardiac arrhythmia, limb numbness, convulsions (swallowed); skin erythema/itching (contact); severe eye irritation/vision blurring (contact); respiratory distress/headache (inhalation).
- Delayed: Neurological sequelae, persistent cardiac conduction disorder may occur 0.5-3 hours after excessive exposure; chronic exposure causes progressive nervous system damage.4.3 Indication of Immediate Medical Attention
- All exposure scenarios (swallowing, eye contact, heavy inhalation, prolonged skin contact) require **immediate professional medical attention**; symptomatic treatment in a hospital is mandatory.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO_2), 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 (>240℃) produces low-toxic amine/aromatic hydrocarbon/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 gear if decomposition fumes occur.
- Keep a safe distance from the fire scene; prevent fire-extinguishing water from entering municipal sewers/natural water bodies.

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 spill site; evacuate all non-essential personnel.
- Do not touch spilled powder with bare hands; avoid inhaling dust during cleanup.6.2 Environmental Precautions
- Prevent spilled powder from entering sewers/rivers/soil. Cover 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/vacuum powder.
- Large Spill: Contain with sandbags/dikes, transfer to a sealed HDPE drum with clear hazard labels, hand over to licensed hazardous waste treatment company. Do not wash spill into drains/water bodies.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 negative pressure fume hood; use dust-free tools to avoid dust generation during weighing/mixing.
- Wear full specified PPE for all handling operations; no eating/drinking/smoking/phone use in work area.
- Wash hands/face/exposed skin thoroughly with soap and water after handling; take a shower if necessary.
- Avoid contact with strong acids/bases/oxidizing agents/heavy metal salts; 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/locked** pharmaceutical warehouse, temperature ≤25℃, relative humidity ≤60%. Keep container tightly sealed with aluminum foil to prevent hygroscopy/contamination.
- Incompatibilities: Strong acids (HCl/H_2SO_4), strong bases (NaOH/KOH), oxidizing agents (H_2O_2/$KMnO_4$), heavy metal salts, alkaline pharmaceutical excipients, esterase-containing substances.
- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties)
- Shelf Life: 36 months (unopened, under specified conditions).
- Segregation: Store separately from all other pharmaceutical raw materials/food/feed/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: 0.08 mg/m³ (8-hour TWA, dust).
- Biological Limit Value (BLV): N/A.8.2 Exposure Controls
- Engineering Controls: Local exhaust ventilation (LEV) with HEPA filter for all dust-generating operations; dust collection system with emission concentration ≤0.05 mg/m³.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical-resistant full face shield (mandatory); safety goggles as secondary protection.

- Skin Protection: Nitrile rubber gloves (thickness ≥0.20 mm), impermeable anti-chemical lab coat, protective shoe covers/disposable arm covers.
- Respiratory Protection: N95 dust mask (routine small-scale operations); powered air-purifying respirator (PAPR) (large-scale weighing/mixing).
- Hand Protection: Replace gloves immediately if damaged/contaminated; change gloves every 2 hours for continuous operation.

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: 255-260℃e) Boiling Point: Not applicable (decomposes before boiling)f) Flammability: Non-combustibleg) Flammability Limits: Not applicableh) Flash Point: Not applicablei) Autoignition Temperature: > 450℃j) Decomposition Temperature: ≥240℃ (mild decomposition, low-toxic fumes)k) pH Value: 4.5-6.0 (1% aqueous solution, 25℃)l) Viscosity: Not applicable (solid)m) Water Solubility: Soluble in water (≈25 g/L, 25℃); freely soluble in ethanol/methanol; slightly soluble in acetone/ethern) Partition Coefficient (log P, n-octanol/water): 3.8 (25℃)o) Vapor Pressure (25℃): < 0.0001 hPap) Density (25℃): 1.33-1.37 g/cm³ (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 (≤25℃, dry, sealed); stable under standard pharmaceutical processing temperature (≤60℃).10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use/processing; hydrolysis may occur in moist/alkaline environment to produce toxic metabolites.10.3 Conditions to Avoid: High temperature (>240℃), direct sunlight, high humidity, contact with incompatible materials, strong mechanical shock, alkaline environment.10.4 Incompatible Materials: Strong acids/bases, oxidizing agents, heavy metal salts, reducing agents, alkaline pharmaceutical excipients, water with high pH value.10.5 Hazardous Decomposition Products: CO_2, H_2O, low-toxic amine/hydrochloride fumes (high-temperature combustion); toxic aromatic amine metabolites (alkaline hydrolysis).

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity:
  - Oral (Rat, LD_{50}): 25 mg/kg (Toxic)
  - Dermal (Rabbit, LD_{50}): 850 mg/kg (Harmful)
  - Inhalation (Rat, LC_{50}): 3 mg/m³ (4-hour exposure, Toxic)
- Skin Corrosion/Irritation: Rabbit 4-hour patch test - moderate redness/edema/rash (Category 2), reversible within 7 days with treatment.
- Eye Irritation: Rabbit eye test - severe conjunctival redness/corneal opacity (Category 2), reversible with treatment within 48 hours.

- Respiratory Irritation: Rat inhalation test - severe bronchial spasm/lung irritation at low dust concentrations (≥0.3 mg/m³).
- Mutagenicity: Ames test/chromosome aberration test - negative; no mutagenic effects.
- Carcinogenicity: IARC Classification - Group 3 (not classifiable as to carcinogenicity to humans).
- Reproductive Toxicity: High doses (≥10 mg/kg) in animal tests cause fetal developmental retardation/miscarriage; no adverse effects at low clinical doses.
- Specific Target Organ Toxicity: Nervous/Cardiovascular systems are main target organs; high dose causes nerve block, cardiac arrhythmia, hypotension, convulsions.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC_{50}): 220 mg/L
- Daphnia (48h EC_{50}): 200 mg/L
- Freshwater Algae (72h EC_{50}): 240 mg/L12.2 Persistence and Degradability: Biodegradable (BOD_5/COD = 0.48); degraded by microorganisms in aquatic/soil environments within 30-40 days, no persistent residues.12.3 Bioaccumulative Potential: Low (log P=3.8); no significant bioaccumulation in aquatic organisms/food chain.12.4 Mobility in Soil: Low mobility; strongly adsorbs to soil organic matter (Koc=720), 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; 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 **toxic hazardous waste**; dispose by licensed facilities via high-temperature incineration (≥800℃) with flue gas treatment.
- Packaging Waste: Rinse with ethanol/acidified water to remove residual powder, dispose as toxic 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/international toxic waste regulations.
- Disposal Compliance: Comply with China HW02, EU EWC 080102, US RCRA Subtitle C and other national hazardous waste regulations.

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 281114.2 UN Proper Shipping Name: Toxic solid, organic, n.o.s. (Bupivacaine Hydrochloride)14.3 Transport Hazard Class: 6.1 (Toxic substances)14.4 Packaging Group: II (Moderate 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/locked cover; affix standard Class 6.1 toxic hazard labels/product identification labels.

- Transport temperature ≤30℃; avoid direct sunlight/rain/collision/extrusion/rough handling during transport.
- Do not transport with food/feed/cosmetics/aquatic products/other pharmaceutical raw materials; transport in dedicated compartment of specialized hazardous chemical vehicles.
- Comply with ADR/RID, IMDG Code, IATA-DGR transport regulations for Class 6.1 toxic substances; provide MSDS/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; Chinese Pharmacopoeia (CP) 2025 compliance; Special Control of Toxic Chemicals Regulations.
- EU: REACH (Annex XVII compliant, no SVHC); CLP (GHS Danger classification); European Pharmacopoeia (EP) 10.0 compliance; ADR/RID Class 6.1 transport regulations.
- US: TSCA (listed on Inventory); DOT Class 6.1 toxic material; FDA pharmaceutical intermediate quality standards; United States Pharmacopeia (USP) 47 compliance; RCRA toxic waste regulations.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Japanese Poisonous and Deleterious Substances Control Law.15.2 Additional Regulatory Requirements
- Provide English MSDS/COA/toxic chemical transport approval documents for customs clearance; apply for special hazardous chemical storage license for on-site storage; provide pharmacopoeia compliance certificates for pharmaceutical production use.

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 use only by trained professional operators/transport/storage personnel.
- Revision Date: 25 FEB 2026
- Disclaimer: The supplier is not liable for damage/injury/environmental pollution caused by improper use/storage/transport/disposal beyond specified standards and national/international regulations. All operations must be conducted by trained professionals with strict compliance with safety regulations.