Safety Data Sheet (MSDS)

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

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

1.1 Product Identifiers

- Product Name: Promocaine Hydrochloride
- Product Number: PRO-20260215
- Brand: SIGALD
- CAS-No.: 637-58-1
- Synonyms: 2-(Diethylamino)ethyl 3-(propylamino)benzoate hydrochloride; Propoxycaine Hydrochloride
- Molecular Formula: C_{16} H_{27} ClN_2O_2
- Molecular Weight: 314.85 Da

1.2 Details of the supplier of the safety data sheet

- Company: NEWAY SINOPHC TECH. LIMITED
- 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 raw material (topical/local anesthetic preparations for dermatology, dentistry, urology); pharmaceutical research reagent for anesthetic pharmacology.
- Uses Advised Against: Not for direct oral ingestion; not for intravenous/intramuscular injection without professional formulation; not for use in individuals with hypersensitivity to ester-type local anesthetics or chloride-containing pharmaceuticals.

SECTION 2: Hazards Identification

|Summary of Emergency Measures|White crystalline powder. Causes serious eye irritation and moderate skin irritation; harmful if swallowed in large quantity and may cause central nervous system depression. After inhalation: Move to fresh air and rest, consult a doctor if dizziness/cough occurs. In case of skin contact: Rinse thoroughly with running water for 5-10 minutes, remove contaminated clothing. After eye contact: Rinse with plenty of water for 15 minutes (hold eyelids open), consult an ophthalmologist immediately. After swallowing: Rinse mouth with water, do not induce vomiting, seek medical attention at once. Non-combustible. No explosion risk.| |---|

2.1 GHS Classification

- Serious eye irritation (Category 2)
- Skin irritation (Category 2)

- Acute toxicity, oral (Category 4)
- Specific target organ toxicity (single exposure), central nervous system (Category 2)

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
  - H371: May cause damage to the central nervous system through single exposure
- Precautionary Statements:
  - P261: Avoid breathing dust/fume/gas/mist/vapours/spray
  - P264: Wash hands thoroughly after handling
  - P270: Do not eat, drink or smoke when using this product
  - P272: Contaminated work clothing should not be allowed out of the workplace
  - P280: Wear protective gloves/eye/face protection
  - P301+P312: If swallowed: Call a POISON CENTER/doctor if you feel unwell
  - P302+P352: If on skin: Wash with plenty of water/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
  - P333+P313: If skin irritation or rash occurs: Get medical advice/attention
  - P362+P364: Take off contaminated clothing and wash it before reuse
  - P501: Dispose of contents/container to an approved waste disposal plant

2.3 Physical and Chemical HazardsNon-combustible; no explosive/oxidizing properties; no hazardous physical/chemical hazards under normal use and handling conditions.

2.4 Health Hazards

- Acute effects: Severe eye redness, pain and blurred vision; moderate skin redness, itching and erythema; dizziness, drowsiness, tinnitus if ingested/inhaled in large amounts; convulsions and respiratory depression in extreme overdose.
- Chronic effects: No known chronic toxic effects at normal occupational exposure levels; long-term repeated skin contact may cause persistent sensitization in sensitive individuals.

2.5 Environmental HazardsLow toxicity to aquatic organisms; readily biodegradable via ester hydrolysis; no significant bioaccumulation potential; no long-term adverse environmental effects at normal use levels.

2.6 Other HazardsNo additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure chemical compound**|3.1 Main Component|Promocaine Hydrochloride (100%)| |---|---| |CAS-No.:|637-58-1| |EC-No.:|211-292-0| |Hazard Classification|Serious eye irritation 2; Skin irritation 2; Acute oral toxicity 4; CNS toxicity 2|

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- **Inhaled**: Move the victim to fresh air, keep warm and at rest. If breathing is difficult, supply oxygen. Consult a doctor immediately if dizziness, headache, chest tightness or convulsions occur.
- **Skin Contact**: Immediately remove all contaminated clothing and footwear. Rinse the affected area thoroughly with plenty of running water and mild soap for 5-10 minutes. Consult a doctor if irritation, redness or rash appears and lasts more than 24 hours.
- **Eye Contact**: **IMMEDIATELY** hold the eyelids open and rinse the eyes continuously with clean running water for at least 15 minutes. Do not use any eye drops without medical advice. Consult an ophthalmologist without delay, even if no obvious symptoms are present.
- **Swallowed**: Rinse the mouth with clean water. Do **NOT** induce vomiting (risk of respiratory depression and convulsions). Drink a small amount of water only if the victim is conscious and alert. Call a poison center or doctor immediately for specific treatment, especially for large dosage ingestion.

4.2 Most Important Symptoms and Effects

- **Acute Effects**: Serious eye irritation, moderate skin irritation, dizziness, drowsiness, tinnitus, convulsions, respiratory depression (extreme overdose).
- **Delayed Effects**: Persistent neurological discomfort in severe ingestion/inhalation cases; delayed skin sensitization in sensitive individuals.

4.3 Immediate Medical Attention and Special TreatmentImmediate medical attention is mandatory for oral ingestion of large dosage, inhalation of high concentration dust, convulsions or respiratory depression. No specific antidote; symptomatic treatment for CNS depression, anticonvulsants for convulsions, and respiratory support if needed.

4.4 Notes to PhysicianInform the physician that the exposed substance is Promocaine Hydrochloride (CAS 637-58-1), an ester-type local anesthetic hydrochloride salt. Perform a comprehensive ophthalmic examination for eye contact cases; monitor vital signs (blood pressure, heart rate, respiratory rate) and neurological status for ingestion/inhalation cases; provide anticonvulsant and respiratory support treatment as needed.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable**: Water spray, dry powder, carbon dioxide (CO_2), foam.
- **Unsuitable**: No limitations of extinguishing agents; do not use high-pressure water jet to avoid dust dispersion.

5.2 Special Hazards Arising from the Substance or MixtureNon-combustible; no flammable vapors or hazardous combustion gases under normal fire conditions. Thermal decomposition at high temperature (>300℃) releases non-toxic carbon dioxide, water, hydrogen chloride and small amounts of nitrogen oxides.

5.3 Advice for FirefightersWear full fire-fighting protective gear (self-contained breathing apparatus, chemical-resistant fire suit, anti-corrosion gloves, face shield) to avoid inhalation of thermal decomposition products and skin/eye contact. Keep containers cool with water spray if exposed to fire to prevent thermal decomposition. Prevent fire water from entering water bodies and soil to avoid environmental contamination.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency ProceduresWear basic personal protective equipment (N95 respirator, chemical-resistant goggles, nitrile rubber gloves, lab coat) before cleanup. Ensure good ventilation in the spill area; evacuate non-essential personnel and set up warning signs to prevent unauthorized access. Avoid breathing dust and direct contact with the spilled material.

6.2 Environmental PrecautionsPrevent the spilled powder from entering sewers, rivers, lakes and soil (use sand/vermiculite to contain and absorb). Collect all contaminated absorbent materials and dispose of as hazardous waste; do not flush the spilled material into the sewer with water.

6.3 Methods and Materials for Containment and Cleaning Up

- **Small Spill**: Cover the spilled powder with dry sand/vermiculite to prevent dust dispersion; sweep up with a clean dry brush and transfer to a sealed HDPE container marked **HAZARDOUS** for disposal.
- **Large Spill**: Contain the spill with plastic dikes/sand bags; transfer the spilled material to sealed metal drums with a clean shovel; clean the spill area with a damp cloth (avoid dust) and collect the cleaning waste as hazardous waste.

6.4 Reference to Other SectionsFor disposal of the spilled material and related waste, see Section 13.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

- Operate in a well-ventilated workshop with local exhaust ventilation and dust collection system; use low-dust handling equipment (e.g., vacuum feeder) to avoid powder dispersion.
- Avoid direct skin contact and eye exposure; wear mandatory PPE during all handling operations (see Section 8).
- Do not eat, drink, smoke or apply cosmetics in the handling area; wash hands thoroughly with soap and water after handling, and take a shower if necessary.
- Contaminated work clothing must be washed separately and cannot be worn out of the workplace; clean up spills immediately and keep the handling area clean and tidy.

- Avoid contact with strong acids, strong bases, oxidizing agents and esterase-containing substances to prevent chemical reactions and degradation of the active ingredient.
- Personnel with hypersensitivity to ester-type local anesthetics, severe neurological disease or respiratory disorders are prohibited from handling this product.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

- **Storage Conditions**: Store in a cool, dry, dark and well-ventilated pharmaceutical raw material warehouse; keep the container tightly sealed and protected from light; storage temperature ≤ 25℃; relative humidity ≤ 60%.
- **Incompatibilities**: Strong acids (pH < 3), strong bases (pH > 10), strong oxidizing agents (e.g., hydrogen peroxide, potassium permanganate), heavy metal salts (e.g., copper sulfate, ferric chloride), esterase enzymes.
- **Storage Class (TRGS 510)**: 10 (Hazardous Solids - Irritant/Organ Toxicant)
- **Shelf Life**: 36 months (unopened, under the above specified storage conditions); 6 months after opening (resealed immediately with vacuum, stored under the same conditions and used as soon as possible).
- **Storage Labeling**: Clearly mark the container with product name, CAS number, batch number, hazard classification, **WARNING** and **ESTER-TYPE LOCAL ANESTHETIC (HYDROCHLORIDE)** labels.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

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Component	CAS-No.	Value	Control Parameters	Basis
Promocaine Hydrochloride	637-58-1	5 mg/m³	8h TWA (Respirable dust)	EU OEL, China GBZ 2.1-2019
		15 mg/m³	15min STEL	EU OEL, China GBZ 2.1-2019

8.2 Exposure Controls

- **Engineering Controls**: Local exhaust ventilation with dust collection efficiency ≥99%; regular maintenance of ventilation equipment to ensure normal operation.
- **Personal Protective Equipment (MANDATORY)**:
  - **Eye/Face Protection**: Chemical-resistant goggles + face shield (full eye and face coverage).
  - **Skin Protection**: Nitrile rubber gloves (thickness ≥0.18mm) + chemical-resistant lab coat + protective shoes.
  - **Respiratory Protection**: Disposable N95 respirator for normal handling; powered air-purifying respirator (PAPR) for large-scale processing or spill cleanup.
- **Hygiene Measures**: Set up emergency eye wash and hand washing facilities in the workplace; provide skin care cream for daily use to protect the skin from irritation; conduct pre-

employment and regular occupational health checks for operators (neurological and respiratory function, allergy screening).

SECTION 9: Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Propertiesa) Physical State: Crystalline powderb) Color: White to off-whitec) Odor: Slight characteristic ester odord) Melting Point/Freezing Point: 148-152℃ (Capillary Method)e) Initial Boiling Point and Boiling Range: Decomposes before boilingf) Flammability (Solid): Non-combustibleg) Upper/Lower Flammability or Explosive Limits: Not applicable (solid)h) Flash Point: Not applicablei) Autoignition Temperature: > 300℃j) Decomposition Temperature: ≥ 200℃ (slow decomposition)k) pH Value (25℃): 4.0-6.0 (1% aq. solution)l) Viscosity: Not applicable (solid); 3-5 mPa·s (10% aq. solution)m) Water Solubility: Freely soluble (≥10 g/100 mL, 25℃); soluble in ethanol, methanol, slightly soluble in chloroformn) Partition Coefficient (n-octanol/water): Log P = 2.8 (25℃)o) Vapor Pressure (25℃): < 0.0001 hPap) Density (25℃): 1.10-1.15 g/cm³ (bulk density)q) Relative Vapor Density: 10.8 (air = 1)r) Particle Characteristics: ≥95% passing 80 meshs) Explosive Properties: Not explosivet) Oxidizing Properties: Noneu) Hygroscopy: Slightly hygroscopic

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions (≤25℃, dry, dark, sealed); no degradation within the shelf life and the active ingredient content remains above 99.0%.10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal use and handling conditions; no polymerization occurs.10.3 Conditions to Avoid: High temperature (>200℃), direct sunlight, high humidity (>60%), contact with strong acids/alkalis/oxidizing agents/esterase.10.4 Incompatible Materials: Concentrated sulfuric acid, hydrochloric acid, sodium hydroxide, potassium hydroxide (≥10%), hydrogen peroxide (≥30%), potassium permanganate, heavy metal salts, esterase-containing substances.10.5 Hazardous Decomposition Products: Carbon dioxide (CO_2), water (H_2O), hydrogen chloride (HCl), small amounts of nitrogen oxides and aromatic amines (at high temperature >300℃).

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

- **Acute Toxicity**: Oral (Rat, LD_{50}): 480 mg/kg; Dermal (Rabbit, LD_{50}): > 2000 mg/kg; Inhalation (Rat, LC_{50}): > 8 mg/m³ (4-hour exposure, respirable dust).
- **Skin Corrosion/Irritation**: Category 2 (Rabbit test: moderate redness and edema after 24h exposure, reversible within 72h).
- **Serious Eye Damage/Eye Irritation**: Category 2 (Rabbit test: severe conjunctival irritation and corneal haze after single exposure, reversible within 7 days).
- **Respiratory or Skin Sensitization**: Low potential for skin sensitization (Guinea pig test: weak positive in sensitive strains).

- **Germ Cell Mutagenicity**: Negative (Ames test, chromosome aberration test, mouse micronucleus test).
- **Carcinogenicity**: Not classified as carcinogenic by IARC, EPA or NTP.
- **Reproductive Toxicity**: No reproductive harm at normal occupational exposure levels (rat and rabbit studies); high oral doses may cause mild fetal developmental changes in animals.
- **Specific Target Organ Toxicity (Single/Repeated Exposure)**: Central nervous system is the main target organ; acute high-dose exposure causes CNS depression (dizziness, drowsiness, convulsions) and respiratory depression; no target organ toxicity at chronic low-dose exposure.
- **Aspiration Hazard**: Low (crystalline powder, no aspiration risk in normal use).

SECTION 12: Ecological Information

12.1 Toxicity:

- Fish (Zebrafish, LC_{50}): 350 mg/L (96-hour exposure)
- Daphnia (Daphnia magna, EC_{50}): 300 mg/L (48-hour exposure)
- Algae (Chlorella vulgaris, EC_{50}): 400 mg/L (72-hour exposure)12.2 Persistence and Degradability: Readily biodegradable (BOD_5/COD = 0.60-0.70); degrades rapidly in the natural environment (half-life 8-12 days in water) via ester hydrolysis.12.3 Bioaccumulative Potential: Low bioaccumulation potential (Log P = 2.8); no significant accumulation in aquatic organisms (BCF < 90).12.4 Mobility in Soil: Moderate mobility in soil (Koc = 220); binds to soil organic matter and degrades rapidly; no significant leaching to groundwater.12.5 Results of PBT and vPvB Assessment: Not classified as PBT/vPvB (readily biodegradable, low bioaccumulation).12.6 Endocrine Disrupting Properties: No data available; no known endocrine-disrupting effects based on current research.12.7 Other Adverse Effects: No known long-term adverse environmental effects at normal use levels; high concentrations may cause temporary toxicity to aquatic organisms.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- **Product Waste**: Classified as **hazardous chemical waste** (irritant/organ toxicant); must be disposed of at an approved hazardous waste incineration facility (high-temperature incineration at ≥800℃ with flue gas treatment to remove HCl, nitrogen oxides and aromatic amines); **no landfill or composting disposal**.
- **Packaging Waste**: Rinse the packaging with a small amount of ethanol (do not use water); collect the rinse liquid as hazardous waste; dispose of the contaminated packaging at an approved hazardous waste disposal facility; no recycling or reuse of the packaging.
- **Cleaning Waste**: Collect all contaminated absorbent materials, cleaning cloths and dust generated during production and cleanup as hazardous waste and dispose of them in accordance with local hazardous waste regulations.

13.2 Disposal RegulationsComply with local, national and international hazardous waste disposal regulations (e.g., China HW03, EU EWC 07 02 06). Obtain a hazardous waste disposal

approval certificate before disposal; entrust a qualified hazardous waste disposal unit for treatment; keep complete disposal records for at least 5 years for future inspection.

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 3077; IMDG: 3077; IATA-DGR: 307714.2 UN Proper Shipping Name:

- ADR/RID: Environmentally hazardous substances, solid, n.o.s. (Promocaine Hydrochloride)
- IMDG: Environmentally hazardous substances, solid, n.o.s. (Promocaine Hydrochloride)
- IATA-DGR: Environmentally hazardous substances, solid, n.o.s. (Promocaine Hydrochloride)14.3 Transport Hazard Class(es): 9 (Miscellaneous dangerous goods) (ADR/RID/IMDG/IATA)14.4 Packaging Group: III (ADR/RID/IMDG/IATA)14.5 Environmental Hazards: Yes (ADR/RID/IMDG/IATA); Marine Pollutant: No (IMDG)14.6 Special Precautions for User
- Transport by licensed hazardous goods carriers only with complete transportation qualification documents and hazardous goods transport permits.
- Transport at ≤25℃; use sealed, light-proof, shockproof and chemical-resistant packaging (HDPE/metal drums with inner plastic lining).
- Clearly mark the package with UN 3077, Class 9, hazard pictograms, **WARNING** and **ESTER-TYPE LOCAL ANESTHETIC (HYDROCHLORIDE)** labels.
- Avoid transport with food, beverages, medicines, cosmetics, strong acids, strong bases, oxidizing agents and esterase-containing substances; load and unload gently to prevent packaging breakage and light exposure.

SECTION 15: Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

- **National Regulations (China)**:
  - Hazardous Chemical Safety Management Regulation (Classified as hazardous chemical)
  - Pharmaceutical Administration Law (Approved for pharmaceutical raw material use)
  - Hazardous Waste Pollution Control Law
  - Occupational Exposure Limit for Hazardous Factors in the Workplace (GBZ 2.1-2019)
- **International Regulations**:
  - GHS Classification (Rev. 9): Serious eye irritation 2; Skin irritation 2; Acute oral toxicity 4; Specific target organ toxicity (single exposure) CNS 2
  - REACH (EU): Registered; listed in Annex XVII (no restriction)
  - TSCA (US): Listed on the TSCA Inventory
  - USP/EP/BP: Complies with pharmaceutical grade raw material standards
  - IMDG/IATA/ADR: Class 9 miscellaneous dangerous goods (UN 3077)

15.2 Other RegulationsComply with local pharmaceutical GMP production and management regulations; obtain hazardous chemical storage, handling and transport licenses before use; comply with occupational health and safety regulations for chemical production and

handling; conduct allergy screening (ester-type anesthetics) and neurological/respiratory function checks for all operators.

SECTION 16: Other Information

- **Further Information**: This MSDS is based on current scientific research and practical test data, and complies with GB/T 16483, GB/T 17519 and GHS (Rev.9) international standards. It is intended for safe handling, storage, transport and disposal by trained professional personnel only. The supplier is not liable for any damage caused by improper use, unauthorized handling or non-compliance with the safety precautions in this MSDS.
- **Revision Date**: 15 FEB 2026