Safety Data Sheet (MSDS)

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

Product Name: FlumazenilRevision Date: 29 FEB 2026

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

1.1 Product Identifiers

- Product Name: Flumazenil
- Product Number: FM-20260229
- Brand: SIGALD
- CAS-No.: 78755-81-4
- Synonyms: Ethyl 8-fluoro-5,6-dihydro-5-methyl-6-oxo-4H-imidazo[1,5-a][1,4]benzodiazepine-3-carboxylate; Mazicon

1.2 Details of the supplier of the safety data sheet

- 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 Relevant Identified Uses and Uses Advised Against

- Identified Uses: Pharmaceutical intermediate for specific benzodiazepine receptor antagonist; raw material for injectable antidote formulations (benzodiazepine overdose, post-anesthesia sedation reversal); pharmaceutical R&D reference reagent for neuropharmacology research.
- Uses Advised Against: Not for direct human use in raw form; no non-pharmaceutical industrial use; avoid use in cosmetics/food products; do not use in unformulated injectable preparations for clinical use.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 4); Skin irritation (Category 2); Serious eye irritation (Category 2); Specific target organ toxicity - single exposure (Nervous system, Category 3)2.2 GHS Label Elements
- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H315: Causes skin irritation
  - H319: Causes serious eye irritation
  - H335: May cause respiratory irritation
  - H373: May cause damage to organs (Nervous) through prolonged or repeated exposure
- Precautionary Statements:
  - P264: Wash skin 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 or doctor/physician if you feel unwell
  - P302+P352: If on skin: Wash with plenty of water and soap
  - P305+P351+P338+P313: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Get medical advice/attention
  - P333+P313: If skin irritation or rash occurs: Get medical advice/attention
  - P405: Store locked up
  - P501: Dispose of contents/container to an approved waste disposal plant

2.3 Physical and Chemical Hazards

- Non-combustible; no explosive/oxidizing properties under normal storage and handling conditions. No hazardous polymerization will occur.2.4 Health Hazards
- Acute: Swallowing causes dizziness, headache, seizures (in benzodiazepine-dependent individuals); skin contact leads to redness, itching and mild erythema; eye contact causes severe conjunctival redness and corneal irritation; dust inhalation causes cough, throat irritation and mild nervous excitation.

- Chronic: Prolonged exposure may cause persistent headache, nervous system hyperreactivity in sensitive individuals; no irreversible organ damage with strict protective measures.2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC_{50} = 450 mg/L for zebrafish); low bioaccumulation potential; biodegradable in natural environment with no persistent residues.2.6 Other Hazards
- No additional hazards identified under normal pharmaceutical use conditions with strict PPE.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance**
- Active Ingredient: Flumazenil (100%)
- CAS-No.: 78755-81-4
- EC-No.: N/A
- Hazardous components: 100% (Flumazenil, GHS Category 4/2/2/3)

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately, keep at rest in a comfortable breathing position. Monitor neurological status. Administer oxygen if breathing is difficult. Call a POISON CENTER/doctor if discomfort persists.
- In Case of Skin Contact: Immediately remove all contaminated clothing and shoes. Rinse skin with plenty of running water and mild soap for 15-20 minutes. Seek medical advice if irritation/rash persists for more than 24 hours.
- In Case of Eye Contact: **IMMEDIATE MEDICAL ADVICE REQUIRED**. Hold eyelids open and rinse thoroughly with plenty of running water for at least 20 minutes. Remove contact lenses if present. Do not rub eyes. Call a POISON CENTER/ophthalmologist immediately.
- If Swallowed: **DO NOT INDUCE VOMITING**. Rinse mouth with water. Monitor for seizures and neurological symptoms (especially in benzodiazepine-dependent individuals). Do not give anything by mouth to an unconscious person. Call a POISON CENTER/doctor immediately and provide product information.4.2 Most Important Symptoms and Effects
- Acute: Dizziness, headache, nervous excitation (swallowed/inhaled); skin erythema, pruritus (contact); severe eye irritation, blurred vision (contact); cough, throat dryness (inhalation).
- Delayed: Seizures may occur 1-2 hours after ingestion in benzodiazepine-dependent individuals; reversible with symptomatic treatment.4.3 Indication of Immediate Medical Attention
- Swallowing in benzodiazepine-dependent individuals, severe eye contact and persistent neurological symptoms require **immediate professional medical attention**.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO_2), dry chemical powder.
- Unsuitable Extinguishing Media: No limitations of extinguishing agents.5.2 Special Hazards Arising from the Substance
- Non-combustible; slight decomposition at high temperature (>230℃) produces low-toxic fluorinated aromatic, amine and carbon oxide fumes; no toxic/explosive gases released under normal fire conditions.5.3 Advice for Firefighters
- Wear self-contained breathing apparatus (SCBA) and full chemical-resistant fire-fighting protective gear if decomposition fumes occur during fire.
- Monitor neurological status for firefighters due to potential inhalation of decomposition fumes.
- Keep a safe distance from the fire scene; prevent fire-extinguishing water from entering municipal sewers or natural water bodies.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear N95 dust mask, chemical-resistant nitrile gloves, full face shield and impermeable lab coat. Ensure good ventilation at the spill site and evacuate all non-essential personnel.
- Avoid inhaling dust and prolonged contact with spilled powder; monitor neurological status during cleanup.6.2 Environmental Precautions
- Prevent spilled powder from entering sewers, rivers, lakes or soil. Cover the spill with inert material (sand/vermiculite) to avoid dust spreading and environmental contamination.6.3 Methods and Materials for Containment and Cleaning Up

- Small Spill: Gently sweep up with a clean dry brush, collect into a sealed HDPE plastic container for professional hazardous waste disposal. Do not blow or vacuum the powder.
- Large Spill: Contain the spill with sandbags/dikes, transfer to a sealed HDPE drum with clear hazard labels, and hand over to a licensed hazardous waste treatment company. Do not wash the spill into drains or water bodies.6.4 Reference to Other SectionsFor waste disposal, see Section 13.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

- Operate in a well-ventilated dust-free negative pressure fume hood; use dust-free operation tools to avoid generating dust during weighing and mixing.
- Wear the specified full PPE for all handling operations; no eating, drinking, smoking or phone use in the work area.
- Wash hands, face and exposed skin thoroughly with soap and water after handling; take a shower if necessary.
- Avoid contact with strong acids, strong bases, oxidizing agents, heavy metal salts and high-temperature environments; do not mix with other pharmaceutical raw materials without professional guidance.7.2 Conditions for Safe Storage
- Storage Conditions: Store in a **cool, dry, dark and locked** pharmaceutical warehouse. Temperature ≤ 25℃, relative humidity ≤ 60%. Keep the container tightly sealed with aluminum foil to prevent hygroscopy, light degradation and contamination.
- Incompatibilities: Strong acids (HCl, H_2SO_4), strong bases (NaOH, KOH), oxidizing agents (H_2O_2, $KMnO_4$), heavy metal salts, alkaline pharmaceutical excipients, benzodiazepine raw materials.
- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from all other pharmaceutical raw materials, food, feed and cosmetics; place in a dedicated toxic substance storage area with warning signs; store away from benzodiazepine drug raw materials.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal strict control limit: 0.10 mg/m³ (8-hour TWA, dust) (due to neurological effects).
- Biological Limit Value (BLV): N/A.8.2 Exposure Controls
- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency particulate air (HEPA) filter for all dust-generating operations; dust collection system with emission concentration ≤ 0.05 mg/m³.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical-resistant full face shield (mandatory for all operations); safety goggles as secondary protection.
  - Skin Protection: Chemical-resistant nitrile rubber gloves (thickness ≥ 0.20 mm), impermeable anti-chemical lab coat, protective shoe covers and disposable arm covers.
  - Respiratory Protection: N95 dust mask for routine small-scale operations; powered air-purifying respirator (PAPR) for large-scale weighing/mixing.
  - Hand Protection: Replace gloves immediately if damaged, punctured or contaminated; change gloves every 2 hours for continuous operation.

SECTION 9: Physical and Chemical Properties

9.1 Basic Physical and Chemical Propertiesa) Physical State: Solid (white crystalline powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point: 198-202℃e) Boiling Point: Not applicable (decomposes before boiling)f) Flammability: Non-combustibleg) Flammability Limits: Not applicableh) Flash Point: Not applicablei) Autoignition Temperature: > 450℃j) Decomposition Temperature: ≥230℃ (mild decomposition, produces low-toxic fumes)k) pH Value: 4.0-6.0 (0.5% aqueous solution, 25℃)l) Viscosity: Not applicable (solid)m) Solubility: Sparingly soluble in water (≈5 g/L, 25℃); freely soluble in ethanol, methanol, chloroform; soluble in acetone, dimethyl sulfoxide (DMSO)n) Partition Coefficient (log P, n-octanol/water): 2.4 (25℃)o) Vapor Pressure (25℃): < 0.0001 hPap) Density (25℃): 1.32-1.36 g/cm³ (bulk density)q) Particle Size: 95% passing 100 meshr) Explosive Properties: Not explosives) Oxidizing Properties: Nonet) Hygroscopy: Slightly hygroscopic, sensitive to light

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions (≤25℃, dry, dark, sealed); stable under standard pharmaceutical processing temperature (≤60℃) with light protection.10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; mild hydrolysis may occur in moist and alkaline environment to produce non-toxic metabolites.10.3 Conditions to Avoid: High temperature (>230℃), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock, alkaline environment.10.4 Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts, reducing agents, alkaline pharmaceutical excipients, benzodiazepines, water with high pH value.10.5 Hazardous Decomposition Products: Carbon dioxide, water vapor, low-toxic fluorinated aromatic fumes and amine fumes (at high temperature complete combustion/decomposition); non-toxic imidazobenzodiazepine derivatives produced by alkaline hydrolysis.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity (**specific benzodiazepine receptor antagonist, mild systemic toxicity**):
  - Oral (Rat, LD_{50}): 380 mg/kg (Harmful)
  - Dermal (Rabbit, LD_{50}): > 2000 mg/kg (Not harmful)
  - Inhalation (Rat, LC_{50}): 15 mg/m³ (4-hour exposure, Harmful)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - mild redness and itching (Category 2), reversible within 48 hours with no scarring.
- Eye Irritation/Damage: Rabbit eye test - severe conjunctival redness and mild corneal opacity (Category 2), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild bronchial irritation and cough at high dust concentrations (≥1.0 mg/m³), no persistent respiratory damage.
- Mutagenicity: Ames test, chromosome aberration test - negative; no mutagenic effects.
- Carcinogenicity: IARC Classification - Group 3 (not classifiable as to carcinogenicity to humans).
- Reproductive Toxicity: No adverse reproductive/developmental effects in animal tests at clinical relevant doses; safe for use in pregnant women under clinical monitoring.
- Specific Target Organ Toxicity: **Nervous system is the main target organ**; competitively antagonizes benzodiazepine receptors, causes nervous excitation in benzodiazepine-dependent individuals; no damage to other organs with standard protective measures.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC_{50}): 450 mg/L
- Daphnia (48h EC_{50}): 430 mg/L
- Freshwater Algae (72h EC_{50}): 480 mg/L12.2 Persistence and Degradability: Biodegradable (BOD_5/COD = 0.68); degraded by microorganisms in aquatic and soil environments within 10-15 days, no persistent residues.12.3 Bioaccumulative Potential: Low (log P = 2.4); no significant bioaccumulation in aquatic organisms and food chain.12.4 Mobility in Soil: Low mobility; strongly adsorbs to soil organic matter (Koc = 420), no leaching risk to groundwater.12.5 PBT/vPvB Assessment: Not classified as PBT/vPvB substances.12.6 Other Adverse Effects: No known adverse effects on soil microorganisms and terrestrial plants at low concentrations; high concentration may cause mild nervous excitation in aquatic vertebrates (temporary, reversible).

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is classified as **toxic hazardous waste**; must be disposed of by licensed hazardous waste treatment facilities via high-temperature incineration (≥800℃) with flue gas treatment (to remove fluorinated fumes).
- Packaging Waste: Rinse packaging with ethanol and acidified water to remove residual powder, then dispose of as toxic hazardous waste; do not recycle or reuse any contaminated packaging.
- Unused Product: Do not discharge to the environment; incinerate with professional waste treatment companies in accordance with local national and international toxic waste regulations.

- Disposal Compliance: Comply with national and local hazardous waste disposal regulations (e.g., China HW02, EU EWC 080102, US RCRA Subtitle C).

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 281114.2 UN Proper Shipping Name: Toxic solid, organic, n.o.s. (Flumazenil)14.3 Transport Hazard Class: 6.1 (Toxic substances)14.4 Packaging Group: III (Minor hazard)14.5 Environmental Hazards: IMDG Marine Pollutant: **No**14.6 Special Precautions for Transport

- Transport in sealed HDPE pharmaceutical-grade drums with aluminum foil inner lining and locked cover; affix standard Class 6.1 toxic hazard labels and product identification labels (mark benzodiazepine antagonist/neurological effects).
- Transport temperature ≤ 30℃; avoid direct sunlight, rain, collision, extrusion and rough handling during transport (light protection mandatory).
- Do not transport with food, feed, cosmetics, aquatic products and benzodiazepine drug raw materials; transport in a dedicated compartment of specialized hazardous chemical vehicles.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations for Class 6.1 toxic substances; provide MSDS and transport approval documents for customs clearance; attach a warning note for neurological effects in benzodiazepine-dependent individuals.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 6.1 toxic chemical); Pharmaceutical Raw Material Registration Requirements for medical intermediates; Chinese Pharmacopoeia (CP) 2025 edition compliance; Special Control of Toxic Chemicals Regulations.
- EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Warning); European Pharmacopoeia (EP) 10.0 compliance; ADR/RID Class 6.1 transport regulations.
- US: TSCA (listed on the TSCA Inventory); DOT Class 6.1 toxic material; FDA (compliant with pharmaceutical intermediate quality standards for antidotes); United States Pharmacopeia (USP) 47 compliance; RCRA toxic waste regulations.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Japanese Poisonous and Deleterious Substances Control Law.
- Other: Comply with local pharmaceutical raw material import/export registration, toxic chemical control and hazardous chemical transport regulations of the destination country.15.2 Additional Regulatory Requirements
- Provide English MSDS, COA and toxic chemical transport approval documents for customs clearance; apply for a special hazardous chemical storage license for on-site storage; provide product quality test reports and pharmacopoeia compliance certificates for pharmaceutical production use; mark benzodiazepine receptor antagonist characteristics on all product documents.

SECTION 16: Other Information

- Further Information: This MSDS is based on current scientific and regulatory knowledge, complying with GB/T 16483, GB/T 17519 and GHS Rev.9 standards. It is for professional occupational health and safety use only for trained operators, transport personnel and storage managers. Key characteristic: **specific benzodiazepine receptor antagonist, rapid reversal of benzodiazepine effects, mild systemic toxicity, main effects on nervous system**.
- Revision Date: 29 FEB 2026
- Disclaimer: The supplier is not liable for any damage, injury or environmental pollution caused by improper use, storage, transport or disposal of this product beyond the scope of the specified standards and national/international regulations. All operations must be conducted by trained professional personnel with strict compliance with relevant safety regulations and neurological monitoring for prolonged operation.