



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: Levobupivacaine Hydrochloride Revision Date: 26 FEB 2026

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

1.1 Product Identifiers

- Product Name: Levobupivacaine Hydrochloride
- Product Number: LH-20260226
- Brand: SIGALD
- CAS-No.: 160708-40-7
- Synonyms: (S)-(-)-1-Butyl-N-(2,6-dimethylphenyl)piperidine-2-carboxamide hydrochloride; L-Bupivacaine 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 long-acting amide local anesthetic (S-enantiomer); raw material for injectable local anesthetic formulations (epidural, spinal, peripheral nerve block, postoperative analgesia); 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, Category 3); 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
 - 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+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



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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 dizziness, limb numbness, mild cardiac conduction abnormalities; skin contact leads to redness, itching and rash; eye contact causes severe conjunctival redness and corneal irritation; dust inhalation causes cough, headache and throat discomfort.
- Chronic: Prolonged exposure may cause mild persistent neurological numbness in sensitive individuals; **no significant cardiac toxicity** (distinction from racemic bupivacaine) with standard protective measures.2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC₅₀ = 280 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 (S-enantiomer)**
- Active Ingredient: Levobupivacaine Hydrochloride (100%)
- CAS-No.: 160708-40-7
- EC-No.: N/A
- Hazardous components: 100% (Levobupivacaine Hydrochloride, GHS Category 3/2/2/3)

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. Administer oxygen if breathing is difficult. Call a POISON CENTER/doctor at once.
- 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. Seek medical advice if irritation/rash persists for more than 24 hours.
- In Case of Eye Contact: **IMMEDIATE MEDICAL ATTENTION 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. 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: Gastrointestinal discomfort, limb numbness, mild dizziness (swallowed); skin erythema and pruritus (contact); severe eye irritation and blurred vision (contact); cough and chest tightness (inhalation).
- Delayed: Mild neurological numbness may occur 1-3 hours after excessive exposure; no severe cardiac adverse effects (key characteristic of the S-enantiomer).4.3 Indication of Immediate Medical Attention
- All exposure scenarios (swallowing, eye contact, heavy inhalation) require **immediate professional medical attention**; symptomatic treatment in a hospital is recommended for severe exposure.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO₂), 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 (>245°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.

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 negative pressure 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 (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 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: 0.12 mg/m^3 (8-hour TWA, dust) (higher than racemic bupivacaine due to lower toxicity).

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 $\geq 0.20 \text{ mm}$), impermeable anti-chemical lab coat, protective shoe covers and disposable arm covers.
 - 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: Practically odorless d) Melting Point/Freezing Point: 258-262°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°C j) Decomposition Temperature: ≥245°C (mild decomposition, produces low-toxic fumes) k) pH Value: 4.5-6.0 (1% aqueous solution, 25°C) l) Viscosity: Not applicable (solid) m) Water Solubility: Soluble in water (≈24 g/L, 25°C); freely soluble in ethanol, methanol; slightly soluble in acetone, ethern) Partition Coefficient (log P, n-octanol/water): 3.7 (25°C) o) Vapor Pressure (25°C): < 0.0001 hPa p) Density (25°C): 1.34-1.38 g/cm³ (bulk density) q) Particle Size: 95% passing 80 mesh r) Explosive Properties: Not explosives s) Oxidizing Properties: None t) Hygroscopy: Slightly hygroscopic, stable to light

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions (≤25°C, dry, dark, sealed); stable under standard pharmaceutical processing temperature (≤60°C); **optical purity remains stable** for the shelf life under specified conditions. 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 (>245°C), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock, alkaline environment. 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 and hydrochloride fumes (at high temperature complete combustion/decomposition); non-toxic aromatic amine derivatives produced by alkaline hydrolysis.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity (**lower toxicity than racemic bupivacaine**):
 - Oral (Rat, LD₅₀): 40 mg/kg (Toxic)
 - Dermal (Rabbit, LD₅₀): 900 mg/kg (Harmful)
 - Inhalation (Rat, LC₅₀): 5 mg/m³ (4-hour exposure, Toxic)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - moderate redness, edema and rash (Category 2), reversible within 7 days with treatment.
- Eye Irritation/Damage: Rabbit eye test - severe conjunctival redness, mild corneal opacity (Category 2), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - moderate bronchial spasm and cough at low dust concentrations (≥0.4 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 (≥15 mg/kg) in animal tests cause mild fetal developmental retardation; no adverse effects at low clinical doses.
- Specific Target Organ Toxicity: Nervous system is the main target organ; **no significant cardiac toxicity** (key advantage of S-enantiomer); high dose causes nerve block, dizziness and mild central nervous system depression.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC₅₀): 280 mg/L
 - Daphnia (48h EC₅₀): 260 mg/L
 - Freshwater Algae (72h EC₅₀): 290 mg/L
- 12.2 Persistence and Degradability: Biodegradable (BOD₅/COD = 0.50); degraded by microorganisms in aquatic and soil environments within 30-35 days, no persistent residues. 12.3 Bioaccumulative Potential: Low (log P = 3.7); no significant bioaccumulation in aquatic organisms and food chain. 12.4 Mobility in Soil: Low mobility; strongly adsorbs to soil organic matter (K_{oc} = 700), no leaching risk to groundwater. 12.5



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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 ($\geq 800^{\circ}\text{C}$) 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. (Levobupivacaine 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 and locked cover; affix standard Class 6.1 toxic hazard labels and product identification labels.
- Transport temperature $\leq 30^{\circ}\text{C}$; 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.
- EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Danger); 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



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storage managers. Key characteristic: **S-enantiomer with significantly lower cardiac toxicity than racemic bupivacaine.**

- Revision Date: 26 FEB 2026

