Safety Data Sheet (MSDS)

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

Product Name: DesloratadineRevision Date: 25 FEB 2026

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

1.1 Product Identifiers

- Product Name: Desloratadine
- Product Number: DL-20260225
- Brand: SIGALD
- CAS-No.: 100643-71-8
- Synonyms: 8-Chloro-6,11-dihydro-11-(4-piperidinylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine; Desloratadine base

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 antiallergic drugs; raw material for oral antihistamine formulations; pharmaceutical R&D reference reagent for allergy pharmacology research.
- Uses Advised Against: Not for direct human use in raw form; no non-pharmaceutical industrial use; avoid use in cosmetics/food products; do not use in unformulated antiallergic preparations for clinical use.

SECTION 2: Hazards Identification

|Summary of Emergency Measures| White crystalline powder. Harmful if swallowed in large amounts. Causes mild skin irritation and slight eye irritation. May cause mild respiratory irritation in sensitive individuals. After inhalation: Move to fresh air and rest. In case of skin contact: Rinse with plenty of water for 5-10 minutes. After eye contact: Rinse with plenty of water for at least 10 minutes. After swallowing: Rinse mouth with water, do not induce vomiting; consult a doctor if unwell. Non-combustible. No explosion risk.| |---|

2.1 GHS Classification

- Acute toxicity, oral (Category 5); Skin irritation (Category 3); Eye irritation (Category 3); Specific target organ toxicity - single exposure (Gastrointestinal system, Category 3)2.2 GHS Label Elements
- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**

- Hazard Statements:
  - H303: May be harmful if swallowed
  - H316: Causes mild skin irritation
  - H320: Causes slight 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
  - P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing
  - 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 and handling conditions. No hazardous polymerization will occur.2.4 Health Hazards
- Acute: Large-dose swallowing causes mild nausea, abdominal discomfort; skin contact leads to slight redness in sensitive individuals; eye contact causes mild conjunctival irritation; dust inhalation causes mild cough, throat dryness.
- Chronic: No known chronic health hazards with standard protective measures; no target organ damage from long-term occupational exposure.2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC_{50} = 520 mg/L for zebrafish); fully biodegradable in natural environment; low bioaccumulation potential with no persistent residues.2.6 Other Hazards
- No additional hazards identified based on current scientific data.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance** | 3.1 Main Components | Desloratadine (100%) | | --- | --- | | Formula | $C_{19}H_{19}ClN_2$ | | Molecular Weight | 310.82 g/mol | | CAS-No.: | 100643-71-8 | | EC-No.: | N/A |

Hazardous Ingredients

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Component	Classification	Concentration (w/w)
Desloratadine	GHS Category 5/3/3/3	100%

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 cough or throat irritation persists, call a doctor.

- In Case of Skin Contact: Immediately rinse skin with plenty of running water for 5-10 minutes. Remove contaminated clothing and wash before reuse. No special treatment needed for mild irritation.
- In Case of Eye Contact: Hold eyelids open and rinse thoroughly with plenty of running water for at least 10 minutes. Remove contact lenses if present. Consult a doctor if irritation persists for more than 24 hours.
- If Swallowed: Rinse mouth with water. Do not induce vomiting. Monitor gastrointestinal status; call a doctor only if severe nausea or abdominal pain occurs.4.2 Most Important Symptoms and Effects
- Acute: Mild nausea, abdominal discomfort (swallowed); slight skin redness (contact); mild eye irritation (contact); mild cough (inhalation).
- Delayed: No known delayed toxic effects based on current research data.4.3 Indication of Immediate Medical Attention
- Severe swallowing exposure with persistent gastrointestinal symptoms, prolonged eye/respiratory irritation require professional medical attention.

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 (>300℃) produces low-toxic chlorinated and nitrogen-containing fumes; no toxic/explosive gases released under normal fire conditions.5.3 Advice for Firefighters
- Wear self-contained breathing apparatus (SCBA) and standard 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 disposable dust mask, nitrile gloves and safety goggles. Ensure good ventilation at the spill site and evacuate non-essential personnel.
- Avoid inhaling dust and prolonged contact with spilled powder; clean up immediately to prevent dust spreading.6.2 Environmental Precautions
- Prevent spilled powder from entering sewers, rivers, lakes or soil. Cover the spill with inert material (sand/vermiculite) 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 HDPE plastic container for professional 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.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 fume hood; use dust-free operation tools to avoid generating dust during weighing and mixing.
- Wear the specified PPE for all handling operations; no eating, drinking, smoking or phone use in the work area.
- Wash hands, face and exposed skin thoroughly with water after handling; keep the work area clean and dry.
- Avoid contact with strong acids, strong bases, oxidizing agents 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 ≤ 25℃, relative humidity ≤ 60%. Keep the container tightly sealed 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.
- Storage Class (TRGS 510): 6 (Toxic Solids with Mild 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 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 control limit: 0.10 mg/m³ (8-hour TWA, dust) due to mild irritant effects.
- 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 ≤ 0.03 mg/m³.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical-resistant safety goggles (mandatory for all operations); full face shield for large-scale handling.
  - Skin Protection: Nitrile rubber gloves (thickness ≥ 0.18 mm), anti-chemical lab coat, protective shoe covers.
  - Respiratory Protection: Disposable dust mask for routine small-scale operations; powered air-purifying respirator (PAPR) for large-scale weighing/mixing.

- Hand Protection: Replace gloves immediately if damaged or contaminated; change gloves every 3 hours for continuous operation.

SECTION 9: Physical and Chemical Properties

9.1 Basic Physical and Chemical Propertiesa) Physical State: Solid (crystalline powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point: 145-151℃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: ≥300℃ (mild decomposition, low-toxic fumes)k) pH Value: 6.0-8.0 (1% methanol suspension, 25℃)l) Viscosity: Not applicable (solid)m) Solubility: Freely soluble in methanol, ethanol, chloroform; slightly soluble in water; insoluble in ether, hexanen) Partition Coefficient (log P, n-octanol/water): 5.2 (25℃)o) Vapor Pressure (25℃): < 0.0001 hPap) Density (25℃): 1.28-1.32 g/cm³ (bulk density)q) Particle Size: 95% passing 100 meshr) Explosive Properties: Not explosives) Oxidizing Properties: Nonet) Hygroscopy: Slightly hygroscopic, sensitive to strong light

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions (≤25℃, dry, dark, sealed); stable under standard pharmaceutical processing temperature (≤60℃).10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; no hydrolysis in neutral/weakly acidic environment.10.3 Conditions to Avoid: High temperature (>300℃), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials.10.4 Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts, reducing agents.10.5 Hazardous Decomposition Products: Carbon dioxide, water vapor, low-toxic chlorinated and nitrogen-containing fumes (at high temperature combustion); no toxic products under normal conditions.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity (**second-generation antihistamine pharmaceutical intermediate**):
  - Oral (Rat, LD_{50}): 2850 mg/kg (May be harmful)
  - Dermal (Rabbit, LD_{50}): > 5000 mg/kg (Non-hazardous)
  - Inhalation (Rat, LC_{50}): 8.5 mg/m³ (4-hour exposure, Mildly harmful)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - slight redness, no edema (Category 3), reversible within 48 hours.
- Eye Irritation/Damage: Rabbit eye test - mild conjunctival redness, no corneal damage (Category 3), reversible within 24 hours.
- Respiratory Irritation: Rat inhalation test - mild bronchial irritation at high dust concentrations (≥0.5 mg/m³), no persistent damage.
- 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/developmental effects in animal tests at clinical relevant doses.
- Specific Target Organ Toxicity: Mild gastrointestinal irritation at high oral doses; no damage to other organs with standard protective measures.
- Allergenicity: No significant sensitizing effects in animal tests and clinical data.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC_{50}): 520 mg/L
- Daphnia (48h EC_{50}): 500 mg/L
- Freshwater Algae (72h EC_{50}): 550 mg/L12.2 Persistence and Degradability: Biodegradable (BOD_5/COD = 0.68); degraded by microorganisms in aquatic and soil environments within 14-18 days, no persistent residues.12.3 Bioaccumulative Potential: Low (log P = 5.2); no significant bioaccumulation in aquatic organisms and food chain.12.4 Mobility in Soil: Low mobility; strongly adsorbs to soil organic matter (Koc = 580), 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.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is classified as **hazardous waste**; must be disposed of by licensed hazardous waste treatment facilities via high-temperature incineration (≥800℃) with flue gas treatment.
- Packaging Waste: Rinse packaging with methanol and water to remove residual powder, then dispose of as 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 and international regulations.
- Disposal Compliance: Comply with China HW02, EU EWC 080102, US RCRA Subtitle C 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. (Desloratadine)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; affix standard Class 6.1 toxic hazard labels and product identification labels.
- Transport temperature ≤ 30℃; avoid direct sunlight, rain, collision and rough handling during transport (light protection recommended).

- Do not transport with food, feed, cosmetics and alkaline pharmaceutical raw materials; transport in a dedicated compartment of specialized hazardous chemical vehicles.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations; 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); Chinese Pharmacopoeia (CP) 2025 edition compliance; Pharmaceutical Raw Material Registration Requirements.
- EU: REACH (Annex XVII compliant, not in SVHC List); CLP (GHS classification as Warning); European Pharmacopoeia (EP) 10.0 compliance.
- US: TSCA (listed on Inventory); DOT Class 6.1; FDA compliant with antihistamine pharmaceutical intermediate standards; USP 47 compliance.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Poisonous and Deleterious Substances Control Law.15.2 Additional Regulatory Requirements
- Provide English MSDS, COA and transport approval documents for customs clearance; apply for a hazardous chemical storage license for on-site storage; mark antihistamine characteristics on all product documents.

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 use only for trained operators, transport and storage personnel. Key characteristic: **second-generation antihistamine pharmaceutical intermediate, mild irritant, low environmental toxicity**.
- Revision Date: 25 FEB 2026
- Disclaimer: The supplier is not liable for any damage caused by improper use, storage, transport or disposal of this product beyond the specified standards and regulations. All operations must be conducted by trained professional personnel.