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Safety Data Sheet (MSDS) - Midazolam Maleate

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0

Product Name: Midazolam Maleate **CAS Number:** 81826-61-1 **Product Number:** MM-20260220 **Brand:** SIGALD **Revision Date:** 20 FEB 2026 **Supplier:** NEWAY SINOPHC TECH. LIMITED **Address:** RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE **Telephone/Fax:** +86-021-50350029 **Emergency Telephone:** +86-021-50350029 (24h Psychotropic Drug Emergency Response)

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

1.1 Product Identifiers

- Product Name: Midazolam Maleate
- CAS-No.: 81826-61-1
- MDL No.: MFCD00058477
- Synonyms: 8-Chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine maleate; Dormicum maleate
- Product Number: MM-20260220

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses:** Pharmaceutical raw material for the production of clinical sedative/anesthetic preparations (only for licensed pharmaceutical enterprises).
- **Uses Advised Against:** Non-pharmaceutical use, direct clinical administration (raw material only), household use, unauthorized processing/sale, use in food/cosmetic production, and unlicensed clinical use.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 4)
- Acute toxicity, dermal (Category 4)
- Acute toxicity, inhalation (dust/mist, Category 4)
- Specific target organ toxicity - single exposure (central nervous system, Category 3)
- Eye irritation (Category 2)
- Skin irritation (Category 2)

2.2 GHS Label Elements

- **Hazard Pictograms:** Exclamation mark (!)
- **Signal Word:** Warning
- **Hazard Statements:**
 - H302: Harmful if swallowed
 - H312: Harmful in contact with skin
 - H332: Harmful if inhaled
 - H315: Causes skin irritation
 - H319: Causes serious eye irritation
 - H373: May cause damage to organs (central nervous system) through prolonged or repeated exposure
- **Precautionary Statements:**
 - P261: Avoid breathing dust/fume/gas/mist/vapors/spray
 - 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
 - P302+P352: If on skin: Wash with plenty of soap and water
 - P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
 - P312: Call a POISON CENTER/doctor if you feel unwell

- P405: Store locked up
- P501: Dispose of contents/container in accordance with local/national/international regulations

2.3-2.6 Hazards Summary

- **Physical/Chemical Hazards:** Non-flammable, non-explosive, non-oxidizing under normal use; stable at recommended storage temperature.
- **Health Hazards:** Inhalation/skin contact/swallowing causes central nervous system depression (drowsiness, dizziness, sedation); skin and serious eye irritation; prolonged exposure may cause chronic central nervous system damage and physical dependence.
- **Environmental Hazards:** Low toxicity to aquatic organisms; no long-term adverse environmental effects; slightly biodegradable in aquatic environments.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture:** Pure pharmaceutical grade substance (100% w/w)
- **Active Ingredient:** Midazolam Maleate (CAS:81826-61-1) | Hazard classification: see Section 2
- **No other ingredients/additives**

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- **Inhaled:** Move victim to fresh air; keep respiratory tract open. If breathing is difficult, give oxygen; consult a physician if sedation/dizziness/shortness of breath persists.
- **Skin Contact:** Remove contaminated clothing and shoes; rinse skin with plenty of soap and running water for 10~15 minutes. If irritation/redness occurs, apply mild emollient and seek medical advice.
- **Eye Contact:** Rinse eyes thoroughly with plenty of sterile water for injection for 15 minutes (lift upper/lower eyelids); remove contact lenses if worn. **Consult an ophthalmologist immediately** (causes serious eye irritation).
- **Swallowed:** Do not induce vomiting; rinse mouth with water. Call a poison center/physician at once; provide symptomatic treatment for central nervous system depression (e.g., respiratory support) if needed.

4.2 Most Important Symptoms

Acute: Drowsiness, dizziness, mild sedation, nausea, skin redness/irritation, serious eye irritation; severe oral intake may cause deep sedation, confusion and impaired consciousness. Delayed: Prolonged exposure may cause physical dependence, chronic fatigue and central nervous system dysfunction.

4.3 Medical Attention

Inform the physician of the product name (Midazolam Maleate) and CAS number; treat symptomatically (e.g., respiratory support for central nervous system depression, benzodiazepine antagonists for severe intoxication).

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable:** Dry powder, carbon dioxide (CO₂), foam; water spray (for cooling fire-exposed containers).
- **Unsuitable:** No restrictions; avoid direct high-pressure water on bulk powder (to prevent dust spread and inhalation).

5.2 Special Hazards

No hazardous combustion products under normal fire conditions; thermal decomposition at high temperature (>250°C) produces small amounts of carbon monoxide (CO), nitrogen oxides (NO_x), hydrogen chloride (HCl) and hydrogen fluoride (HF).

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and full fire-fighting protective gear; fight fire from upwind; cool containers with water spray until fire is out; prevent fire water from entering drainage systems and water bodies; collect fire debris as hazardous waste for disposal.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear full PPE (nitrile rubber gloves, chemical safety goggles, N95 dust mask, impermeable protective clothing); avoid any contact with spilled material.
- Evacuate non-essential personnel to a safe distance; set up warning zones; operate in a well-ventilated area with local exhaust ventilation.
- The product is a psychotropic controlled drug—**report the spill to the drug regulatory department in a timely manner.**

6.2 Environmental Precautions

Prevent spilled powder/leachate from entering sewers, rivers, lakes, soil and groundwater; contain spilled material with inert absorbents (e.g., sand, diatomite) to avoid environmental contamination.

6.3 Containment and Cleaning Up

- **Small Spill:** Absorb with inert absorbent; place into a sealed hazardous waste container for pharmaceutical waste disposal; mark the container clearly.
- **Large Spill:** Contain with dikes; collect with an anti-static vacuum cleaner into a sealed stainless steel drum; dispose of by licensed hazardous waste treatment enterprises.
- Do not reuse contaminated absorbents; do not wash spilled material into drainage systems; decontaminate the spill area with neutral detergent and rinse with water.

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate only in GMP-certified workshops by trained pharmaceutical production personnel with psychotropic drug operation qualifications.
- Use closed operation and local exhaust ventilation/dust collection system to avoid dust generation/inhalation.
- Do not eat, drink or smoke during handling; wash hands/face thoroughly with soap and water after operation; change work clothes if contaminated.
- Avoid contact with strong acids, strong bases, high temperature (>50°C) and strong light (to prevent degradation and decomposition).

7.2 Safe Storage

- **Storage Conditions:** 2 ~ 8°C (refrigerated, dark place); tightly sealed HDPE/aluminum foil/stainless steel containers; relative humidity ≤60%.
- **Incompatibilities:** Strong acids (pH<2), strong bases (pH>10), oxidizing agents (e.g., hydrogen peroxide, potassium permanganate), heavy metal salts (e.g., silver nitrate, copper sulfate).
- **Storage Class:** Psychotropic controlled pharmaceutical raw material (locked storage in a dedicated, alarm-equipped pharmaceutical warehouse with 24h monitoring).
- **Shelf Life:** 24 months (unopened, 2~8°C refrigeration); 6 months after opening (sealed, refrigerated).

SECTION 8: Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits

- No official national/international OEL for Midazolam Maleate; use **best practice exposure control** (closed system, dust collection) to minimize exposure.
- Biological limit: No established standard; regular physical examination for operators (focus on central nervous system function).

8.2 Exposure Controls

- **Engineering Controls:** Closed operation system, local exhaust ventilation, dust collection system, GMP workshop air filtration (HEPA filter).
- **Personal Protective Equipment (PPE):**
 - Eye/Face: Chemical safety goggles + face shield (for bulk powder handling)
 - Skin: Nitrile rubber gloves (thickness ≥ 0.1 mm) + impermeable protective clothing + anti-static shoes
 - Respiratory: N95 dust mask (for normal powder handling); no respiratory protection needed for liquid formulation handling
 - Other: Disposable hairnet/mask/gown (GMP compliance), emergency eye wash and shower equipment.
- **Hygiene:** Dedicated hand washing station; no food/drinks in the operation area; separate storage of work clothes and daily clothes.

SECTION 9: Physical and Chemical Properties

表格

Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	120 ~ 124°C
Boiling Point	Decomposes before boiling (>200°C)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>300°C
Solubility	Freely soluble in water/methanol; soluble in ethanol; slightly soluble in ether
pH Value (1% aqueous solution, 25°C)	3.0 ~ 4.5
Density (25°C, solid)	1.38 g/cm ³
Vapor Pressure (25°C)	<0.001 hPa (negligible)
Particle Size	95% pass through 100-mesh sieve (pharmaceutical grade)
Stability	Stable at 2~8°C; degrades at >25°C (long-term) and >50°C (rapid)

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended storage conditions (2~8°C, dark, sealed)**; no degradation for the shelf life and good compatibility with common pharmaceutical excipients.

10.2-10.5 Reactivity Summary

- No hazardous reactions under normal use/handling conditions.
- **Conditions to Avoid:** High temperature (>50°C), direct strong light, moisture, contact with strong acids/alkalis/oxidizing agents/heavy metal salts.
- **Incompatible Materials:** Concentrated HCl/H₂SO₄, NaOH/KOH, hydrogen peroxide, potassium permanganate, silver nitrate, ferric chloride.
- **Hazardous Decomposition Products:** Carbon monoxide (CO), nitrogen oxides (NO_x), HCl, HF and aromatic hydrocarbons (at >250°C).
- No polymerization under normal storage and use conditions.

SECTION 11: Toxicological Information

11.1 Key Toxicological Data

- **Acute Toxicity:**
 - Oral (Rat, LD₅₀): 420 mg/kg bw

- Dermal (Rabbit, LD₅₀): 480 mg/kg bw
- Inhalation (Rat, LC₅₀, 4h): 1.8 mg/m³ (dust)
- **Skin Irritation (Rabbit):** Moderate irritation (4h exposure, erythema and slight edema; reversible)
- **Eye Irritation (Rabbit):** Severe irritation (24h exposure, conjunctivitis and corneal redness; reversible within 72h)
- **Sensitization:** No skin/respiratory sensitization (Guinea pig test)
- **Carcinogenicity:** IARC Class 3 (Not classifiable as to its carcinogenicity to humans)
- **Reproductive Toxicity:** No teratogenic/fertility damage effects at clinical relevant doses (rat/mouse tests); high doses may cause fetal growth retardation.
- **Target Organ Toxicity:** Central nervous system (sedation/depression); no other organ toxicity at occupational exposure levels.

11.2 Toxicity Summary

The main toxic effect of Midazolam Maleate is central nervous system depression at high exposure levels; it causes moderate skin irritation and serious eye irritation as local effects. No chronic toxic effects, carcinogenicity or obvious reproductive toxicity at occupational exposure levels; all acute effects are reversible with symptomatic treatment and benzodiazepine antagonists (e.g., flumazenil) can be used for severe intoxication.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC₅₀, 96h): 15.6 mg/L
- Daphnia (EC₅₀, 48h): 10.2 mg/L
- Algae (EC₅₀, 72h): 18.5 mg/L
- **Conclusion:** Low toxicity to aquatic organisms; no acute lethal effect on aquatic life at normal environmental concentrations.

12.2-12.7 Ecological Properties

- **Persistence/Degradability:** Slightly biodegradable (BOD₅/COD = 0.25~0.35) in aquatic environments; degraded by microbial action in natural water bodies.
- **Bioaccumulative Potential:** Low (log Kow=3.5; bioaccumulation factor (BAF) <200 in fish)
- **Mobility in Soil:** Low (adsorbs to soil organic matter; no leaching to groundwater)
- **PBT/vPvB:** Not classified as PBT/vPvB
- **Other Adverse Effects:** No adverse effects on soil microorganisms and terrestrial plants; no eutrophication risk.

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- **Product Waste:** Classified as **pharmaceutical hazardous waste** and **psychotropic drug waste**; dispose of by licensed hazardous waste treatment enterprises (incineration at >800°C with flue gas purification treatment to remove HCl/HF).
- **Packaging Waste:** Rinse packaging with methanol (3 times); collect the rinse solution and incinerate with the product waste; decontaminate the clean packaging and dispose of as pharmaceutical hazardous waste (no recycling).
- **Do not dispose of with household waste, general industrial waste or medical waste;** do not discharge into sewers/rivers/soil/groundwater.

13.2 Disposal Regulations

Comply with China's **Hazardous Waste Pollution Control Law, Psychotropic Drug Administration Law, Pharmaceutical Waste Disposal Standards** and EU **REACH/WEEE** regulations.

SECTION 14: Transport Information

14.1-14.7 Transport Details

- **UN Number:** UN 3077 (Environmentally hazardous substance, solid, n.o.s.)
- **UN Proper Shipping Name:** Midazolam Maleate (psychotropic pharmaceutical raw material)

- **Transport Hazard Class:** 9 (Miscellaneous dangerous goods)
- **Packaging Group:** III
- **Marine Pollutant:** No
- **Special Transport Requirements:**
 1. Classified as **Category IV psychotropic controlled drug**; transport with **psychotropic drug transport license** (issued by drug regulatory department).
 2. Refrigerated transport (2~8°C) with real-time temperature monitoring; use sealed, shockproof, moisture-proof, light-proof and tamper-proof packaging.
 3. Load/unload gently; avoid package damage; store separately from food, feed, strong acids/alkalis and oxidizing agents in the transport vehicle.
 4. The transport vehicle is equipped with fire-fighting equipment and emergency spill treatment materials; the driver and escort have professional training certificates for psychotropic drugs.
- **International Transport:** Comply with **UN Convention on Psychotropic Substances (1971)** and IATA/IMDG/ADR regulations for Class 9 dangerous goods.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China:**
 - Psychotropic Drug Administration Law (Category IV psychotropic controlled drug)
 - Hazardous Chemical Safety Management Regulation (Class 9 miscellaneous dangerous goods)
 - Chinese Pharmacopoeia (2025 Edition)
 - GMP for Pharmaceutical Raw Materials
- **International:**
 - UN Convention on Psychotropic Substances (1971) (Schedule IV)
 - GHS Rev.9 (hazard classification)
 - USP 45 / EP 10.0 (pharmacopoeial standards)
 - REACH (EU) (registered; not in SVHC Candidate List)
 - TSCA (US) (listed on the TSCA Inventory)
 - IATA/IMDG (Class 9 transport regulations)

15.2 Other Requirements

- Production/sale/use limited to **licensed pharmaceutical enterprises** with GMP certification and psychotropic drug operation license.
- Occupational operation requires professional pharmaceutical production and psychotropic drug management training; compliance with GMP/GLP guidelines and strict account management.

SECTION 16: Other Information

- **MSDS Validity:** This MSDS is valid for 3 years from the revision date (20 FEB 2026) unless the product formula or hazard information changes.
- **Disclaimer:** This MSDS is based on current scientific and technical knowledge; the supplier is not liable for any damage caused by improper use, non-compliance with regulations, or unauthorized handling of the product.
- **Additional Information:** For more technical/formulation data, contact the supplier's technical department (+86-021-50350029 ext. 810).
- **Key Reminder:** This product is a **Category IV psychotropic controlled drug**; any illegal production/sale/use/transport will be subject to legal liability in accordance with the law.