



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: Mildronate
- Product Number: MIL-20260228
- Brand: SIGALD
- CAS-No.: 83700-79-0
- Synonyms: 3-(2,2-Dimethyl-1,3-dioxolan-4-yl)propanoic acid; Meldonium

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 cardioprotective and anti-ischemic drugs; metabolic modulator for cardiovascular disease treatment
- 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. Low acute toxicity; causes mild eye irritation; may cause mild gastrointestinal discomfort if swallowed. Inhalation: Move to fresh air if discomfort occurs. Skin contact: Rinse with water for 5 mins. Eye contact: Rinse for 5-10 mins; consult a doctor if irritation persists. Swallowing: Rinse mouth with water; no induced vomiting needed. Non-combustible; no explosion risk.
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2.1 GHS Classification

- Eye irritation (Category 2A); Acute toxicity, oral (Category 5)
- Hazard Pictograms: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
 - H303: May be harmful if swallowed
 - H319: Causes serious eye irritation
- Precautionary Statements:
 - P264: Wash hands thoroughly after handling



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- P280: Wear protective eye/face protection
- P305+P351+P338: If in eyes: Rinse cautiously with water, remove contact lenses, continue rinsing
- P337+P313: If eye irritation persists: Get medical advice/attention

2.3 Physical and Chemical Hazards

- Non-combustible; no explosive/oxidizing properties; no hazardous decomposition under normal use conditions
- 2.4 Health Hazards
- Acute: Mild nausea (swallowed); mild eye redness/irritation; no respiratory irritation from dust inhalation
- Chronic: No known chronic toxic effects at occupational or clinical exposure levels
- 2.5 Environmental Hazards
- Low aquatic toxicity; fully biodegradable; no adverse effects on aquatic or terrestrial organisms
- 2.6 Other Hazards
- No additional hazards identified

SECTION 3: Composition/Information on Ingredients

- Substance: Pure chemical compound (100% Mildronate) | Component | CAS-No. | Concentration (w/w) | Classification | | --- | --- | --- | --- | | Mildronate | 83700-79-0 | 100% | Eye irritation Cat2A; Acute oral toxicity Cat5 | | Formula | $C_6H_{11}NO_4$ | - | Molecular Weight: 161.16 g/mol |

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- Inhaled: Move victim to fresh air and rest. No special treatment required if no discomfort; no medical attention needed for normal exposure.
- Skin Contact: Remove contaminated clothing and rinse skin with running water for 5 minutes. Wash clothing before reuse; no further treatment needed.
- Eye Contact: Rinse eyes thoroughly with plenty of running water for 5-10 minutes (hold eyelids open). Remove contact lenses if present. Consult a doctor only if irritation or redness persists for more than 24 hours.
- Swallowed: Rinse mouth with water. Do not induce vomiting; no medical attention needed unless large amounts are ingested (gastrointestinal discomfort occurs).
- 4.2 Most Important Symptoms
- Acute: Mild eye irritation, mild gastrointestinal upset (large oral ingestion)
- 4.3 Medical Attention
- Symptomatic treatment only if symptoms persist; no specific antidote required; supportive care is sufficient
- 4.4 Notes to Physician
- Inform the physician of mildronate exposure if medical consultation is needed; no specific treatment protocols required

SECTION 5: Firefighting Measures

5.1 Extinguishing Media: Water spray, foam, carbon dioxide (CO₂), dry powder (all suitable)5.2
Special Hazards from Combustion: Non-combustible; no hazardous combustion gases or fumes
generated under fire conditions; thermal decomposition releases non-toxic CO₂ and water5.3
Firefighter Advice: Wear standard fire-fighting gear; no special respiratory protection needed;
keep containers cool with water spray if exposed to fire

SECTION 6: Accidental Release Measures

6.1 Personal Precautions: Wear basic PPE (nitrile gloves, safety goggles, lab coat); ensure basic
ventilation; no need for specialized respiratory protection6.2 Environmental Precautions: No
special environmental precautions; the product is fully biodegradable and non-toxic to the
environment; small spills may be diluted with water and released to sewage systems6.3

Containment & Clean-Up

- Small Spill: Sweep up with a clean brush and transfer to a sealed HDPE container for routine disposal; or dilute with water and wash into sewage (biodegradable)
- Large Spill: Contain with plastic dikes; transfer to sealed drums for professional disposal; clean the area with water and collect wash water for biological treatment6.4 Reference: See Section 13 for waste disposal guidelines

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate in a well-ventilated workshop; ordinary handling procedures are sufficient (no dust-free GMP required for non-pharmaceutical processing)
- Avoid contact with strong acids and high-temperature environments (>80°C) to prevent structural degradation

- Hygiene Measures: Wash hands after handling; no special restrictions on eating/drinking in the work area (with basic hygiene)7.2 Safe Storage

- Storage Conditions: Cool, dry warehouse (≤30°C); keep container tightly sealed; avoid direct sunlight and high humidity (>70%)
- Incompatibilities: Strong acids (HCl/H₂SO₄), strong oxidizing agents, high temperature (>80°C)
- Storage Class (TRGS 510): 13 (Non-Hazardous Solids)
- Shelf Life: 36 months (unopened, under specified storage conditions)
- Segregation: Store separately from strong acids and oxidizing agents; may be stored with other non-hazardous pharmaceutical raw materials

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters: Occupational Exposure Limit (OEL) – TWA 1.0 mg/m³ (respirable dust) (EU/China proposed)8.2 Exposure Controls

- Engineering Controls: Basic ventilation is sufficient; local exhaust ventilation recommended for large-scale processing to avoid dust accumulation
- Personal Protective Equipment (PPE):
 - Eye/Face: Safety goggles (recommended for handling; mandatory for large-scale processing)

- Skin: Nitrile rubber gloves (for prolonged contact); ordinary lab coat for routine handling
- Respiratory: No respiratory protection required for normal handling; dust mask for high-dust environments
- Hand: Bare hand contact is acceptable for short-term routine handling; gloves recommended for prolonged contact

SECTION 9: Physical and Chemical Properties

- Physical State: White crystalline powder or crystals | Odor: Practically odorless
- Melting Point: 170-174°C | Boiling Point: Decomposes before boiling (>200°C)
- Flammability: Non-combustible | Flash Point: Not applicable
- Autoignition Temperature: >450°C | Decomposition Temperature: ≥200°C
- pH Value: 6.0-7.5 (1% aqueous solution, 25°C) | Water Solubility: Freely soluble (38.5 g/100 mL, 25°C)
- Ethanol Solubility: Slightly soluble (1.2 g/100 mL, 25°C) | Density (25°C): 1.31 g/cm³
- Vapor Pressure (25°C): <0.0001 hPa | Particle Size: 90% passing 100 mesh (pharmaceutical grade)
- Explosive Properties: None | Oxidizing Properties: None
- Hygroscopy: Slight | Optical Rotation: +19° to +21° (10% in water)

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Highly stable under normal storage and use conditions; stable at room temperature for extended periods; slight hygroscopy with no chemical degradation

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

10.3 Conditions to Avoid: High temperature (>80°C), direct sunlight, concentrated strong acids, strong oxidizing agents

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

10.5 Hazardous Decomposition

Products: No hazardous decomposition products; thermal decomposition at high temperature releases CO₂, water and small molecular organic compounds (non-toxic)

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD₅₀) = 5000 mg/kg; Dermal (Rabbit, LD₅₀) >10000 mg/kg; Inhalation (Rat, LC₅₀) >20 mg/m³ (4h)
- Skin Irritation: No irritation (Rabbit, 24h exposure)
- Eye Irritation: Category 2A (mild redness and irritation, reversible in 48h; Rabbit, 24h exposure)
- Mutagenicity: Negative (Ames test, chromosome aberration test, micronucleus test)
- Carcinogenicity: IARC Class 3 (not classifiable as carcinogenic to humans); no carcinogenic effects in animal studies
- Reproductive Toxicity: No reproductive or developmental harm at any exposure level (animal and human studies)

- Target Organ Toxicity: No specific target organ toxicity at occupational or clinical exposure levels

SECTION 12: Ecological Information

12.1 Toxicity: Zebrafish (LC_{50}) = >1000 mg/L (96h); Daphnia (EC_{50}) = >1000 mg/L (48h); Algae (EC_{50}) = >1000 mg/L (72h)
12.2 Persistence & Degradability: Fully biodegradable ($BOD_5/COD = 0.75-0.85$) in aquatic environments; degrades completely within 20 days
12.3 Bioaccumulative Potential: No bioaccumulation potential ($\log P = -1.8$); no accumulation in aquatic or terrestrial organisms
12.4 Mobility in Soil: Moderate mobility; partially dissolves in soil water but no leaching to groundwater (biodegrades rapidly)
12.5 PBT/vPvB: Not classified as PBT/vPvB; meets all environmental safety standards
12.6 Other Adverse Effects: No adverse ecological effects at any concentration; biodegradation products are non-toxic to the environment

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- Product Waste: Classified as non-hazardous pharmaceutical waste; may be incinerated at ordinary waste incineration facilities or treated by biological wastewater treatment systems (fully biodegradable)
 - Packaging Waste: Rinse packaging with water; dispose of as non-hazardous plastic waste or recycle
- 13.2 Disposal Regulations: Comply with China general solid waste disposal regulations; no hazardous waste disposal requirements; may be disposed with municipal solid waste (after proper treatment)

SECTION 14: Transport Information

14.1 UN Number: N/A (Non-hazardous goods)
14.2 UN Proper Shipping Name: Non-hazardous solids, organic (Mildronate)
14.3 Transport Hazard Class: N/A | Packaging Group: N/A
14.4 Environmental Hazards: Marine Pollutant (No)
14.5 Special Transport Precautions: Transport at $\leq 30^\circ\text{C}$; use sealed HDPE/fiber drums; avoid direct sunlight and high temperature; no special transport restrictions (ordinary freight)
14.6 Compatibility: May be transported with other non-hazardous chemicals and pharmaceutical raw materials; avoid transport with strong acids and oxidizing agents

SECTION 15: Regulatory Information

15.1 National & International Regulations

- China: NMPA Pharmaceutical Raw Material; Pharmacopoeia (2020); Non-hazardous Chemicals List
 - EU: REACH Registered; Ph. Eur. 10.0 compliant; ECHA non-SVHC; non-hazardous classification (CLP)
 - US: TSCA Listed; USP 45 compliant; FDA-regulated pharmaceutical raw material; non-hazardous (OSHA)
- 15.2 Other: Comply with local pharmaceutical manufacturing and GMP regulations; no hazardous chemical management requirements



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SECTION 16: Other Information

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

