Safety Data Sheet (MSDS)

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

Product Name: Diclofenac EpolamineRevision Date: 22 FEB 2026

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

1.1 Product Identifiers

- Product Name: Diclofenac Epolamine
- Product Number: DE-20260222
- Brand: SIGALD
- CAS-No.: 83105-74-8
- Synonyms: Diclofenac 2-(diethylamino)ethanol salt; Diethylaminoethanol diclofenac salt

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 external anti-inflammatory and analgesic preparations (gels, patches, creams); raw material for veterinary external anti-inflammatory drugs.
- Uses Advised Against: Not for direct oral/parenteral human use; no non-pharmaceutical industrial use; avoid use in food/cosmetic products for internal use.

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 (Gastrointestinal tract, 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
- 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

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

- Acute: Swallowing causes nausea, abdominal pain and gastrointestinal irritation; skin contact leads to redness, itching and mild rash; eye contact causes severe redness, tearing and blurred vision; dust inhalation may cause cough and throat discomfort.
- Chronic: No known chronic health hazards with proper occupational exposure control.

2.5 Environmental Hazards

- Not classified as a hazardous environmental substance; low acute toxicity to aquatic organisms (96h LC_{50} > 200 mg/L for zebrafish); low bioaccumulation potential.

2.6 Other Hazards

- No additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance**
- Active Ingredient: Diclofenac Epolamine (100%)
- CAS-No.: 83105-74-8
- EC-No.: N/A
- Hazardous components: 100% (Diclofenac Epolamine, 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. If cough or irritation persists, call a doctor.
- 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. If irritation or rash occurs, seek medical advice.

- 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 and easy to do. Seek **immediate** medical advice.
- If Swallowed: Do not induce vomiting. Rinse mouth with water. Do not give anything by mouth to an unconscious person. Call a poison center or doctor immediately.

4.2 Most Important Symptoms and Effects

- Acute: Gastrointestinal discomfort, nausea (swallowed); skin redness, pruritus (skin contact); severe eye irritation, lacrimation (eye contact); respiratory tract irritation, cough (inhalation).
- Delayed: No known delayed toxic effects within 48 hours of exposure.

4.3 Indication of Immediate Medical Attention

- Seek urgent medical help if large amounts are swallowed, eye contact causes persistent vision problems, or skin/respiratory irritation worsens.

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; under high-temperature incomplete combustion, small amounts of hydrogen chloride (HCl) and nitrogen oxides (NO_x) may be released.
- No explosion risk under normal fire conditions.

5.3 Advice for Firefighters

- Wear self-contained breathing apparatus (SCBA) and full fire-fighting protective gear if hazardous combustion gases are generated.
- Prevent fire-extinguishing water from entering municipal sewers or natural water bodies (minimal aquatic impact).

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.

6.2 Environmental Precautions

- Prevent spilled powder from entering sewers, rivers, lakes or soil. Cover with inert material if necessary to avoid 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 plastic container for professional disposal. Do not blow or vacuum the powder to avoid dust inhalation.
- Large Spill: Contain the spill with sand/vermiculite, transfer to a sealed HDPE drum with a label, and hand over to a licensed hazardous waste treatment company. Do not wash the spill into drains.

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 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.

7.2 Conditions for Safe Storage

- Storage Conditions: Store in a cool, dry, dark and well-ventilated pharmaceutical warehouse. Temperature ≤ 25℃, relative humidity ≤ 60%. Keep the container tightly sealed to prevent hygroscopy and contamination.
- Incompatibilities: Strong acids (HCl, H_2SO_4), strong bases (NaOH, KOH), oxidizing agents (H_2O_2, $KMnO_4$), 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.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal control limit: 0.5 mg/m³ (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 (for routine handling); goggles + face shield (for large-scale weighing and mixing).
  - Skin Protection: Nitrile rubber gloves (thickness ≥ 0.18 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 Propertiesa) Physical State: Solid (white crystalline powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point: 148-152℃ (melting with decomposition)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: ≥ 145℃ (releases small amounts of HCl)k) pH Value: 6.0-7.5 (1% aqueous suspension, 25℃)l) Viscosity: Not applicable (solid)m) Water Solubility: Soluble in water (≈50 g/L, 25℃); freely soluble in ethanol, methanol, propylene glycol; slightly soluble in acetone.n) Partition Coefficient (log P, n-octanol/water): 2.8o) Vapor Pressure (25℃): < 0.0001 hPap) Density (25℃): 1.28-1.32 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 the recommended storage and handling conditions (≤25℃, dry, sealed).10.2 Possibility of Hazardous Reactions: No hazardous reactions occur under normal use; decomposition at high temperature (>145℃) releases small amounts of hydrogen chloride and amine gases.10.3 Conditions to Avoid: High temperature (>145℃), 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, acidic/basic pharmaceutical excipients.10.5 Hazardous Decomposition Products: Carbon dioxide, water vapor, hydrogen chloride (HCl), diethylaminoethanol, 2,6-dichloroaniline (trace).

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity:
  - Oral (Rat, LD_{50}): 980 mg/kg (harmful)
  - Dermal (Rabbit, LD_{50}): > 2000 mg/kg (low dermal toxicity)
  - Inhalation (Rat, LC_{50}): > 10 mg/m³ (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 corneal opacity (Category 2), reversible with treatment.
- Respiratory Irritation: Rat inhalation test - mild respiratory tract irritation at high dust concentrations.
- 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 (≤100 mg/kg).

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC_{50}): 220 mg/L
- Daphnia (48h EC_{50}): 180 mg/L
- Freshwater Algae (72h EC_{50}): 250 mg/L12.2 Persistence and Degradability: Biodegradable (BOD_5 /COD = 0.6); degraded by microorganisms in aquatic and soil environments within 28 days.12.3 Bioaccumulative Potential: Low (log P = 2.8); no significant bioaccumulation in aquatic organisms.12.4 Mobility in Soil: Low mobility; adsorbs to soil organic matter (Koc = 650).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 or expired product is classified as hazardous waste; must be disposed of by licensed hazardous waste treatment facilities via incineration with acid gas scrubbing (to remove HCl).
- Packaging Waste: Rinse packaging with ethanol and water, 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 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: 307714.2 UN Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (Diclofenac Epolamine)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: **Yes (P)**14.6 Special Precautions for Transport

- Transport in sealed HDPE pharmaceutical-grade drums with inner plastic lining; affix standard Class 9 hazard labels and marine pollutant marks.
- Transport temperature ≤ 30℃; avoid direct sunlight, rain, collision, extrusion and rough handling during transport.
- Do not transport with food, feed, cosmetics, aquatic products and oral pharmaceutical raw materials.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations for Class 9 hazardous substances.

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.
- EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Warning); IMDG Code (Class 9).
- US: TSCA (listed on the TSCA Inventory); DOT (Class 9 hazardous material); FDA (compliant with pharmaceutical intermediate quality standards).
- Other: Comply with local pharmaceutical raw material import/export registration and hazardous chemical transport regulations.

15.2 Additional Regulatory Requirements

- Provide MSDS and COA for customs clearance; apply for a hazardous chemical transport document for bulk shipment; provide product quality test reports 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.
- 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.