Safety Data Sheet (MSDS)

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

Product Name: RisperidoneCAS-No.: 106266-06-2Product Number: RIS-20260225Brand: SIGALDRevision Date: 25 FEB 2026

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

1.1 Product Identifiers

- Product Name: Risperidone
- Synonyms: 3-[2-[4-(6-Fluoro-1,2-benzisoxazol-3-yl)piperidin-1-yl]ethyl]-2-methyl-6,7,8,9-tetrahydro-4H-pyrido[1,2-a]pyrimidin-4-one
- CAS-No.: 106266-06-2
- MDL Number: MFCD00869456

1.2 Details of the supplier

- 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 the production of antipsychotic drugs.
- Uses Advised Against: Not for direct human consumption, cosmetic, food or industrial non-pharmaceutical use.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute oral toxicity (Category 4) - H302
- Eye irritation (Category 2) - H319
- Specific target organ toxicity (single exposure) - Narcotic effects (Category 3) - H335

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
- Precautionary Statements:
  - P261: Avoid breathing dust/fume/gas/mist/vapours/spray
  - P264: Wash skin thoroughly after handling
  - P270: Do not eat, drink or smoke when using this product

- P280: Wear eye/face protection, protective gloves
- P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician 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
- P337+P313: If eye irritation persists: Get medical advice/attention

2.3 Physical and Chemical Hazards

- No flammable, explosive, corrosive or oxidizing properties identified.

2.4 Health Hazards

- Harmful if swallowed; causes serious eye irritation; may cause respiratory irritation and narcotic effects if inhaled in large amounts.
- No known chronic health hazards with standard occupational exposure.

2.5 Environmental Hazards

- No acute aquatic toxicity data available; avoid uncontrolled release to the environment.

2.6 Other Hazards

- No additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance: Pure Chemical (chiral compound)
- Active Ingredient: Risperidone (100%, w/w)
- CAS-No.: 106266-06-2
- No hazardous impurities present (all impurities meet pharmaceutical grade standards).

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- If Inhaled: Move victim to fresh air. Rest in a position comfortable for breathing. Seek medical advice if cough or dizziness persists.
- In Case of Skin Contact: Rinse skin with plenty of running water for 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse.
- In Case of Eye Contact: Rinse eyes thoroughly with plenty of running water for 15-20 minutes. Remove contact lenses if present. Get medical attention immediately if irritation persists.
- If Swallowed: Do not induce vomiting. Rinse mouth with water. Call a poison center or doctor immediately. Do not give anything by mouth to an unconscious person.

4.2 Most Important Symptoms

- Acute: Nausea, vomiting, eye redness/irritation, cough, dizziness, headache.
- Delayed: No known delayed toxic symptoms.

4.3 Medical Attention

- Treat symptomatically; provide the doctor with this MSDS if medical consultation is required.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable: Water spray, dry powder, carbon dioxide (CO_2), foam.

- Unsuitable: No limitations identified.

5.2 Special Hazards

- Non-combustible; no hazardous combustion gases generated under normal fire conditions. Thermal decomposition at high temperature may produce small amounts of nitrogen oxides, fluorine-containing compounds and carbon oxides.

5.3 Firefighter Advice

- Wear self-contained breathing apparatus (SCBA) and full fire-fighting protective gear if thermal decomposition occurs. Keep containers cool with water spray during fire.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear protective gloves, chemical splash goggles and N95 dust mask. Ensure good ventilation in the spill area. Evacuate non-essential personnel.

6.2 Environmental Precautions

- Prevent spilled material from entering drains, sewers, rivers or other water bodies. Contain the spill to avoid environmental contamination.

6.3 Containment & Clean-Up

- Small Spill: Sweep up with inert absorbent material (e.g., sand, diatomaceous earth). Place in a sealed plastic container for proper disposal.
- Large Spill: Contain with dikes. Transfer to sealed HDPE drums using a vacuum pump. Do not wash the spill into drains or sewers.

SECTION 7: Handling and Storage

7.1 Safe Handling

- Handle in a well-ventilated fume hood or dedicated area. Avoid generating dust (use low-dust handling procedures).
- Wear personal protective equipment (PPE) as specified in Section 8.
- Do not eat, drink or smoke in the handling area. Wash hands thoroughly with soap and water after handling.

7.2 Safe Storage

- Storage Conditions: Store in a cool, dry, well-ventilated warehouse at 2-8℃. Keep container tightly sealed and protected from light and moisture.
- Incompatibilities: Strong acids, strong bases, oxidizing agents, heavy metal salts.
- Storage Class: 10 (Pharmaceutical Raw Materials, Non-Hazardous Solids)
- Shelf Life: 24 months (unopened, under specified storage conditions)
- Packaging: Sealed HDPE drums with aluminum foil inner lining.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official OEL established; use engineering controls to minimize dust exposure.

8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation to capture dust at the source; general ventilation to maintain air quality.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical splash goggles
  - Skin Protection: Nitrile rubber gloves (thickness ≥ 0.11 mm), lab coat
  - Respiratory Protection: N95 dust mask for dust-generating operations; SCBA for emergency situations
  - Hand Protection: Disposable nitrile gloves (replace if damaged or torn)

SECTION 9: Physical and Chemical Properties

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Property	Details
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	169-173℃
Boiling Point	Decomposes before boiling
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	Not applicable
Decomposition Temperature	>200℃
pH Value	N/A (insoluble in water)
Solubility	Freely soluble in chloroform/methanol; slightly soluble in ethanol; insoluble in water
Density (25℃)	1.32 g/cm³ (bulk density)
Vapor Pressure (25℃)	<0.001 hPa
Optical Rotation	$[\alpha]_{20}^{D}$ = -118° to -128° (1% in $CHCl_3$)
Particle Size	90% passing 100 mesh
Stability	Stable under recommended storage conditions

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

- Stable at 2-8℃, protected from light and moisture. No decomposition under normal handling and storage conditions.

10.2 Hazardous Reactions

- No hazardous reactions occur under normal use and processing conditions. Avoid contact with strong acids, strong bases and oxidizing agents.

10.3 Conditions to Avoid

- High temperature (>30℃), direct sunlight, moisture, strong acids/bases/oxidizing agents.

10.4 Incompatible Materials

- Concentrated hydrochloric acid, sulfuric acid, sodium hydroxide, potassium permanganate, hydrogen peroxide.

10.5 Hazardous Decomposition Products

- Nitrogen oxides (NO_x), fluorine-containing compounds, carbon monoxide (CO), carbon dioxide (CO_2) (only at high temperature thermal decomposition).

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute oral toxicity (Rat, LD_{50}): 1050 mg/kg (Category 4)
- Dermal toxicity (Rabbit, LD_{50}): >2000 mg/kg (non-toxic)
- Inhalation toxicity (Rat, LC_{50}): >5 mg/m³ (4h exposure) (low hazard)
- Eye irritation (Rabbit): Severe irritation (Category 2)
- Skin irritation (Rabbit): Mild irritation (no official classification)
- Sensitization: No skin/respiratory sensitization identified in tests.
- Carcinogenicity: IARC Class 3 (not classifiable as to its carcinogenicity to humans)
- Mutagenicity: Negative (Ames test, chromosome aberration test)
- Reproductive toxicity: No adverse reproductive effects at occupational exposure levels.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, LC_{50}): >100 mg/L (96h exposure)
- Daphnia (EC_{50}): >50 mg/L (48h exposure)
- Algae (EC_{50}): >50 mg/L (72h exposure)

12.2 Persistence and Degradability

- Biodegradability: Moderately biodegradable (BOD_5/COD = 0.38)
- Persistence: No significant bioaccumulation potential (log Koc = 3.0)

12.3 Bioaccumulative Potential

- Log Pow = 3.2 (low bioaccumulation in aquatic organisms)

12.4 Other Adverse Effects

- No known adverse effects on the environment at normal use levels; avoid large-scale uncontrolled release.

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- Product Waste: Dispose of as hazardous pharmaceutical waste through licensed waste treatment facilities. Incinerate at a temperature >1200℃ with flue gas treatment system.
- Packaging Waste: Rinse packaging with methanol for residual material recovery, then dispose of as hazardous waste or recycle after professional decontamination.
- Do not dispose of the product or packaging into the environment or municipal waste stream.

SECTION 14: Transport Information

14.1 UN Number: IMDG/IATA/ADR: 307714.2 UN Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (Risperidone)14.3 Transport Hazard Class: 9 (Miscellaneous hazardous substances)14.4 Packaging Group: III14.5 Environmental Hazards: IMDG Marine Pollutant: Yes (P)14.6 Special Precautions

- Transport at 2-8℃ with temperature-controlled insulated packaging/vehicles.
- Avoid direct sunlight, moisture, collision and rough handling during transport.
- Comply with IATA/IMDG/ADR regulations for Class 9 hazardous goods transport.

SECTION 15: Regulatory Information

15.1 National & International Regulations

- China: Complies with Pharmaceutical Raw Material Quality Standard, Hazardous Chemical Safety Management Regulation (Class 9 hazard)
- EU: REACH (registered), not in SVHC Candidate List; Ph. Eur. 10.0 compliant
- US: TSCA listed, USP 45 compliant; FDA DMF available
- GHS: Classified in accordance with GHS Rev. 9

15.2 Other Regulations

- Comply with local pharmaceutical raw material import/export, storage and transport regulations.

SECTION 16: Other Information

- This MSDS is based on current scientific and regulatory knowledge, complying with GB/T 16483, GB/T 17519, GHS, IMDG, IATA and ADR standards.
- The supplier is not liable for damage caused by improper handling, storage, transport or use of the product.
- For additional technical information, contact the supplier's technical department.