



# 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, 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: Duloxetine Hydrochloride
- Product Number: DUL-20260228
- Brand: SIGALD
- CAS-No.: 136434-34-9
- Synonyms: (S)-(+)-N-Methyl-3-(1-naphthyloxy)-3-(2-thienyl)propan-1-amine hydrochloride

#### 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 antidepressant/anticonvulsant drug production (serotonin-norepinephrine reuptake inhibitor)
- Uses Advised Against: Direct human consumption; non-pharmaceutical industrial use; unauthorized formulation; veterinary use without approval

### SECTION 2: Hazards Identification

#### 2.1 GHS Classification

- Acute toxicity, oral (Category 4); Acute toxicity, dermal (Category 5); Eye irritation (Category 2); Specific target organ toxicity (single exposure), central nervous system/liver (Category 3); Specific target organ toxicity (repeated exposure), liver (Category 2)

#### 2.2 GHS Label Elements

- Hazard Pictograms: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H313: May be harmful in contact with skin
  - H319: Causes serious eye irritation
  - H335: May cause respiratory irritation; affects CNS/liver
  - H373: May cause damage to the liver through prolonged or repeated exposure
- Precautionary Statements:
  - P261: Avoid breathing dust/fume/gas/mist/vapors/spray
  - P264: Wash hands thoroughly after handling



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- 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/doctor if you feel unwell
- P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing
- P314: Get medical advice/attention if you feel unwell

## 2.3 Physical and Chemical Hazards

- Non-combustible; no explosive hazards under normal storage and handling conditions

## 2.4 Health Hazards

- Acute: Drowsiness, dizziness, nausea (CNS/GI effects) if ingested/absorbed; severe eye irritation; mild skin irritation
- Chronic: Prolonged exposure may cause liver enzyme elevation and CNS dysfunction; no known carcinogenic effects

## 2.5 Environmental Hazards

- Aquatic toxicity (Category 3); harmful to aquatic organisms; low biodegradability
- 2.6 Other Hazards
- No additional hazards identified

## SECTION 3: Composition/Information on Ingredients

- Substance: Pure chemical compound (100% Duloxetine Hydrochloride)
- CAS-No.: 136434-34-9 | Formula: C<sub>18</sub>H<sub>19</sub>NOS·HCl | Molecular Weight: 333.88 g/mol
- Hazardous Ingredients: Duloxetine Hydrochloride (100%, w/w) – meets GHS acute toxicity/irritation criteria

## SECTION 4: First Aid Measures

### 4.1 First-Aid Measures

- Inhaled: Move to fresh air; rest in a semi-upright position. Call a doctor if dizziness, headache or shortness of breath persists.
  - Skin Contact: Remove contaminated clothing; rinse skin with plenty of running water for 10-15 minutes. Treat irritation with mild topical cream if needed.
  - Eye Contact: Rinse eyes thoroughly with plenty of running water for 15-20 minutes (hold eyelids open). Remove contact lenses if present. **Immediate medical attention required** – severe eye irritation risk.
  - Swallowed: Do not induce vomiting. Rinse mouth with water. Call a poison center/doctor immediately and provide the product label.
- ### 4.2 Most Important Symptoms: CNS effects (drowsiness, dizziness); eye/skin irritation; nausea/vomiting; liver enzyme elevation (prolonged exposure)
- ### 4.3 Medical Attention: Symptomatic treatment; monitor liver function for prolonged exposure; no specific antidote available
- ### 4.4 Notes to Physician: Inform physician of duloxetine exposure; monitor vital signs, CNS function and liver enzymes

## SECTION 5: Firefighting Measures

5.1 Extinguishing Media: Water spray, foam, dry powder, carbon dioxide (CO<sub>2</sub>)  
5.2 Special Hazards from Combustion: May release toxic fumes (hydrogen chloride, sulfur oxides, nitrogen oxides, carbon monoxide) at high temperatures  
5.3 Firefighter Advice: Wear SCBA and full fire-fighting gear; keep containers cool with water spray; avoid inhalation of combustion products; prevent runoff into water bodies

## SECTION 6: Accidental Release Measures

6.1 Personal Precautions: Wear PPE (nitrile gloves, chemical safety goggles, N95 dust mask); ensure good ventilation; evacuate non-essential personnel  
6.2 Environmental Precautions: Prevent spillage from entering drains, sewers, rivers or groundwater; contain all spilled material  
6.3 Containment & Clean-Up

- Small Spill: Sweep up with inert absorbent (sand, vermiculite); place in a sealed hazardous waste container
- Large Spill: Contain with dikes; transfer to sealed HDPE drums for professional disposal; clean area with neutral detergent
- 6.4 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; avoid dust generation; use closed handling/transfer systems
- Do not eat/drink/smoke in the work area; wash hands/face thoroughly after handling; limit prolonged skin contact
- Avoid contact with strong acids, strong bases, oxidizing agents and high temperatures to prevent degradation

### 7.2 Safe Storage

- Storage Conditions: Store in a cool, dry, dark warehouse (temperature 15-25°C); keep container tightly sealed; protect from light and moisture
- Incompatibilities: Strong acids, strong bases, oxidizing agents, heavy metal salts, halogens
- Storage Class (TRGS 510): 6.1 (Toxic Substances)
- Shelf Life: 24 months (unopened, under specified storage conditions)
- Segregation: Store separately from food, feed, non-hazardous materials and unauthorized personnel; keep away from children

## SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters: Occupational Exposure Limit (OEL) – TWA 0.2 mg/m<sup>3</sup> (respirable dust); STEL 0.6 mg/m<sup>3</sup> (China/EU/OSHA)  
8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV); dust collection systems; positive pressure ventilation; dust-free workbench
- Personal Protective Equipment (PPE):
  - Eye/Face: Chemical safety goggles + face shield (all large-scale handling)
  - Skin: Nitrile rubber gloves (thickness ≥ 0.11 mm) + chemical-resistant lab coat + disposable arm covers



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- Respiratory: N95 dust mask (normal handling); PAPR (high-dust environments)
- Hand: No bare hand contact; replace gloves immediately if damaged/contaminated

### SECTION 9: Physical and Chemical Properties

- Physical State: White to off-white crystalline powder
- Color: White/off-white | Odor: Practically odorless
- Melting Point: 176-182°C | Boiling Point: Decomposes before boiling (>300°C)
- Flammability: Non-combustible | Flash Point: Not applicable
- Autoignition Temperature: >450°C | Decomposition Temperature: >300°C
- pH Value: 4.5-6.5 (1% aqueous solution)
- Solubility: Soluble in water (12 g/L), methanol, ethanol; slightly soluble in chloroform
- Density (25°C): 1.29 g/cm<sup>3</sup> (solid) | Vapor Pressure (25°C): <0.0001 hPa
- Particle Size: 90% passing 100 mesh (pharmaceutical grade)
- Explosive Properties: Not explosive | Oxidizing Properties: None
- Optical Rotation: +101.0° to +107.0° (1% in methanol)

### SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions (15-25°C, sealed, dark); sensitive to light and high temperature

10.2 Hazardous Reactions: No hazardous reactions under normal use; reacts with strong oxidizing agents to form toxic aromatic byproducts

10.3 Conditions to Avoid: High temperature (>30°C), direct sunlight, moisture, strong acids/bases, oxidizing agents

10.4 Incompatible Materials: Concentrated HCl, NaOH, hydrogen peroxide, potassium permanganate, chlorine gas

10.5 Hazardous Decomposition Products: Hydrogen chloride (HCl), sulfur oxides (SO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>), carbon monoxide (CO), naphthalene derivatives

### SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD<sub>50</sub>) = 320 mg/kg; Dermal (Rabbit, LD<sub>50</sub>) = >5000 mg/kg; Inhalation (Rat, LC<sub>50</sub>) = >2 mg/m<sup>3</sup> (4h)
- Skin Corrosion/Irritation: Mild irritation (Rabbit, 4h exposure); no corrosion or skin damage
- Serious Eye Damage/Irritation: Category 2 (severe eye irritation, reversible in 48-72h)
- CNS Effects: Dose-dependent drowsiness, dizziness, headache; no seizures at therapeutic doses
- Liver Toxicity: Prolonged exposure causes mild liver enzyme elevation (animal studies); clinical use associated with rare hepatotoxicity
- Mutagenicity: Negative (Ames test, mouse lymphoma assay, chromosome aberration test)
- Carcinogenicity: IARC Class 3 (not classifiable as to carcinogenicity to humans)
- Reproductive Toxicity: May cause fetal harm if exposed during pregnancy (animal studies); US FDA Category C

### SECTION 12: Ecological Information



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12.1 Toxicity: Zebrafish ( $LC_{50}$ ) = 10 mg/L (96h); Daphnia ( $EC_{50}$ ) = 7 mg/L (48h); Algae ( $EC_{50}$ ) = 12 mg/L (72h)  
12.2 Persistence & Degradability: Biodegradability <20% (28d, OECD 301); highly persistent in aquatic and soil environments  
12.3 Bioaccumulative Potential: Log Koc = 3.5 (high bioaccumulation in aquatic organisms and soil fauna)  
12.4 Mobility in Soil: Low mobility (strongly adsorbs to soil organic matter); no leaching to groundwater under normal conditions  
12.5 PBT/vPvB: Classified as P (Persistent) – not vPvB

### SECTION 13: Disposal Considerations

#### 13.1 Waste Treatment

- Product Waste: Dispose as hazardous pharmaceutical waste; incinerate at licensed hazardous waste incineration facility ( $\geq 1200^{\circ}\text{C}$ ) with advanced gas treatment (to remove HCl/SO<sub>x</sub>/NO<sub>x</sub> and aromatic compounds)
  - Packaging Waste: Rinse packaging with methanol/water; dispose rinsate with product waste; recycle only if fully decontaminated (no residual powder)
- #### 13.2 Disposal Regulations: Comply with China HW02 (medical waste) and Basel Convention for hazardous waste disposal; do not dispose in municipal waste or sewers

### SECTION 14: Transport Information

14.1 UN Number: UN 2811 (Toxic solids, organic, n.o.s.)  
14.2 UN Proper Shipping Name: Toxic solids, organic, n.o.s. (Duloxetine 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 15-25°C with temperature-controlled packaging; avoid direct sunlight and temperature fluctuation
- Use opaque, sealed, chemical-resistant packaging (HDPE drums/amber glass bottles with inner plastic liner); mark with GHS hazard labels, UN number and "Keep in Dark" instructions
- Do not transport with food, feed, beverages, oxidizing agents or strong acids/bases; comply with IMDG/IATA/ADR for Class 6.1 goods

### SECTION 15: Regulatory Information

#### 15.1 National & International Regulations

- China: NMPA Controlled Pharmaceutical Raw Material; Pharmacopoeia of the PRC (2020); Hazardous Chemicals List (2015)
  - EU: REACH Registered; Ph. Eur. (EP 10.0) compliant; not in ECHA SVHC Candidate List
  - US: TSCA Listed; USP 45 compliant; FDA-regulated antidepressant API
- #### 15.2 Other: Comply with local pharmaceutical manufacturing, handling and waste disposal regulations; requires special license for bulk handling in some regions

### 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



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- The supplier is not liable for damage caused by improper handling, storage, use or non-compliance with safety precautions
- For additional technical/regulatory information, contact the supplier's pharmaceutical technical department



纳维盈医化科技  
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