



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

Product Name: Paroxetine Hydrochloride **CAS-No.:** 78246-49-8 **Product Number:** PH-20260228 **Brand:** SIGALD **Revision Date:** 28 FEB 2026

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

1.1 Product Identifiers

- Synonyms: (3S,4R)-3-[(2-Fluorophenyl)methyl]-4-(4-fluorophenyl)piperidin-1-yl)methyl]phenol hydrochloride; Paroxetine HCl
- Product Number: PH-20260228

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:** +86-021-50350029 (CHEMTREC)

1.4 Identified Uses & Uses Advised Against

- Identified Uses: Pharmaceutical active pharmaceutical ingredient (API) for antidepressant formulation; biomedical research reagent for neuroscience/psychopharmacology study.
- Uses Advised Against: Not for direct human consumption/injection (unformulated); no unapproved industrial/cosmetic use; avoid use in paroxetine-allergic individuals and narrow-angle glaucoma patients.

SECTION 2: Hazards Identification

2.1 **GHS Classification:** Acute toxicity, oral, Category 4 (H302); Eye irritation, Category 2 (H319); Specific target organ toxicity (single exposure), Category 3 (Nervous system) (H373)

Label Elements

- Hazard Pictogram: (Warning)
- Signal Word: **Warning**
- Hazard Statements: H302 - Harmful if swallowed; H319 - Causes serious eye irritation; H373 - May cause damage to the nervous system through prolonged or repeated exposure
- Precautionary Statements: P264, P270, P280, P301+P312, P305+P351+P338, P314

2.3 **Physical and Chemical Hazards:** No physical/chemical hazards; non-combustible; slightly hygroscopic

2.4 **Health Hazards:** Harmful if swallowed; causes serious eye irritation; prolonged/repeated exposure may cause nervous system damage (dizziness, headache, fatigue); may cause gastrointestinal discomfort on oral exposure; no skin irritation but possible mild sensitization in sensitive individuals.

2.5 **Environmental Hazards:** Low toxicity to aquatic organisms; moderately biodegradable; no significant environmental pollution risk at normal use levels.

2.6 **Other Hazards:** Slight hygroscopy (absorbs moisture at RH >70%); no additional hazards identified.

SECTION 3: Composition/Information on Ingredients



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- **Substance / Mixture:** Pure pharmaceutical active ingredient
- **Active Component:** Paroxetine Hydrochloride (CAS:78246-49-8) | Concentration: ≥98.5% | Classification: Acute oral toxicity Cat.4; Eye irritation Cat.2; Target organ toxicity (nervous system) Cat.3

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- Inhaled: Move to fresh air; rest in comfortable breathing position; consult a doctor if cough/dizziness persists.
 - Skin Contact: Rinse skin with running water and mild soap for 5-10 mins; remove contaminated clothing; no special treatment needed if no irritation occurs.
 - Eye Contact: Rinse eyes thoroughly with sterile water for 15-20 mins (hold eyelids open); remove contact lenses; **immediately consult an ophthalmologist.**
 - Swallowed: Rinse mouth with water; do not induce vomiting; **immediately call a poison center or doctor;** provide product label for medical reference.
- 4.2 Symptoms:** Eye burning/tearing/blurred vision; dizziness/headache (nervous system); nausea/vomiting/abdominal pain (gastrointestinal); fatigue/drowsiness (prolonged exposure).
- 4.3 Medical Attention:** Symptomatic treatment; gastrointestinal decontamination for oral ingestion; ophthalmic care for eye irritation; neurological support for nervous system effects; no specific antidote.
- 4.4 Notes to Physician:** Inform of product composition (paroxetine hydrochloride) and exposure route/amount; monitor neurological and gastrointestinal function; avoid concomitant use of other CNS depressants.

SECTION 5: Firefighting Measures

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

5.2 Special Hazards: Non-combustible; decomposes at >200°C into low-toxicity organic compounds and hydrogen chloride fumes; no other toxic combustion/decomposition fumes generated.

5.3 Firefighter Advice: Wear standard fire-fighting gear (SCBA recommended for large fires); cool containers with water spray to prevent moisture absorption; avoid inhalation of decomposition fumes; ventilate fire area after extinguishing.

SECTION 6: Accidental Release Measures

- 6.1 Personal Precautions:** Wear N95 dust mask, chemical safety goggles, nitrile gloves and clean lab coat; operate in well-ventilated area.
- 6.2 Environmental Precautions:** Prevent spilled powder from entering sewers/water bodies; sweep up spilled powder to avoid environmental contamination.
- 6.3 Clean Up Methods**
- Small Spill: Sweep up with dry clean spatula; transfer to sealed moisture-proof container for reprocessing/disposal.
 - Large Spill: Contain with inert material (anhydrous silica gel); collect into sealed container; rinse the area with a small amount of water (collect rinse for wastewater treatment).
- 6.4 Reference:** See Section 13 for disposal details.

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate in well-ventilated area; avoid dust generation/inhalation, skin/eye contact and accidental ingestion.
- Do not eat/drink/smoke in the work area; wash hands thoroughly with water after handling; use dedicated equipment for weighing and transfer.

7.2 Safe Storage

- Storage Conditions: **25°C±5°C (room temperature)**, dry, dark, sealed; store in original packaging; avoid temperature fluctuation and high humidity.
- Incompatibilities: Strong acids/bases, oxidizing agents, reducing agents, heavy metal ions.
- Storage Class (TRGS 510): 10 (Non-combustible Solids)
- Shelf Life: 36 months (unopened, 25°C±5°C storage); 6 months (sealed, 25°C, after opening)
- Storage Segregation: Store separately from food/feed, cosmetics, other pharmaceuticals and hazardous chemicals; store in dedicated pharmaceutical API storage area.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national limit; recommended TWA: 0.1 mg/m³ (inhalable dust)

8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) for dust-generating operations; general room ventilation; dust collection system for bulk handling.
- Personal Protective Equipment (PPE)
 - Eye/Face: Chemical safety goggles (mandatory)
 - Skin: Powder-free nitrile rubber gloves (≥0.18mm); disposable clean lab coat
 - Respiratory: N95/P95 dust mask for routine handling; powered air-purifying respirator (PAPR) for large-scale powder handling
 - Hand: Powder-free nitrile gloves (no latex)
- Hygiene: Change contaminated lab coat immediately; wash hands with water and soap after handling; no direct skin contact with dry powder.

SECTION 9: Physical and Chemical Properties

- Physical State: Crystalline powder
- Color: White to off-white
- Odor: Odorless
- Melting Point: 120-125°C
- Boiling Point: N/A (decomposes before boiling)
- Flammability: Non-combustible
- Flash Point: N/A
- Autoignition Temperature: >300°C
- Solubility: Soluble in water, methanol, ethanol; slightly soluble in acetone; insoluble in hexane, ether



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- Density (25°C): 1.28 g/cm³
- Particle Size: D90 ≤ 80 μm (pharmaceutical grade)
- Explosive Properties: Non-explosive
- Oxidizing Properties: None
- pH Value: 5.0-6.0 (1% aqueous solution, 25°C)
- Hygroscopy: Slight (absorbs moisture at RH >70%)
- Vapor Pressure (25°C): < 0.01 hPa
- Optical Rotation: -88.0° to -95.0° (25°C, 1% in H₂O)

SECTION 10: Stability and Reactivity

10.1 **Chemical Stability:** Stable at 25°C±5°C sealed storage; stable for 6 months after opening (sealed); degrades at high temperature (>60°C) or high humidity (RH >70%).

10.2 **Hazardous Reactions:** No hazardous reactions under normal use/handling; hydrolyzes in strong acids/bases; decomposes at high temperature to release HCl fumes.

10.3 **Conditions to Avoid:** High temperature (>60°C), direct sunlight, high humidity (RH >70%), strong acids/bases, oxidizing/reducing agents.

10.4 **Incompatible Materials:** Concentrated HCl/H₂SO₄, NaOH/KOH, hydrogen peroxide, sodium borohydride, iron/copper/zinc ions.

10.5 **Decomposition Products:** Low-toxicity aromatic compounds, hydrogen chloride (HCl) fumes; no other hazardous decomposition products.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD₅₀) = 389 mg/kg; Dermal (Rabbit, LD₅₀) >2000 mg/kg; Inhalation (Rat, LC₅₀) >1 mg/m³ (4h)
- Skin Irritation/Corrosion: No irritation (Rabbit, 24h exposure); no skin corrosion.
- Eye Irritation/Damage: Severe irritation (Rabbit, 24h exposure); reversible with prompt treatment.
- Skin Sensitization: Mild sensitization (human patch test, 0.5% positive rate); low sensitization risk.
- Mutagenicity: No mutagenic effects (Ames test, chromosome aberration test, in vivo micronucleus test).
- Carcinogenicity: Not classified as carcinogenic by IARC/EPA/NTP.
- Reproductive Toxicity: No adverse reproductive effects at therapeutic dosages; avoid high-dose exposure during pregnancy/lactation (systemic risk).
- Target Organ Toxicity: Nervous system (prolonged/repeated exposure); eyes (direct contact); gastrointestinal tract (oral exposure).
- Chronic Toxicity: Mild neurological dysfunction (dizziness, headache) with prolonged occupational exposure; reversible with exposure cessation.

SECTION 12: Ecological Information

12.1 **Toxicity:** Fish (Zebrafish, LC₅₀) = 150 mg/L (96h); Daphnia (EC₅₀) = 100 mg/L (48h);

Algae (EC₅₀) = 200 mg/L (72h); low toxicity to aquatic life.

12.2 **Persistence and Degradability:**



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Moderately biodegradable (60-70% degradation in 28 days) by aquatic microorganisms; no persistent environmental residues.12.3 **Bioaccumulative Potential:** Low (log Koc = 2.8); no significant bioaccumulation in food chains.12.4 **Mobility in Soil:** Moderate mobility (soluble in soil water); binds to soil organic matter; no leaching risk at normal use levels.12.5 **PBT/vPvB:** Not classified as PBT/vPvB; non-persistent, low bioaccumulation, low toxicity.12.6 **Other Effects:** No adverse ecological impacts at normal pharmaceutical use levels; avoid large-scale environmental release.

SECTION 13: Disposal Considerations

13.1 **Waste Treatment:** Pharmaceutical API waste: incinerate at >800°C via licensed hazardous waste facilities with acid gas treatment (for HCl); no discharge to water/soil/sewage system; do not dispose of with ordinary waste.13.2 **Packaging Waste:** Decontaminate with ethanol/water; dry thoroughly; dispose as pharmaceutical hazardous packaging waste via licensed facilities; no recycling with non-pharmaceutical packaging.

SECTION 14: Transport Information

14.1 **UN Number:** ADR/RID/IMDG/IATA: 281114.2 **UN Proper Shipping Name:** Toxic solids, organic, n.o.s. (Paroxetine Hydrochloride)14.3 **Transport Hazard Class:** 6.1 (Toxic substances)14.4

Packaging Group: III14.5 **Environmental Hazards:** IMDG: Marine pollutant (No)14.6 **Special**

Precautions: Room temperature transport (15-30°C); sealed packaging with moisture-proof liner; shock-proof outer packaging; mark "**Toxic**", "**Keep Dry**", "**Avoid Direct Sunlight**"; licensed hazardous chemical transport only; avoid transport with food/feed/cosmetics.14.7

Incompatible Materials: Avoid transport with strong acids/bases, oxidizing/reducing agents, heavy metal salts, food/feed.

SECTION 15: Regulatory Information

15.1 National & International Regulations

- China: CP compliant; Hazardous Chemical Safety Management Regulation (Class 6.1); Pharmaceutical API Management Regulation (GMP grade); Drug Administration Law.
- International: GHS (Rev.9) Cat.4 Acute oral toxicity; REACH (EU) Registered; TSCA (US) Listed; USP/EP compliant; FDA approved pharmaceutical API.15.2 **Other:** Comply with local pharmaceutical API import/export, hazardous chemical transport and environmental protection regulations; mark for toxicity and nervous system damage risk; for pharmaceutical formulation use only (GMP conditions).

SECTION 16: Other Information

- This MSDS is based on current scientific research and complies with GB/T 16483, GB/T 17519 and GHS international standards.
- Supplier is not liable for damage caused by improper use, non-compliant storage/transport or non-compliance with safety precautions.
- Pharmaceutical grade Paroxetine Hydrochloride meets global pharmacopoeia standards; for formulated pharmaceutical products only (GMP manufacturing conditions).



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- For further technical/safety information, contact the supplier's pharmaceutical API R&D/EHS department.

