



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>

Safety Data Sheet (MSDS)

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

Revision Date: 28 FEB 2026

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

1.1 Product Identifiers

- Product Name: Donepezil Hydrochloride
- Product Number: DON-20260228
- Brand: SIGALD
- CAS-No.: 103474-53-9
- Synonyms: 2-[(1-Benzylpiperidin-4-yl)methyl]-5,6-dimethoxyindan-1-one hydrochloride; Aricept HCl

1.2 Supplier Details

- 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 Identified Uses & Uses Advised Against

- Identified Uses: Pharmaceutical raw material for anti-Alzheimer's disease drugs (cholinesterase inhibitor)
- Uses Advised Against: Direct human consumption; unauthorized pharmaceutical formulation; non-pharmaceutical use; veterinary use without official approval

SECTION 2: Hazards Identification

Summary of Emergency Measures	White crystalline powder. Harmful if swallowed; causes serious eye irritation; may cause mild respiratory irritation. Inhalation: Move to fresh air, rest. Skin contact: Rinse with water for 10 mins. Eye contact: Rinse for 10-15 mins, seek medical help. Swallowing: Rinse mouth, do not induce vomiting, call poison center immediately. Non-combustible; no explosion risk.
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2.1 GHS Classification

- Acute toxicity, oral (Category 4); Eye irritation (Category 2); Specific target organ toxicity (single exposure), respiratory system (Category 3)

2.2 GHS Label Elements

- Hazard Pictograms: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
 - H302: Harmful if swallowed
 - H319: Causes serious eye irritation
 - H335: May cause respiratory irritation



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- Precautionary Statements:
 - P261: Avoid breathing dust
 - P264: Wash hands thoroughly after handling
 - P270: Do not eat, drink or smoke when using
 - P280: Wear protective gloves/eye/face protection
 - P301+P312: If swallowed: Call a POISON CENTER/doctor if unwell
 - P305+P351+P338: If in eyes: Rinse cautiously with water, remove contact lenses, continue rinsing
 - P391: Collect spillage

2.3 Physical and Chemical Hazards

- Non-combustible; no explosive/oxidizing properties; no hazardous decomposition under normal use conditions

2.4 Health Hazards

- Acute: Nausea/vomiting (swallowed); severe eye redness/tearing; mild cough/nasal irritation from dust inhalation
- Chronic: No known chronic toxic effects at occupational exposure levels

2.5 Environmental Hazards

- Harmful to aquatic organisms (low concentration); low biodegradability; no significant bioaccumulation potential

2.6 Other Hazards

- No additional hazards identified

SECTION 3: Composition/Information on Ingredients

- Substance: Pure chemical compound (100% Donepezil Hydrochloride) | Component | CAS-No. | Concentration (w/w) | Classification | | --- | --- | --- | --- | | Donepezil Hydrochloride | 103474-53-9 | 100% | Acute oral toxicity Cat4; Eye irritation Cat2 | | Formula | $C_{24}H_{29}NO_3 \cdot HCl$ | - | Molecular Weight: 415.96 g/mol |

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- Inhaled: Move victim to fresh air and place in a comfortable position. Consult a doctor if cough or chest tightness persists.
- Skin Contact: Remove contaminated clothing and rinse skin with running water for 10 minutes. Wash clothing before reuse.
- Eye Contact: Rinse eyes thoroughly with plenty of running water for 10-15 minutes (hold eyelids open). Remove contact lenses if present. **Seek immediate medical attention** if irritation lasts.
- Swallowed: Rinse mouth with water. Do not induce vomiting. Call a poison center or doctor immediately and provide the product label.

4.2 Most Important Symptoms

- Acute: Gastrointestinal upset, severe eye irritation, mild respiratory discomfort from dust inhalation

4.3 Medical Attention

- Symptomatic treatment required; monitor gastrointestinal and neurological function for acute ingestion; no specific antidote (supportive care only)

4.4 Notes to Physician

- Inform the physician of donepezil hydrochloride exposure; monitor vital signs and gastrointestinal status

SECTION 5: Firefighting Measures

5.1 Extinguishing Media: Water spray, foam, carbon dioxide (CO₂), dry powder (all suitable)5.2

Special Hazards from Combustion: Non-combustible; no hazardous combustion gases or fumes generated under fire conditions5.3 Firefighter Advice: Wear standard fire-fighting gear and a

dust mask; avoid inhalation of dust from fire-related disturbance; keep containers cool with water spray if exposed to fire

SECTION 6: Accidental Release Measures

6.1 Personal Precautions: Wear full PPE (nitrile gloves, chemical safety goggles, N95 dust mask, lab coat); ensure good ventilation; evacuate non-essential personnel from the spill area6.2

Environmental Precautions: Prevent spillage from entering drains, rivers or groundwater; collect spilled material to avoid aquatic contamination6.3 Containment & Clean-Up

- Small Spill: Sweep up with a clean brush and transfer to a sealed HDPE container for professional disposal
- Large Spill: Contain with plastic dikes; transfer to sealed drums with a clean shovel; clean the area with a small amount of water and collect wash water for disposal6.4 Reference: See Section 13 for waste disposal guidelines

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate in a well-ventilated, dust-free GMP workshop; use closed handling/transfer systems to avoid dust generation and inhalation
- Avoid contact with strong acids, strong bases and high-temperature environments (>60°C) to prevent structural degradation
- Hygiene Measures: Wash hands and face thoroughly after handling; no eating/drinking/smoking in the work area7.2 Safe Storage
- Storage Conditions: Cool, dry, well-ventilated warehouse (≤25°C); keep container tightly sealed; avoid direct sunlight and high humidity (>60%)
- Incompatibilities: Strong acids (HCl/H₂SO₄), strong bases (NaOH/KOH), oxidizing agents
- Storage Class (TRGS 510): 6.1 (Toxic Solids)
- Shelf Life: 24 months (unopened, under specified storage conditions)
- Segregation: Store separately from food, feed and non-pharmaceutical materials; keep away from children and unauthorized personnel

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters: Occupational Exposure Limit (OEL) – TWA 0.2 mg/m³ (respirable dust) (EU/China proposed)8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency dust collection; dust-free workbench (pharmaceutical grade)

- Personal Protective Equipment (PPE):
 - Eye/Face: Chemical safety goggles + face shield (mandatory for all handling)
 - Skin: Nitrile rubber gloves (≥ 0.11 mm) + chemical-resistant lab coat + disposable arm covers
 - Respiratory: N95 dust mask (normal handling); powered air-purifying respirator (PAPR) for high-dust environments
 - Hand: No bare hand contact; replace gloves immediately if damaged or contaminated

SECTION 9: Physical and Chemical Properties

- Physical State: White to off-white crystalline powder | Odor: Practically odorless
- Melting Point: 210-214°C | Boiling Point: Decomposes before boiling ($>250^{\circ}\text{C}$)
- Flammability: Non-combustible | Flash Point: Not applicable
- Autoignition Temperature: $>400^{\circ}\text{C}$ | Decomposition Temperature: $\geq 250^{\circ}\text{C}$
- pH Value: 3.5-5.5 (0.5% aqueous solution, 25°C) | Water Solubility: Soluble (6.8 g/100 mL, 25°C)
- Methanol Solubility: Freely soluble (≥ 20 g/100 mL, 25°C) | Density (25°C): 1.29 g/cm³
- Vapor Pressure (25°C): <0.0001 hPa | Particle Size: 90% passing 100 mesh (pharmaceutical grade)
- Explosive Properties: None | Oxidizing Properties: None
- Hygroscopy: Slight | Optical Rotation: $0^{\circ} \pm 1^{\circ}$ (racemic mixture)

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions ($\leq 25^{\circ}\text{C}$, dry, sealed); slight hygroscopy with no chemical degradation

10.2 Hazardous Reactions: No hazardous reactions under normal use and handling conditions

10.3 Conditions to Avoid: High temperature ($>60^{\circ}\text{C}$), direct sunlight, high humidity ($>60\%$), strong acids/bases, oxidizing agents

10.4 Incompatible Materials: Concentrated hydrochloric acid, sulfuric acid, sodium hydroxide, hydrogen peroxide (30%+)

10.5 Hazardous Decomposition Products: No hazardous decomposition products; thermal decomposition at high temperature releases non-toxic organic and inorganic compounds

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD_{50}) = 1350 mg/kg; Dermal (Rabbit, LD_{50}) >2000 mg/kg; Inhalation (Rat, LC_{50}) >5 mg/m³ (4h)
- Skin Irritation: No irritation (Rabbit, 4h exposure)
- Eye Irritation: Category 2 (severe redness and tearing, reversible in 72h; Rabbit, 24h exposure)
- Mutagenicity: Negative (Ames test, chromosome aberration test)
- Carcinogenicity: IARC Class 3 (not classifiable as carcinogenic to humans)
- Reproductive Toxicity: No reproductive harm at normal occupational exposure; high doses cause mild fetal developmental changes (animal studies)
- CNS Toxicity: Mild cholinergic effects (salivation, bradycardia) at high exposure levels

SECTION 12: Ecological Information



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12.1 Toxicity: Zebrafish (LC_{50}) = 42 mg/L (96h); Daphnia (EC_{50}) = 28 mg/L (48h); Algae (EC_{50}) = 45 mg/L (72h)
12.2 Persistence & Degradability: Moderate biodegradability ($BOD_5/COD = 0.35-0.45$) in aquatic environments; degrades within 50 days
12.3 Bioaccumulative Potential: Low ($\log P = 2.4$); no significant accumulation in aquatic organisms
12.4 Mobility in Soil: Low (binds to soil organic matter; no leaching to groundwater under normal conditions)
12.5 PBT/vPvB: Not classified as PBT/vPvB
12.6 Other Adverse Effects: Temporary inhibition of aquatic organism feeding behavior at high concentrations; no long-term ecological harm

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- Product Waste: Classified as hazardous pharmaceutical waste; incinerate at licensed hazardous waste incineration facilities ($\geq 1200^\circ\text{C}$) with gas treatment
 - Packaging Waste: Rinse packaging with a small amount of methanol; collect rinsate for hazardous waste treatment; dispose of packaging as hazardous waste
- #### 13.2 Disposal Regulations:
- Comply with China HW02 (Medical Waste) and Basel Convention; do not dispose with municipal solid waste or aquatic environments

SECTION 14: Transport Information

14.1 UN Number: UN 2811
14.2 UN Proper Shipping Name: Toxic solids, organic, n.o.s. (Donepezil Hydrochloride)
14.3 Transport Hazard Class: 6.1 (Toxic Substances) | Packaging Group: III
14.4 Environmental Hazards: Marine Pollutant (No)
14.5 Special Transport Precautions: Transport at $\leq 25^\circ\text{C}$; use sealed HDPE/fiber drums; mark with GHS hazard labels + UN 2811; avoid direct sunlight and high humidity; do not transport with strong acids/bases/oxidizing agents

SECTION 15: Regulatory Information

15.1 National & International Regulations

- China: NMPA Pharmaceutical Raw Material; Pharmacopoeia (2020); Hazardous Chemicals List (2015)
 - EU: REACH Registered; Ph. Eur. 10.0 compliant; ECHA non-SVHC
 - US: TSCA Listed; USP 45 compliant; FDA-regulated pharmaceutical raw material
- #### 15.2 Other:
- Comply with local pharmaceutical manufacturing, GMP and hazardous waste disposal regulations

SECTION 16: Other Information

- This MSDS complies with GB/T 16483, GB/T 17519 and GHS Rev.9; based on current scientific and regulatory knowledge
- Supplier is not liable for damage caused by improper handling, storage, use or non-compliance with safety precautions
- For additional technical or regulatory information, contact the supplier's pharmaceutical technical department