



# 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: Nitrazepam
- Product Number: NTZ-20260228
- Brand: SIGALD
- CAS-No.: 146-22-5
- Synonyms: 1,3-Dihydro-7-nitro-5-phenyl-2H-1,4-benzodiazepin-2-one; Mogadon

#### 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 sedative/hypnotic/anti-anxiety drug production (benzodiazepine class)
- Uses Advised Against: Direct human consumption; unauthorized pharmaceutical formulation; non-pharmaceutical use; veterinary use without approval

### SECTION 2: Hazards Identification

<b>Summary of Emergency Measures</b>	<b>Pale yellow crystalline powder. Harmful if swallowed; causes serious eye irritation; affects central nervous system (sedation/drowsiness). Inhalation: Move to fresh air, rest. Skin contact: Rinse with water for 10 mins. Eye contact: Rinse for 10-15 mins, seek medical help. Swallowing: Rinse mouth, do not induce vomiting, call poison center. Non-combustible; decomposes at high temp to release toxic NO<sub>x</sub>. No explosion risk.</b>
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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:
  - H302: Harmful if swallowed
  - H319: Causes serious eye irritation



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- 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
- P280: Wear protective gloves/eye/face protection
- P301+P312: If swallowed: Call a POISON CENTER/doctor if unwell
- P305+P351+P338: If in eyes: Rinse cautiously with water, remove contact lenses, 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  $>250^{\circ}\text{C}$  to release toxic nitrogen oxides ( $\text{NO}_x$ ) and carbon monoxide

### 2.4 Health Hazards

- Acute: Sedation/drowsiness/dizziness (CNS); severe eye irritation; mild gastrointestinal upset (swallowed); mild respiratory irritation from dust
- Chronic: No known chronic toxic effects; potential CNS tolerance with prolonged exposure (pharmaceutical use only)

### 2.5 Environmental Hazards

- Harmful to aquatic organisms; low biodegradability; may accumulate in aquatic environments

### 2.6 Other Hazards

- No additional hazards identified

## SECTION 3: Composition/Information on Ingredients

- Substance: Pure chemical compound (100% Nitrazepam) | Component | CAS-No. | Concentration (w/w) | Classification | | --- | --- | --- | --- | | Nitrazepam | 146-22-5 | 100% | Acute oral toxicity Cat4; Eye irritation Cat2; CNS toxicity Cat3 | | Formula |  $\text{C}_{15}\text{H}_{11}\text{N}_3\text{O}_3$  | - | Molecular Weight: 281.27 g/mol |

## SECTION 4: First Aid Measures

### 4.1 First-Aid Measures

- Inhaled: Move victim to fresh air, place in a comfortable breathing position. Seek medical help if dizziness/sedation/ cough persists.
- Skin Contact: Remove contaminated clothing, rinse skin with running water for 10 minutes. Apply mild moisturizer if irritation occurs.
- Eye Contact: Rinse eyes thoroughly with running water for 10-15 minutes (hold eyelids open). Remove contact lenses. **Seek immediate medical attention** if irritation/redness persists.
- Swallowed: Rinse mouth with water. Do not induce vomiting (CNS depression risk). Call a poison center/doctor immediately and provide product label.

- Acute: CNS depression (sedation/drowsiness/dizziness), eye redness/tearing, nausea; severe ingestion may cause confusion/ataxia4.3 Medical Attention
- Symptomatic treatment; supportive care for CNS depression (airway management); no specific antidote (flumazenil for benzodiazepine overdose, clinical use only)4.4 Notes to Physician
- Inform of nitrazepam (benzodiazepine) exposure; monitor CNS function and vital signs; flumazenil may be used for severe overdose (per clinical guidelines)

## 5. Firefighting Measures

5.1 Extinguishing Media: Water spray, foam, dry powder, carbon dioxide (CO<sub>2</sub>) (all suitable)5.2

Special Hazards from Combustion: Non-combustible; thermal decomposition at >250°C

releases toxic nitrogen oxides (NO<sub>x</sub>), carbon monoxide (CO) and aromatic fumes5.3 Firefighter

Advice: Wear self-contained breathing apparatus (SCBA) and full fire-fighting gear; keep containers cool with water spray; avoid inhalation of decomposition fumes; prevent combustion products from entering water bodies

## 6. Accidental Release Measures

6.1 Personal Precautions: Wear full PPE (nitrile gloves, chemical safety goggles, N95 dust mask, lab coat); ensure good ventilation; evacuate non-essential personnel from spill area6.2

Environmental Precautions: Prevent spillage into drains/rivers/groundwater; collect spillage (do not wash into water); use inert absorbent to avoid environmental contamination6.3

Containment & Clean-Up

- Small Spill: Sweep up with inert absorbent (sand/vermiculite), transfer to sealed hazardous waste container
- Large Spill: Contain with plastic dikes, transfer to sealed HDPE drums for professional disposal; clean area with small amount of ethanol (avoid water wash to prevent aquatic contamination)6.4 Reference: See Section 13 for waste disposal guidelines

## SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate in well-ventilated, dust-free GMP workshop; use closed handling/transfer systems to avoid dust generation/inhalation
- Avoid contact with strong acids/bases/high temperatures (causes decomposition); no eating/drinking/smoking in work area
- Wash hands/face thoroughly after handling; avoid skin/eye contact7.2 Safe Storage
- Storage Conditions: Cool, dry, dark warehouse (2-8°C); keep container tightly sealed; protect from light and high temperature (>25°C)
- Incompatibilities: Strong acids, strong bases, oxidizing agents, high temperature, direct sunlight
- Storage Class (TRGS 510): 6.1 (Toxic Substances)
- Shelf Life: 24 months (unopened, specified conditions)

- Segregation: Store separately from food/feed/non-pharmaceutical materials; keep away from children/unauthorized personnel; store away from aquatic environment sources

## SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters: Occupational Exposure Limit (OEL) – TWA 0.5 mg/m<sup>3</sup> (respirable dust) (EU/China)8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency dust collection; dust-free workbench (pharmaceutical grade); light-proof processing equipment
- Personal Protective Equipment (PPE):
  - Eye/Face: Chemical safety goggles + face shield (mandatory for all handling)
  - Skin: Nitrile rubber gloves (≥0.11 mm) + chemical-resistant lab coat + disposable arm covers
  - Respiratory: N95 dust mask (normal handling); PAPR (high-dust environments)
  - Hand: No bare hand contact; replace gloves if damaged/contaminated

## SECTION 9: Physical and Chemical Properties

- Physical State: Pale yellow crystalline powder | Odor: Practically odorless
- Melting Point: 226-231 °C | Boiling Point: Decomposes before boiling (>250 °C)
- Flammability: Non-combustible | Flash Point: Not applicable
- Autoignition Temperature: >400 °C | Decomposition Temperature: ≥250 °C
- pH Value: 6.0-8.0 (0.5% in ethanol, 25 °C) | Water Solubility: Practically insoluble (<0.1 g/100 mL)
- Ethanol Solubility: Sparingly soluble (1-5 g/100 mL) | Density (25 °C): 1.41 g/cm<sup>3</sup>
- 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)

## SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions (2-8 °C, dark, sealed); sensitive to light and high temperature

10.2 Hazardous Reactions: No hazardous reactions under normal use; decomposes at >250 °C/strong acids/bases to release toxic NO<sub>x</sub> and aromatic compounds

10.3 Conditions to Avoid: Direct sunlight, high temperature (>25 °C), strong acids, strong bases, oxidizing agents

10.4 Incompatible Materials: Concentrated HCl/NaOH, hydrogen peroxide, potassium permanganate, strong oxidizers

10.5 Hazardous Decomposition Products: Nitrogen oxides (NO<sub>x</sub>), carbon monoxide (CO), benzene derivatives, carbon dioxide (CO<sub>2</sub>)

## SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD<sub>50</sub>) = 1500 mg/kg; Dermal (Rabbit, LD<sub>50</sub>) >2000 mg/kg; Inhalation (Rat, LC<sub>50</sub>) >3 mg/m<sup>3</sup> (4h)
- Skin Irritation: No irritation (Rabbit, 4h exposure)
- Eye Irritation: Category 2 (severe redness/tearing, reversible in 72h)

- CNS Toxicity: Dose-dependent sedation/drowsiness/dizziness; severe overdose causes confusion/ataxia/coma
- Mutagenicity: Negative (Ames test, chromosome aberration test)
- Carcinogenicity: IARC Class 3 (not classifiable as carcinogenic to humans)
- Reproductive Toxicity: No reproductive harm at normal OEL; high doses cause fetal CNS effects (animal studies); US FDA Category D
- Sensitization: No skin/respiratory sensitization (human/animal studies)

## SECTION 12: Ecological Information

12.1 Toxicity: Zebrafish (LC<sub>50</sub>) = 25 mg/L (96h); Daphnia (EC<sub>50</sub>) = 18 mg/L (48h); Algae (EC<sub>50</sub>) = 30 mg/L (72h)  
12.2 Persistence & Degradability: Low biodegradability (<20% in 28d, OECD 301); persistent in aquatic/soil environments  
12.3 Bioaccumulative Potential: Moderate (Log K<sub>oc</sub> = 3.2); may bioaccumulate in aquatic organisms  
12.4 Mobility in Soil: Low (adsorbs to soil organic matter; no leaching to groundwater)  
12.5 PBT/vPvB: Classified as P (Persistent) and B (Bioaccumulative); not vPvB  
12.6 Other Adverse Effects: Harmful to aquatic invertebrates; may disrupt aquatic food chains at high concentrations

## SECTION 13: Disposal Considerations

### 13.1 Waste Treatment

- Product Waste: Classified as hazardous pharmaceutical waste; incinerate at licensed hazardous waste incineration facility (≥1200°C) with gas treatment (removes NO<sub>x</sub>/aromatic fumes)
  - Packaging Waste: Rinse with ethanol, collect rinsate for hazardous waste treatment; dispose packaging as hazardous waste (no recycling)
- 13.2 Disposal Regulations: Comply with China HW02 (Medical Waste) and Basel Convention; do not dispose with municipal solid waste/aquatic environments

## SECTION 14: Transport Information

14.1 UN Number: UN 2811  
14.2 UN Proper Shipping Name: Toxic solids, organic, n.o.s. (Nitrazepam)  
14.3 Transport Hazard Class: 6.1 (Toxic Substances) | Packaging Group: III  
14.4 Environmental Hazards: Marine Pollutant (No)

- 14.5 Special Transport Precautions
- Transport at 2-8°C (cold chain); use light-proof, sealed HDPE/amber glass packaging; mark with GHS hazard labels + UN 2811
- Avoid direct sunlight, high temperature and collision 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 (cold chain transport)

## SECTION 15: Regulatory Information

### 15.1 National & International Regulations

- China: NMPA Controlled Pharmaceutical Raw Material (benzodiazepine class); Pharmacopoeia (2020); Hazardous Chemicals List (2015)
- EU: REACH Registered; Ph. Eur. 10.0 compliant; ECHA non-SVHC; controlled drug (Schedule IV)



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- US: TSCA Listed; USP 45 compliant; FDA-regulated; DEA Schedule IV (controlled substance) 15.2  
Other: Comply with local pharmaceutical manufacturing, controlled drug management and hazardous waste disposal regulations

### **SECTION 16: Other Information**

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

