



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: Aripiprazole **CAS-No.:** 129722-12-9 **Product Number:** AP-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: 7-[4-[4-(2,3-Dichlorophenyl)-1-piperazinyl]butoxy]-3,4-dihydro-2(1H)-quinolinone; Aripiprazole API
- Product Number: AP-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
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- 1.3 **Emergency telephone:** +86-021-50350029 (CHEMTREC)

1.4 Identified Uses & Uses Advised Against

- Identified Uses: Pharmaceutical active pharmaceutical ingredient (API) for atypical antipsychotic formulation; biomedical research reagent for neuroscience/psychopharmacology study (dopamine/serotonin receptor research).
- Uses Advised Against: Not for direct human consumption/injection (unformulated); no unapproved industrial/cosmetic use; avoid use in aripiprazole-allergic individuals, elderly patients with dementia-related psychosis and seizure disorder 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, Liver) (H373)

GHS 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 and liver through prolonged or repeated exposure
- Precautionary Statements: P264, P270, P280, P301+P312, P305+P351+P338, P314, P391

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

2.4 **Health Hazards:** Harmful if swallowed; causes serious eye irritation; prolonged/repeated exposure may cause nervous system (dizziness, somnolence) and liver damage; may cause gastrointestinal discomfort on oral exposure; no skin irritation/sensitization; may cause extrapyramidal symptoms at high exposure levels.

2.5 **Environmental Hazards:** Low toxicity to aquatic organisms; moderately biodegradable; no significant environmental

pollution risk at normal pharmaceutical use levels.2.6 **Other Hazards:** No hygroscopy; no additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- **Substance / Mixture:** Pure pharmaceutical active ingredient
- **Active Component:** Aripiprazole (CAS:129722-12-9) | Concentration: ≥98.0% | Classification: Acute oral toxicity Cat.4; Eye irritation Cat.2; Target organ toxicity (nervous system/liver) Cat.3

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- Inhaled: Move to fresh air; administer oxygen if breathing is difficult; consult a doctor immediately (monitor for neurological symptoms).
- 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 20-30 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/somnolence/tremor (nervous system); nausea/vomiting/abdominal pain (gastrointestinal); elevated liver enzymes (liver damage); extrapyramidal symptoms (high exposure).4.3 **Medical Attention:** Symptomatic treatment; gastrointestinal decontamination for oral ingestion; ophthalmic care for eye irritation; neurological support for CNS effects; liver function monitoring/support for liver damage; no specific antidote.4.4 **Notes to Physician:** Inform of product composition (aripiprazole) and exposure route/amount; monitor neurological, gastrointestinal and liver function; avoid concomitant use of other antipsychotics/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 >250°C into low-toxicity organic compounds and hydrogen chloride (HCl) fumes; no other toxic combustion/decomposition fumes generated.5.3

Firefighter Advice: Wear standard fire-fighting gear (SCBA mandatory for large fires); cool containers with water spray; avoid inhalation of decomposition fumes; ventilate fire area after extinguishing; neutralize any HCl fumes with alkaline mist if needed.

SECTION 6: Accidental Release Measures

6.1 **Personal Precautions:** Wear N95 dust mask, chemical safety goggles + face shield, nitrile gloves and impermeable lab coat; operate in well-ventilated area.6.2 **Environmental**

Precautions: Prevent spilled powder from entering sewers/water bodies/soil; sweep up spilled powder to avoid environmental contamination.6.3 **Clean Up Methods**

- Small Spill: Sweep up with dry clean spatula; transfer to sealed airtight container for reprocessing/disposal.



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- Large Spill: Contain with inert material (anhydrous silica gel); collect into sealed container; do not rinse with water (low solubility); dispose of collected material as hazardous waste.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 stainless steel equipment for weighing and transfer.7.2 Safe Storage

- Storage Conditions: **25°C±5°C (room temperature)**, dry, dark, **airtight sealed**; store in original packaging; avoid temperature fluctuation.

- Incompatibilities: Strong acids/bases, oxidizing agents, halogens, heavy metal ions, organic solvents (long-term contact).

- Storage Class (TRGS 510): 10 (Non-combustible Solids)

- Shelf Life: 48 months (unopened, 25°C±5°C storage); 12 months (airtight sealed, 25°C, after opening)

- Storage Segregation: Store separately from food/feed, cosmetics, other pharmaceuticals and hazardous chemicals; store in **locked dedicated pharmaceutical API storage area** (GMP compliant).

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national limit; recommended TWA: 0.05 mg/m³ (inhalable dust)8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with dust collection for all dust-generating operations; positive pressure clean room for bulk handling; general room ventilation.

- Personal Protective Equipment (PPE)

- Eye/Face: Chemical safety goggles + face shield (mandatory)

- Skin: Powder-free nitrile rubber gloves (≥0.18mm); disposable impermeable lab coat

- Respiratory: N95/P95 dust mask for routine handling; powered air-purifying respirator (PAPR) with full facepiece for large-scale powder handling

- Hand: Powder-free nitrile gloves (no latex, double-layer for bulk handling)

- Hygiene: Change all contaminated PPE immediately; wash hands with water and soap after handling; no direct skin contact with dry powder; regular medical monitoring (liver/neurological function) for prolonged exposure personnel.

SECTION 9: Physical and Chemical Properties

- Physical State: Crystalline powder

- Color: White to off-white

- Odor: Odorless



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- Melting Point: 139-143°C
- Boiling Point: N/A (decomposes before boiling)
- Flammability: Non-combustible
- Flash Point: N/A
- Autoignition Temperature: >350°C
- Solubility: Soluble in acetonitrile, dimethyl sulfoxide (DMSO); slightly soluble in ethanol, methanol; insoluble in water, hexane, ether
- Density (25°C): 1.35 g/cm³
- Particle Size: D90 ≤ 100 μm (pharmaceutical grade)
- Explosive Properties: Non-explosive
- Oxidizing Properties: None
- Hygroscopy: Non-hygroscopic (stable at RH 0-90%)
- Vapor Pressure (25°C): < 0.001 hPa
- Chloride Content: 15.4-16.5% (w/w)

SECTION 10: Stability and Reactivity

10.1 **Chemical Stability:** Stable at 25°C±5°C airtight storage; stable for 12 months after opening (airtight); degrades at high temperature (>80°C) or strong acid/base conditions.

10.2 **Hazardous**

Reactions: No hazardous reactions under normal use/handling; hydrolyzes in strong acids/bases; decomposes at high temperature to release HCl fumes; no reaction with water/air at room temperature.

10.3 **Conditions to Avoid:** High temperature (>80°C), direct sunlight, strong acids/bases (pH <2 or >12), oxidizing agents, halogens.

10.4 **Incompatible**

Materials: Concentrated HCl/H₂SO₄, NaOH/KOH, hydrogen peroxide, chlorine/bromine, iron/copper/zinc ions, strong oxidizers.

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

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD₅₀) = 1227 mg/kg; Dermal (Rabbit, LD₅₀) >2000 mg/kg; Inhalation (Rat, LC₅₀) >0.5 mg/m³ (4h)
- Skin Irritation/Corrosion: No irritation/corrosion (Rabbit, 24h exposure); no skin damage.
- Eye Irritation/Damage: Severe irritation (Rabbit, 24h exposure); reversible with prompt and proper treatment.
- Skin/Respiratory Sensitization: No sensitization (human/animal tests); zero sensitization risk.
- Mutagenicity: No mutagenic effects (Ames test, chromosome aberration test, in vivo micronucleus test, mouse lymphoma assay).
- Carcinogenicity: Not classified as carcinogenic by IARC/EPA/NTP; no carcinogenic potential in animal studies.

- Reproductive Toxicity: No adverse reproductive/teratogenic effects at therapeutic dosages; avoid high-dose exposure during pregnancy/lactation (systemic risk).
- Target Organ Toxicity: Nervous system (prolonged/repeated exposure); liver (prolonged/repeated exposure); eyes (direct contact); gastrointestinal tract (oral exposure).
- Chronic Toxicity: Mild neurological dysfunction (dizziness, tremor) and elevated liver enzymes with prolonged occupational exposure; reversible with exposure cessation and supportive care.
- Extrapyramidal Effects: May occur at high acute/chronic exposure levels; reversible with symptomatic treatment.

SECTION 12: Ecological Information

12.1 **Toxicity:** Fish (Zebrafish, LC₅₀) = 200 mg/L (96h); Daphnia (EC₅₀) = 150 mg/L (48h); Algae (EC₅₀) = 250 mg/L (72h); low toxicity to aquatic life. 12.2 **Persistence and Degradability:** Moderately biodegradable (55-65% degradation in 28 days) by aquatic microorganisms; no persistent environmental residues. 12.3 **Bioaccumulative Potential:** Low (log K_{oc} = 3.2); no significant bioaccumulation in aquatic food chains. 12.4 **Mobility in Soil:** Low mobility (insoluble in water); binds strongly to soil organic matter; no leaching risk to groundwater. 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 of bulk powder.

SECTION 13: Disposal Considerations

13.1 **Waste Treatment:** Pharmaceutical API waste: incinerate at >900°C via licensed hazardous waste facilities with acid gas treatment system (for HCl abatement); no discharge to water/soil/sewage system; do not dispose of with ordinary waste or municipal solid waste. 13.2

Packaging Waste: Decontaminate with acetonitrile/ethanol; dry thoroughly; dispose as pharmaceutical hazardous packaging waste via licensed GMP-compliant facilities; no recycling with non-pharmaceutical packaging.

SECTION 14: Transport Information

14.1 **UN Number:** ADR/RID/IMDG/IATA: 2811 14.2 **UN Proper Shipping Name:** Toxic solids, organic, n.o.s. (Aripiprazole) 14.3 **Transport Hazard Class:** 6.1 (Toxic substances) 14.4 **Packaging Group:** III 14.5 **Environmental Hazards:** IMDG: Marine pollutant (No) 14.6 **Special Precautions:** Room temperature transport (15-30°C); airtight sealed packaging with shock-proof liner; mark "**Toxic**", "**Keep Dry**", "**Avoid Direct Sunlight**"; licensed hazardous chemical transport only (GMP compliant for pharmaceutical API); avoid transport with food/feed/cosmetics/strong acids/bases. 14.7 **Incompatible Materials:** Avoid transport with strong acids/bases, oxidizing agents, halogens, heavy metal salts, food/feed, pharmaceuticals (other classes).

SECTION 15: Regulatory Information

15.1 **National & International Regulations**



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- China: CP compliant; Hazardous Chemical Safety Management Regulation (Class 6.1); Pharmaceutical API Management Regulation (GMP grade); Drug Administration Law; National Pharmaceutical Standards.
- International: GHS (Rev.9) Cat.4 Acute oral toxicity; REACH (EU) Registered; TSCA (US) Listed; USP/EP compliant; FDA approved pharmaceutical API for antipsychotic use.15.2 **Other:** Comply with local pharmaceutical API import/export (GMP certification required), hazardous chemical transport and environmental protection regulations; mark for toxicity, nervous system and liver damage risk; for pharmaceutical formulation use only (GMP manufacturing 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 Aripiprazole meets global pharmacopoeia and pharmaceutical API standards; for formulated pharmaceutical products only (GMP manufacturing and quality control conditions).
- For further technical/safety information, contact the supplier's pharmaceutical API R&D/EHS department (GMP compliance and formulation guidance provided).

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