



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: Quetiapine Fumarate
- Product Number: QTF-20260228
- Brand: SIGALD
- CAS-No.: 111974-72-2
- Synonyms: 2-[2-(4-Dibenzo[b,f][1,4]thiazepin-11-yl-1-piperazinyl)ethoxy]ethanol fumarate; Seroquel fumarate

1.2 Details of the supplier of the safety data sheet

- Company: NEWAY SINOPHC TECH. LIMITED
- 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 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

- Identified Uses: Pharmaceutical raw material for atypical antipsychotic drug production (schizophrenia, bipolar disorder)
- 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; affects central nervous system (sedation, dizziness). Inhalation: Move to fresh air and rest. Skin contact: Rinse with water for 10 mins. Eye contact: Rinse for 10-15 mins, consult a doctor immediately. Swallowing: Rinse mouth, do not induce vomiting, call a poison center at once. Non-combustible; decomposes at high temp to release toxic sulfur/ nitrogen fumes. 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), central nervous system (Category 3); Aquatic toxicity (Category 3)

2.2 GHS Label Elements

- Hazard Pictograms: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:



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- H302: Harmful if swallowed
- H319: Causes serious eye irritation
- H335: May cause respiratory irritation; affects central nervous system
- H402: Harmful to aquatic organisms
- Precautionary Statements:
 - P261: Avoid breathing dust/fume
 - P264: Wash hands thoroughly after handling
 - 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.
 - P391: Collect spillage
 - P501: Dispose of contents/container to approved waste facility

2.3 Physical and Chemical Hazards

- Non-combustible; no explosive/oxidizing properties; decomposes at $>280^{\circ}\text{C}$ to release toxic sulfur dioxide (SO_2), nitrogen oxides (NO_x) and aromatic fumes

2.4 Health Hazards

- Acute: CNS depression (sedation, dizziness, drowsiness) if swallowed/inhaled; severe eye irritation; mild gastrointestinal discomfort (nausea, diarrhea) if ingested
- Chronic: No known chronic toxic effects at occupational exposure levels; prolonged CNS exposure may cause fatigue/headache

2.5 Environmental Hazards

- Harmful to aquatic organisms; low biodegradability; sulfur-containing moiety may cause mild aquatic toxicity

2.6 Other Hazards

- No additional hazards identified

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: Pure chemical compound (100% Quetiapine Fumarate) | Component | CAS-No. | Concentration (w/w) | Classification | | --- | --- | --- | ---
| | Quetiapine Fumarate | 111974-72-2 | 100% | Acute oral toxicity Cat4; Eye irritation Cat2; CNS toxicity Cat3 | | Formula | $\text{C}_{21}\text{H}_{25}\text{N}_3\text{O}_2\text{S}\cdot\text{C}_4\text{H}_4\text{O}_4$ | - | Molecular Weight: 515.57 g/mol |

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move victim to fresh air, place in a comfortable breathing position. Provide oxygen if breathing is difficult. Consult a doctor if dizziness/sedation persists.
- In Case of Skin Contact: Remove contaminated clothing and shoes. Rinse skin with running water for 10 minutes. Wash clothing before reuse.
- In Case of 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** even if no irritation is felt.

- If Swallowed: Rinse mouth with water. Do not induce vomiting (risk of CNS depression-induced aspiration). Call a poison center/doctor immediately and provide the product label.
- 4.2 Most Important Symptoms and Effects, Both Acute and Delayed
- Acute: CNS depression (sedation, dizziness), eye redness/tearing, mild nausea; severe ingestion may cause confusion/tremor
- Delayed Effects: No known delayed toxic effects based on current data
- 4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed
- Symptomatic treatment; supportive care for CNS depression (airway management); no specific antidote
- 4.4 Notes to Physician
- Inform the physician of quetiapine fumarate exposure; monitor CNS function and vital signs; treat gastrointestinal symptoms symptomatically

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO₂), dry powder
- Unsuitable Extinguishing Media: No limitations of extinguishing agents
- 5.2 Special Hazards Arising from the Substance or Mixture
- Non-combustible; thermal decomposition at >280°C releases toxic sulfur dioxide (SO₂), nitrogen oxides (NO_x), aromatic fumes and carbon monoxide (CO)
- 5.3 Advice for Firefighters
- Wear self-contained breathing apparatus (SCBA) and full fire-fighting gear; keep containers cool with water spray if exposed to fire; avoid inhalation of decomposition fumes; prevent combustion products from entering water bodies

SECTION 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

- Wear full PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, lab coat); ensure good ventilation; evacuate non-essential personnel from the spill area
- 6.2 Environmental Precautions
- Prevent spillage from entering drains, sewers, rivers or groundwater; collect all spilled material to avoid aquatic contamination
- 6.3 Methods and Materials for Containment and Cleaning Up
- Small Spill: Sweep up with inert absorbent (sand/vermiculite) and transfer to a sealed hazardous waste container
- Large Spill: Contain with plastic dikes; transfer to sealed HDPE drums with a clean shovel for professional disposal
- 6.4 Reference to Other Sections
- For disposal, see Section 13.

SECTION 7: Handling and Storage

7.1 Precautions for 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, high temperatures (>80°C) and direct sunlight to prevent decomposition
- Hygiene Measures: Wash hands/face thoroughly with soap and water after handling; do not eat/drink/smoke in the work area
- 7.2 Conditions for Safe Storage, Including Any Incompatibilities
- Storage Conditions: Store in a cool, dry, dark warehouse ($\leq 25^{\circ}\text{C}$); keep container tightly sealed; protect from light and moisture
- Incompatibilities: Strong acids (pH <3), strong bases (pH >9), oxidizing agents, high temperatures (>80°C), direct sunlight
- Storage Class (TRGS 510): 6.1 (Toxic Solids)
- Shelf Life: 24 months (unopened, under specified storage conditions)
- Segregation: Store separately from food, feed, non-pharmaceutical materials and aquatic environment sources; keep in a locked storage area for authorized personnel only

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

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Component	CAS-No.	Value	Control Parameters	Basis
Quetiapine Fumarate	111974-72-2	TWA: 0.5 mg/m ³	Respirable dust	EU OEL / China Occupational Exposure Limit

8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency dust collection; dust-free workbench (Class 10000) for pharmaceutical grade handling; light-proof processing equipment
- Personal Protective Equipment (PPE):
 - Eye/Face Protection: Chemical safety goggles + face shield (mandatory for all handling)
 - Skin Protection: Nitrile rubber gloves (≥ 0.11 mm) + chemical-resistant lab coat + disposable arm covers
 - Respiratory Protection: 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
- Control of Environmental Exposure: Install dust collection systems to prevent environmental release; treat any contaminated wastewater before discharge

SECTION 9: Physical and Chemical Properties

- Physical State: White crystalline powder | Odor: Practically odorless
- Melting Point: 174-178°C | Boiling Point: Decomposes before boiling (>280°C)
- Flammability: Non-combustible | Flash Point: Not applicable
- Autoignition Temperature: >380°C | Decomposition Temperature: $\geq 280^{\circ}\text{C}$

- pH Value: 4.0-6.0 (1% in water, 25°C) | Water Solubility: Sparingly soluble (1-5 g/100 mL, 25°C)
- Methanol Solubility: Soluble (≥ 10 g/100 mL, 25°C) | Density (25°C): 1.32 g/cm³
- Vapor Pressure (25°C): <0.0001 hPa | Particle Size: 90% passing 100 mesh (pharmaceutical grade)
- Explosive Properties: None | Oxidizing Properties: None
- Light Sensitivity: Sensitive to direct sunlight (degradation risk) | Hygroscopy: Slightly hygroscopic

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions ($\leq 25^\circ\text{C}$, dark, sealed); slightly hygroscopic but no significant chemical degradation

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

10.3 Conditions to Avoid: Direct sunlight, high temperature ($>80^\circ\text{C}$), strong acids/bases, oxidizing agents

10.4 Incompatible Materials: Concentrated hydrochloric acid/sulfuric acid, sodium hydroxide (50%+), hydrogen peroxide (30%+), potassium permanganate

10.5 Hazardous Decomposition Products: Sulfur dioxide (SO₂), nitrogen oxides (NO_x), aromatic fumes, carbon monoxide (CO), carbon dioxide (CO₂)

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

- Acute Toxicity: Oral (Rat, LD₅₀) = 1800 mg/kg; Dermal (Rabbit, LD₅₀) >2000 mg/kg; Inhalation (Rat, LC₅₀) >4 mg/m³ (4-hour exposure)
- Skin Corrosion/Irritation: No irritation (Rabbit, 4-hour exposure)
- Serious Eye Damage/Eye Irritation: Category 2 (severe redness/tearing, reversible in 72h; Rabbit, 24-hour exposure)
- Germ Cell Mutagenicity: Negative (Ames test, chromosome aberration test)
- Carcinogenicity: IARC Class 3 (not classifiable as carcinogenic to humans)
- Reproductive Toxicity: No reproductive harm at occupational exposure levels; high doses may cause fetal developmental effects (animal studies)
- Specific Target Organ Toxicity (Single/Repeated Exposure): CNS depression (single exposure); no chronic target organ toxicity
- Aspiration Hazard: Low (solid powder, low dustiness for pharmaceutical grade)

SECTION 12: Ecological Information

12.1 Toxicity: Zebrafish (LC₅₀) = 26 mg/L (96h); Daphnia (EC₅₀) = 17 mg/L (48h); Algae (EC₅₀) = 29 mg/L (72h)

12.2 Persistence and Degradability: Low biodegradability (<25% in 28d, OECD 301); persistent in aquatic/soil environments

12.3 Bioaccumulative Potential: Moderate (Log K_{oc} = 3.3); may bioaccumulate in aquatic organisms

12.4 Mobility in Soil: Low (adsorbs to soil organic matter; no leaching to groundwater under normal conditions)

12.5 Results of PBT and vPvB Assessment: Classified as P (Persistent) and B (Bioaccumulative); not vPvB

12.6 Other



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Adverse Effects: Harmful to aquatic invertebrates; sulfur-containing decomposition products may cause mild aquatic acidification

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Classified as hazardous pharmaceutical waste; incinerate at licensed hazardous waste incineration facility ($\geq 1200^{\circ}\text{C}$) with gas treatment system (removes SO_2/NO_x /aromatic fumes)
 - Packaging Waste: Rinse with methanol, collect the rinsate for hazardous waste treatment; dispose of packaging as hazardous waste (do not recycle)
 - Contaminated Wastewater: Treat with activated carbon adsorption + advanced oxidation before discharge to remove residual quetiapine fumarate
- #### 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: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 2811

14.2 UN Proper Shipping Name: Toxic solids, organic, n.o.s. (Quetiapine Fumarate)

14.3 Transport Hazard Class(es): 6.1 (Toxic Substances) | Packaging Group: III

14.4 Environmental Hazards: IMDG Marine Pollutant: No; ADR/RID Environmental Hazard: Yes

14.5 Special Precautions for User

- Transport at $\leq 25^{\circ}\text{C}$; use light-proof, sealed HDPE/amber glass packaging; mark with GHS hazard labels and UN number 2811
- Avoid direct sunlight, high temperature, collision and vibration during transport; do not transport with food/feed/strong acids/bases/oxidizing agents
- Comply with IMDG/IATA/ADR regulations for Class 6.1 toxic solids and local pharmaceutical raw material transport regulations

SECTION 15: Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

- National Regulations (China): NMPA Pharmaceutical Raw Material; Pharmacopoeia (2020); Hazardous Chemicals List (2015); Occupational Exposure Limit 0.5 mg/m^3
 - International Regulations: EU REACH Registered; EP 10.0 compliant; ECHA non-SVHC; US TSCA Listed; USP 45 compliant; FDA-regulated; DEA Schedule IV (controlled substance)
- 15.2 Other Regulations: Comply with local pharmaceutical manufacturing, controlled drug management and hazardous waste disposal regulations; indoor use meets occupational health standards

SECTION 16: Other Information

- Further Information: This MSDS is based on current scientific knowledge and complies with GB/T 16483, GB/T 17519 and GHS Rev.9 standards. It is intended for safe handling, storage, transport and disposal.



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- The supplier is not liable for damage caused by improper use, storage or handling 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
NEWAY SINOPHC TECH