

Safety Data Sheet (MSDS)

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

Product Name: Dexmedetomidine Hydrochloride **Revision Date: 29 FEB 2026**

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

1.1 Product Identifiers

- Product Name: Dexmedetomidine Hydrochloride
- Product Number: DHM-20260229
- Brand: SIGALD
- CAS-No.: 153006-60-5
- Synonyms: (S)-4-[1-(2,3-Dimethylphenyl)ethyl]-1H-imidazole hydrochloride; Dexmedetomidine HCl

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 highly selective α_2 -adrenergic agonist; raw material for injectable sedative/analgesic formulations (surgical anesthesia, ICU sedation); pharmaceutical R&D reference reagent for neuropharmacology 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 injectable preparations for clinical use.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 3); Acute toxicity, dermal (Category 4); Serious eye irritation (Category 2); Specific target organ toxicity - single exposure (Nervous/ Cardiovascular system, Category 3)

2.2 GHS Label Elements

- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Danger**
- Hazard Statements:
 - H301: Toxic if swallowed
 - H312: Harmful in contact with skin
 - H319: Causes serious eye irritation
 - H335: May cause respiratory irritation
 - H373: May cause damage to organs (Nervous, Cardiovascular) 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



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

- Non-combustible; no explosive/oxidizing properties under normal storage and handling conditions. No hazardous polymerization will occur.2.4 Health Hazards
- Acute: Swallowing causes bradycardia, hypotension, sedation, dizziness; skin contact leads to mild redness, numbness; eye contact causes severe conjunctival redness and corneal irritation; dust inhalation causes cough, chest tightness, mild sedation.
- Chronic: Prolonged exposure may cause persistent bradycardia, hypotension in sensitive individuals; mild neurological fatigue with repeated dust inhalation; no irreversible organ damage with strict protective measures.2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC₅₀ = 420 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: Dexmedetomidine Hydrochloride (100%)
- CAS-No.: 153006-60-5
- EC-No.: N/A
- Hazardous components: 100% (Dexmedetomidine Hydrochloride, GHS Category 3/4/2/3)

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. Monitor heart rate/blood pressure. 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. Monitor for hypotension/bradycardia. Seek medical advice if numbness/irritation persists.
- 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. Monitor heart rate/blood pressure closely. 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: Bradycardia, hypotension, central nervous system sedation, dizziness (swallowed/inhaled); skin numbness/erythema (contact); severe eye irritation, blurred vision (contact); cough, chest tightness (inhalation).
- Delayed: Persistent hypotension/bradycardia may occur 2-4 hours after excessive exposure; reversible with symptomatic treatment.4.3 Indication of Immediate Medical Attention
- All exposure scenarios (swallowing, eye contact, heavy inhalation, prolonged skin contact) require **immediate professional medical attention**; cardiac/neurological monitoring is mandatory 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 (>200°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.
- Monitor heart rate/blood pressure for firefighters due to potential inhalation of decomposition fumes.

- 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.
- Monitor heart rate/blood pressure during cleanup; avoid prolonged contact with spilled powder.
- 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.
- Monitor heart rate/blood pressure for personnel with prolonged operation time.

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, β -adrenergic antagonists.
- 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; store away from cardiovascular/neurological drug raw materials.

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/m^3 (8-hour TWA, dust) (due to cardiovascular/neurological effects).
 - Biological Limit Value (BLV): N/A.
- ### 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 $\leq 0.03 \text{ mg/m}^3$.
 - 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 ≥ 0.20 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 (mandatory).
- Hand Protection: Replace gloves immediately if damaged, punctured or contaminated; change gloves every 1 hour 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: 143-147°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: $> 450^{\circ}\text{C}$ j) Decomposition Temperature: $\geq 200^{\circ}\text{C}$ (mild decomposition, produces low-toxic fumes) k) pH Value: 4.5-7.0 (1% aqueous solution, 25°C) l) Viscosity: Not applicable (solid) m) Solubility: Freely soluble in water (≈ 280 g/L, 25°C); freely soluble in ethanol, methanol; slightly soluble in acetone, ether, chloroform n) Partition Coefficient (log P, n-octanol/water): 2.8 (25°C) o) Vapor Pressure (25°C): < 0.0001 hPa p) Density (25°C): 1.18-1.22 g/cm³ (bulk density) q) Particle Size: 95% passing 100 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 ($\leq 25^{\circ}\text{C}$, dry, dark, sealed); stable under standard pharmaceutical processing temperature ($\leq 60^{\circ}\text{C}$); **optical purity remains stable** for the shelf life under specified conditions (no racemization). 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 ($> 200^{\circ}\text{C}$), 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, β -adrenergic antagonists, 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 imidazole and aromatic hydrocarbon derivatives produced by alkaline hydrolysis.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity (**highly selective α_2 -agonist, cardiovascular/neurological effects**):
 - Oral (Rat, LD₅₀): 28 mg/kg (Toxic)
 - Dermal (Rabbit, LD₅₀): 850 mg/kg (Harmful)
 - Inhalation (Rat, LC₅₀): 4 mg/m³ (4-hour exposure, Toxic)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - mild redness, no edema (mild irritation), reversible within 48 hours.
- 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 (≥ 0.3 mg/m³), accompanied by mild sedation.
- 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; safe for use in pregnant women under clinical monitoring.
- Specific Target Organ Toxicity: **Highly selective for α_2 -adrenergic receptors**; main target organs are nervous and cardiovascular systems; causes sedation, bradycardia, hypotension at high exposure; no damage to other organs with standard protective measures.

SECTION 12: Ecological Information



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

12.1 Toxicity

- Fish (Zebrafish, 96h LC₅₀): 420 mg/L
 - Daphnia (48h EC₅₀): 400 mg/L
 - Freshwater Algae (72h EC₅₀): 450 mg/L
- 12.2 Persistence and Degradability: Biodegradable (BOD₅/COD = 0.65); degraded by microorganisms in aquatic and soil environments within 10-15 days, no persistent residues.
- 12.3 Bioaccumulative Potential: Low (log P = 2.8); no significant bioaccumulation in aquatic organisms and food chain.
- 12.4 Mobility in Soil: Low mobility; strongly adsorbs to soil organic matter (K_{oc} = 480), 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; high concentration may cause mild sedation in aquatic vertebrates (temporary, reversible).

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 (≥800°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. (Dexmedetomidine 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 (mark α₂-agonist/cardiovascular effects).
- Transport temperature ≤ 30°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 (especially β-adrenergic antagonists); 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; attach a warning note for cardiac/neurological effects.

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 for injectable sedatives); 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.



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

- 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; mark α_2 -adrenergic agonist 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 occupational health and safety use only for trained operators, transport personnel and storage managers. Key characteristic: **highly selective α_2 -adrenergic agonist with sedative/analgesic effects, low off-target toxicity, main effects on nervous/cardiovascular systems.**
- Revision Date: 29 FEB 2026
- Disclaimer: The supplier is not liable for any damage, injury or environmental pollution caused by improper use, storage, transport or disposal of this product beyond the scope of the specified standards and national/international regulations. All operations must be conducted by trained professional personnel with strict compliance with relevant safety regulations and cardiac/neurological monitoring for prolonged operation.

纳维盈医化科技
NEWAY SINOPHC TECH