



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: 20 FEB 2026

Product Name: Clozapine CAS:5786-21-0

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

1.1 Product Identifiers

- Product Name: Clozapine
- Product Number: CLP-20260220
- Brand: SIGALD
- CAS-No.: 5786-21-0
- Synonyms: 8-Chloro-11-(4-methylpiperazin-1-yl)-5H-dibenzo[b,e][1,4]diazepine

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 atypical antipsychotic drug production (schizophrenia treatment).
- Uses Advised Against: Direct human consumption; non-pharmaceutical use; unauthorized formulation; veterinary use (unapproved).

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), cardiovascular/central nervous system (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/cardiovascular system
 - H373: May cause damage to the liver through prolonged or repeated exposure
- Precautionary Statements:



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- P261: Avoid breathing dust/fume/gas/mist/vapors/spray
- 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.
- P314: Get medical advice/attention if you feel unwell.
- P391: Collect spillage.

2.3 Physical and Chemical Hazards

- Non-combustible; no explosive hazards under normal conditions.
- Acute: Drowsiness, dizziness, hypotension (CVS/CNS effects) if ingested/absorbed; eye/skin irritation; nausea.
- Chronic: Prolonged exposure may cause liver damage; agranulocytosis (rare, but severe; specific to pharmaceutical use); weight gain, metabolic changes (clinical use).

2.5 Environmental Hazards

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

SECTION 3: Composition/Information on Ingredients

- Substance: Pure chemical compound (100% Clozapine)
- CAS-No.: 5786-21-0; Formula: C₁₈H₁₉ClN₄; Molecular Weight: 326.83 g/mol
- Hazardous Ingredients: Clozapine (100%, w/w) – meets GHS acute toxicity/irritation/specific target organ toxicity 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, shortness of breath, or hypotension occurs.
- Skin Contact: Remove contaminated clothing; rinse skin with plenty of running water for 15-20 minutes. Apply mild emollient if irritation occurs; call a doctor for persistent redness.
- 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** (risk of severe irritation).
- Swallowed: Do not induce vomiting. Rinse mouth with water. Call a poison center/doctor immediately; provide product label and inform of clozapine exposure.

4.2 Most Important Symptoms



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- CNS depression (drowsiness, confusion); hypotension, tachycardia (CVS effects); eye/skin irritation; liver enzyme elevation (prolonged exposure); nausea/vomiting (if ingested).4.3

Medical Attention

- Symptomatic treatment; monitor vital signs (blood pressure, heart rate), CNS function, and liver enzymes; no specific antidote available.4.4 Notes to Physician
- Inform physician of clozapine exposure; monitor complete blood count (CBC) and liver function tests (LFTs) for prolonged exposure.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable: Water spray, foam, dry powder, carbon dioxide (CO₂).
- Unsuitable: No limitations identified.5.2 Special Hazards from Combustion
- May release toxic fumes (nitrogen oxides, hydrogen chloride, carbon monoxide, aromatic amines) when burned at high temperature.5.3 Firefighter Advice
- Wear self-contained breathing apparatus (SCBA) and full fire-fighting protective gear; keep containers cool with water spray; avoid inhalation of combustion products; prevent runoff from fire-fighting water into water bodies.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear PPE (nitrile 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; contain spilled material to avoid environmental contamination.6.3 Containment & Clean-Up
- Small Spill (solid powder): Sweep up with inert absorbent (sand, vermiculite); place in sealed hazardous waste container. Do not vacuum (avoids dust generation).
- Large Spill: Contain with dikes; transfer to sealed HDPE drum for professional disposal; clean the area with neutral detergent and water; do not wash spill into drains.6.4 Reference: See Section 13 for waste disposal.

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate in a well-ventilated fume hood/dust-free GMP workshop; avoid dust generation (use low-dust handling techniques); use closed transfer systems to prevent exposure.
- Do not eat/drink/smoke in the work area; wash hands/face thoroughly after handling; avoid contact with eyes/skin/mucous membranes; limit prolonged skin contact.
- Conduct regular medical monitoring (CBC, LFTs) for personnel with repeated exposure.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 (use amber glass/opaque HDPE containers).



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- 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, pharmaceuticals (unrelated), and non-hazardous materials; keep away from children and unauthorized personnel.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): TWA 0.2 mg/m³ (respirable dust); STEL 0.6 mg/m³ (China, EU, OSHA).

8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with dust collection; positive pressure ventilation; dust-free workbench (Class 10000).
- Personal Protective Equipment (PPE):
 - Eye/Face: Chemical safety goggles + face shield (for large-scale handling).
 - Skin: Nitrile rubber gloves (thickness ≥ 0.11 mm); chemical-resistant lab coat; disposable shoe covers and hairnet (GMP workshop).
 - Respiratory: N95 dust mask (normal handling); powered air-purifying respirator (PAPR) for high-dust environments.
 - Hand: No bare hand contact; replace gloves if damaged or contaminated.
- Environmental Exposure: Prevent dust/spillage from entering the environment; use secondary containment for storage/handling.

SECTION 9: Physical and Chemical Properties

- Physical State: Yellow to pale yellow crystalline powder
- Color: Yellow/pale yellow
- Odor: Practically odorless
- Melting Point: 183-187°C
- Boiling Point: Decomposes before boiling (>350°C)
- Flammability: Non-combustible
- Flash Point: Not applicable
- Autoignition Temperature: >450°C
- Decomposition Temperature: >350°C (releases toxic fumes)
- pH Value: N/A (insoluble in water)
- Solubility: Sparingly soluble in water (<0.05 g/100 mL); soluble in chloroform, methanol, dimethylformamide (DMF)
- Density (25°C): 1.32 g/cm³ (solid)
- Vapor Pressure (25°C): <0.0001 hPa (negligible)
- Particle Size: 90% passing 100 mesh (pharmaceutical grade)
- Explosive Properties: Not explosive
- Oxidizing Properties: None

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions (15-25°C, sealed, dark); decomposes at high temperature (>350°C) or strong acid/base conditions; sensitive to light (may discolor on prolonged light exposure). 10.2 Hazardous Reactions: No hazardous reactions under normal use/handling; reacts with strong oxidizing agents (KMnO₄, H₂O₂) to form toxic aromatic byproducts. 10.3 Conditions to Avoid: High temperature (>30°C), direct sunlight, moisture, strong acids/bases, oxidizing agents, halogens. 10.4 Incompatible Materials: Concentrated HCl, NaOH, hydrogen peroxide, potassium permanganate, chlorine gas, heavy metal nitrates. 10.5 Hazardous Decomposition Products: Nitrogen oxides (NO_x), hydrogen chloride (HCl), carbon monoxide (CO), aromatic amines, dibenzoazepine derivatives.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD₅₀) = 275 mg/kg; Dermal (Rabbit, LD₅₀) = >5000 mg/kg; Inhalation (Rat, LC₅₀) = >2 mg/m³ (4h).
- Skin Corrosion/Irritation: Mild irritation (Rabbit, 4h exposure); no corrosion.
- Serious Eye Damage/Irritation: Category 2 (serious eye irritation, reversible in 48-72h).
- CVS/CNS Effects: Hypotension, tachycardia, drowsiness, confusion (dose-dependent); respiratory depression at high doses.
- Liver Toxicity: Prolonged exposure causes liver enzyme elevation (animal studies); clinical use associated with rare hepatotoxicity.
- Mutagenicity: Negative (Ames test, mouse lymphoma assay); no chromosomal aberration.
- Carcinogenicity: IARC Class 3 (not classifiable as to its carcinogenicity to humans).
- Reproductive Toxicity: May cause fetal harm if exposed during pregnancy (animal studies); Category C (US FDA).

SECTION 12: Ecological Information

12.1 Toxicity: Aquatic (Zebrafish, LC₅₀) = 8 mg/L (96h); Daphnia (EC₅₀) = 5 mg/L (48h); Algae (EC₅₀) = 10 mg/L (72h). 12.2 Persistence & Degradability: Biodegradability <15% (28d, OECD 301); highly persistent in aquatic and soil environments. 12.3 Bioaccumulative Potential: Log K_{oc} = 3.8 (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 of as hazardous pharmaceutical waste; incinerate at licensed hazardous waste incineration facility (temperature ≥1200°C) with advanced gas treatment (to remove aromatic amines/HCl).
- Packaging Waste: Rinse packaging with methanol; dispose of rinsate with product waste; recycle packaging only if fully decontaminated, otherwise dispose as hazardous waste.



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Disposal Regulations: Comply with China HW02 (medical waste) and Basel Convention for hazardous waste disposal; do not dispose of in municipal waste.

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. (Clozapine) 14.3 Transport Hazard Class: 6.1 (Toxic substances) 14.4 Packaging Group: III 14.5 Environmental Hazards: Marine Pollutant (No) 14.6 Special Transport Precautions

- Transport at 15-25°C; use opaque, insulated packaging to avoid light and temperature fluctuation; protect from moisture.
- Use 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 transport rules for Class 6.1 goods.

SECTION 15: Regulatory Information

15.1 National & International Regulations

- China: Controlled Pharmaceutical Raw Material (NMPA); Hazardous Chemicals List (2015); Pharmacopoeia of the People's Republic of China (2020).
 - EU: REACH (registered); ECHA SVHC Candidate List (No); Pharmacopoeia Europaea (Ph. Eur.).
 - US: TSCA (listed); FDA-regulated pharmaceutical raw material; DEA Schedule V controlled substance.
- 15.2 Other: Comply with local pharmaceutical manufacturing, handling, and waste disposal regulations; requires special license for bulk handling (China).

SECTION 16: Other Information

- This MSDS is based on current scientific and regulatory knowledge, complying with GB/T 16483, GB/T 17519, GHS Rev.9.
- The supplier is not liable for damage caused by improper handling, storage, use, or non-compliance with safety precautions.
- For additional technical and regulatory information, contact the supplier's pharmaceutical technical department.