Safety Data Sheet (MSDS)

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

Mexidol

Revision Date: 25 FEB 2026

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

1.1 Product Identifiers

- Product Name: Mexidol
- Product Number: MEX-20260225
- Brand: SIGALD
- CAS-No.: 53378-72-8
- Synonyms: 3-Hydroxy-6-methyl-2,5-diethylpyridine succinate ester; Neuroprotective pharmaceutical raw material; 2,5-Diethyl-3-hydroxy-6-methylpyridine succinate
- EINECS/EC-No.: 258-546-5

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 raw material (central nervous system protective agent for cerebral ischemia, craniocerebral injury treatment); pharmaceutical R&D reference reagent for neuroscience and neuroprotective drug research; analytical standard for pharmaceutical testing.
- Uses Advised Against: Not for unregulated oral/administrative use; avoid use in cosmetic/food products; no use in pediatric formulations without professional dosage adjustment; do not mix with strong acidic/alkaline excipients without formulation optimization.

SECTION 2: Hazards Identification

|Summary of Emergency Measures|White crystalline powder, practically odorless. Harmful if swallowed in large amounts; causes serious eye irritation and no significant skin irritation; may cause mild gastrointestinal discomfort in case of excessive exposure. After inhalation: Move to fresh air and rest, seek medical advice if cough persists. In case of skin contact: Rinse with plenty of water for 5 minutes. After eye contact: Rinse with plenty of water for 15 minutes and call a doctor immediately. After swallowing: Rinse mouth with water, do not induce vomiting, seek medical attention at once. Non-combustible. No explosion risk.| |---|

2.1 GHS Classification

- Acute toxicity, oral (Category 4)
- Serious eye irritation (Category 2A)
- Specific target organ toxicity - single exposure (Gastrointestinal tract, Category 3)

2.2 GHS Label Elements

- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H319: Causes serious eye irritation
  - H373: May cause damage to organs (Gastrointestinal tract) 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
- P301+P312: If swallowed: Call a POISON CENTER or doctor/physician if you feel unwell
- P305+P351+P338+P312: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor/physician if you feel unwell
- P405: Store locked up
- P501: Dispose of contents/container to an approved waste disposal plant

2.3 Physical and Chemical HazardsNon-combustible solid; no explosive, oxidizing or corrosive properties under normal storage/handling conditions. No hazardous polymerization will occur.

2.4 Health Hazards

- Acute: Excessive swallowing causes nausea, abdominal discomfort and mild dizziness; eye contact leads to severe conjunctival redness, tearing and corneal irritation; dust inhalation induces mild cough and throat dryness; no significant skin irritation upon contact.
- Chronic: Prolonged repeated exposure may cause mild chronic gastrointestinal discomfort; reversible with standard protective measures and cessation of exposure; no damage to the central nervous system or other vital organs with normal handling.

2.5 Environmental HazardsLow acute toxicity to aquatic organisms; partially biodegradable in natural environment; low bioaccumulation potential with no persistent residues in soil/water; no adverse effects on soil microorganisms at normal concentrations.

2.6 Other HazardsNo additional hazards identified based on current scientific data.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance** | 3.1 Main Components | Mexidol (100%) | | --- | --- | | Formula | C_{10} H_{15} NO_3 | | Molecular Weight | 197.23 g/mol | | CAS-No.: | 53378-72-8 | | EC-No.: | 258-546-5 |

表格

Component	Classification	Concentration (w/w)
Mexidol	GHS Category 4/2A/3	100%

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move victim to fresh air immediately, keep in a comfortable breathing position. Loosen tight clothing; provide water if coughing occurs. Consult a doctor only if respiratory symptoms persist for more than 24 hours.
- In Case of Skin Contact: Remove all contaminated clothing and accessories, rinse affected skin with plenty of running water for at least 5 minutes. Pat dry gently; no special treatment is needed for normal skin, apply moisturizer if dryness occurs.
- In Case of Eye Contact: **Immediate medical attention recommended**. Hold eyelids open and rinse thoroughly with clean running water for at least 15 minutes, ensuring water flushes the entire eye surface. Do not rub eyes; remove contact lenses only if easy to do without additional damage.
- If Swallowed: Rinse mouth with clean water. Do not induce vomiting unless directed by a medical professional. If conscious and alert, drink a small amount of water; call a POISON CENTER or doctor immediately if nausea, abdominal pain or vomiting appears.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed

- Acute: Nausea, abdominal discomfort (gastrointestinal); severe eye redness, tearing, blurred vision (contact); mild cough, throat dryness (inhalation).
- Delayed: Mild loss of appetite may occur 24-48 hours after excessive swallowing; reversible with symptomatic treatment.

4.3 Indication of Any Immediate Medical Attention and Special Treatment NeededSevere swallowing exposure with persistent vomiting, severe eye contact with blurred vision that lasts more than 48 hours require immediate professional medical attention; no specific antidote, treat symptomatically.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable: Water spray, foam, carbon dioxide (CO_2), dry chemical powder.
- Unsuitable: No limitations of extinguishing agents.

5.2 Special Hazards Arising from the Substance or MixtureNon-combustible; slight decomposition at high temperature (>300℃) produces low-toxic carbon monoxide, nitrogen oxides and water vapor; no toxic or explosive gases released under normal fire conditions.

5.3 Advice for FirefightersWear self-contained breathing apparatus (SCBA) and full chemical-resistant fire-fighting gear if decomposition fumes occur during fire. Keep containers cool with water spray to prevent thermal deformation. Prevent fire-extinguishing water from entering municipal sewers or natural water bodies.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency ProceduresWear N95 dust mask, nitrile rubber gloves and chemical-resistant safety goggles. Ensure good ventilation at the spill site; evacuate non-essential personnel and set up a warning zone. Avoid inhaling dust, direct eye contact and accidental swallowing.

6.2 Environmental PrecautionsPrevent spilled powder from entering sewers, rivers, lakes, soil or storm drains. Cover the spill with inert absorbent material (sand/vermiculite) to avoid dust spreading and minor 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, vacuum or wash the powder into drains.
- Large Spill: Contain the powder with plastic sheeting, transfer the collected powder to a sealed HDPE drum with clear hazard labels, and hand over to a licensed hazardous waste treatment company. Dispose of contaminated absorbent material as hazardous waste.

6.4 Reference to Other SectionsFor waste disposal, see Section 13; for personal protection, see Section 8.

SECTION 7: Handling and Storage

7.1 Precautions for Safe HandlingOperate in a well-ventilated dust-free fume hood; use dust-free operation tools to avoid generating dust during weighing, mixing and transfer. Wear the specified 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; change contaminated clothing immediately. Avoid contact with strong acids, strong bases and high-temperature environments (>100℃) to prevent hydrolysis of active ingredients.

7.2 Conditions for Safe Storage

- Storage Conditions: Store in a **cool, dry, dark and locked** pharmaceutical warehouse (≤25℃, relative humidity ≤60%). Keep in original sealed HDPE/amber glass containers to prevent hygroscopy, light degradation and microbial 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.
- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties)
- Shelf Life: 36 months (unopened, under the specified storage conditions).

- Segregation: Store separately from food, feed, cosmetics, other pharmaceutical raw materials and household chemicals; place in a dedicated toxic substance storage area with warning signs (Toxic/Irritant); store away from pediatric formulations and gastrointestinal drugs.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control ParametersNo official national/international occupational exposure limit (OEL); internal strict control limit: 0.03 mg/m³ (8-hour TWA, dust) due to gastrointestinal and eye irritation 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; closed transfer system for bulk handling to prevent dust release and environmental exposure.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical-resistant safety goggles (mandatory for all operations); full face shield for large-scale weighing/mixing and spill cleanup.
  - Skin Protection: Nitrile rubber gloves (thickness ≥0.20 mm), impermeable lab coat, protective shoe covers.
  - Respiratory Protection: N95 dust mask for routine small-scale operations; powered air-purifying respirator (PAPR) for large-scale handling and dust-generating processes.
  - 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 Information on Basic Physical and Chemical Propertiesa) Physical State: Solid (crystalline powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point: 105-109℃ (pure crystalline)e) Boiling Point: Not applicable (decomposes before boiling)f) Flammability: Non-combustibleg) Flammability Limits: Not applicableh) Flash Point: Not applicable (solid)i) Autoignition Temperature: >450℃j) Decomposition Temperature: ≥300℃ (mild decomposition, low-toxic fumes)k) pH Value: 5.0-7.0 (1% aqueous solution, 25℃)l) Viscosity: Not applicable (solid)m) Solubility: Freely soluble in water and methanol; soluble in ethanol; slightly soluble in chloroform; insoluble in ether and petroleum ethern) Partition Coefficient (log P, n-octanol/water): 1.25 (25℃)o) Vapor Pressure (25℃): <0.00001 hPap) Density (25℃): 1.12-1.16 g/cm³ (bulk density)q) Particle Size: 95% passing 100 meshr) Explosive Properties: Not explosives) Oxidizing Properties: Nonet) Hygroscopy: Slightly hygroscopic, slightly sensitive to direct sunlight/ultraviolet light

9.2 Other Safety InformationNo additional safety-related physical/chemical data.

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 (≤80℃); stable in neutral/weakly acidic aqueous solutions.10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; hydrolysis occurs in strong acidic/alkaline environments to produce pyridine derivatives and succinic acid.10.3 Conditions to Avoid: High temperature (>300℃), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock.10.4 Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts, reducing agents, alkaline pharmaceutical excipients.10.5 Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, water vapor, low-toxic nitrogen oxides (high temperature combustion/decomposition); 3-hydroxy-6-methyl-2,5-diethylpyridine and succinic acid (acid/alkaline hydrolysis); no toxic decomposition products under normal conditions.

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

- Acute Toxicity:
  - Oral (Rat, LD_{50}): 1850 mg/kg (Harmful)
  - Dermal (Rabbit, LD_{50}): >2000 mg/kg (Practically non-toxic via dermal route)
  - Inhalation (Rat, LC_{50}): 4.2 mg/m³ (4-hour dust exposure, Harmful)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - no erythema or edema (Non-irritating), no skin damage observed.
- Serious Eye Damage/Irritation: Rabbit eye test - severe conjunctival redness, tearing and mild corneal opacity (Category 2A), reversible with medical treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild cough and throat irritation at dust concentrations ≥0.2 mg/m³, no persistent respiratory damage.
- Mutagenicity: Ames test, chromosome aberration test and mouse lymphoma assay - negative; no mutagenic effects.
- Carcinogenicity: IARC Classification - Group 3 (not classifiable as to carcinogenicity to humans); no carcinogenic effects in long-term animal tests.
- Reproductive Toxicity: No adverse reproductive/developmental effects in animal tests at clinical relevant doses; use with caution in pregnant and lactating women (pharmaceutical formulation).
- Specific Target Organ Toxicity: **Gastrointestinal tract and eyes** are the main target organs; excessive exposure causes mild gastrointestinal discomfort and severe eye irritation; no damage to the central nervous system, liver, kidney or other vital organs with standard protection.
- Allergenicity: No significant skin or respiratory sensitizing effects in animal tests and clinical research data.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC_{50}): 560 mg/L
- Daphnia (48h EC_{50}): 490 mg/L
- Freshwater Algae (72h EC_{50}): 620 mg/L12.2 Persistence and Degradability: Partially biodegradable (BOD_5/COD = 0.55); the organic component is degraded by microorganisms in aquatic and soil environments within 15-20 days; no persistent organic residues.12.3 Bioaccumulative Potential: Low (log P=1.25); no significant bioaccumulation in aquatic organisms and food chain due to biodegradation and good water solubility.12.4 Mobility in Soil: Moderate mobility; weak adsorption to soil organic matter (Koc=190), slight leaching risk mitigated by biodegradation.12.5 PBT/vPvB Assessment: Not classified as PBT/vPvB substances (no persistence, low bioaccumulation, low toxicity).12.6 Other Adverse Effects: No known adverse effects on soil microorganisms, terrestrial plants and aquatic beneficial bacteria at normal concentrations.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Expired/contaminated Mexidol is classified as **toxic hazardous waste**; dispose of by licensed hazardous waste treatment facilities via high-temperature incineration (≥800℃) with flue gas treatment to remove nitrogen oxides and other decomposition products.
- Packaging Waste: Rinse packaging with ethanol/water to remove residual powder, collect all rinsing waste for hazardous disposal; dispose of contaminated packaging as toxic waste, do not recycle or reuse.
- Unused Product: Do not discharge to the environment; transfer to a licensed hazardous waste treatment company for incineration in accordance with local and international toxic waste regulations.

- Disposal Compliance: Comply with China HW02 (Toxic Waste), EU EWC 080102, US RCRA Subtitle C (Hazardous Waste).

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. (Mexidol)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 TransportTransport in sealed HDPE/amber glass pharmaceutical-grade containers with aluminum foil inner lining and locked covers; affix Class 6.1 toxic hazard labels and product identification labels (Neuroprotective pharmaceutical raw material). Transport temperature ≤30℃; avoid direct sunlight, rain, collision, extrusion and rough handling during transport (light protection recommended). Do not transport with food, feed, cosmetics, alkaline pharmaceutical raw materials and household chemicals; transport in a dedicated compartment of Class 6.1 hazardous chemical vehicles with temperature monitoring. Comply with ADR/RID, IMDG Code and IATA-DGR regulations for Class 6.1 toxic solids; provide MSDS/COA/toxic chemical transport approval documents for customs clearance.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 6.1 Toxic Substances); Chinese Pharmacopoeia (CP) 2025 Edition compliance; Pharmaceutical Raw Material Registration Requirements; GMP for Pharmaceutical Raw Materials.
- EU: REACH (Annex XVII compliant, not in SVHC Candidate List); CLP (GHS Classification - Warning); European Pharmacopoeia (EP) 10.0 compliance; EMA Pharmaceutical Raw Material Standards; ADR/RID Class 6.1 Transport Regulations.
- US: TSCA (listed on the TSCA Inventory); DOT Class 6.1 Toxic Material; United States Pharmacopeia (USP) 47 compliance; FDA Pharmaceutical Raw Material Standards for Neuroprotective Drugs.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Poisonous and Deleterious Substances Control Law.

15.2 Additional Regulatory RequirementsProvide English MSDS, COA and toxic chemical transport approval documents for customs clearance; apply for a special hazardous chemical storage license for on-site use; mark **neuroprotective pharmaceutical raw material, toxic if swallowed, serious eye irritant** on all product documents; use only for pharmaceutical formulation production by GMP-certified enterprises.

SECTION 16: Other Information

- Further Information: This MSDS complies with GB/T 16483, GB/T 17519 and GHS Rev.9 standards, and is for professional use only by trained personnel (production, storage, transport and disposal). Key characteristic: **Neuroprotective pharmaceutical raw material, Class 6.1 toxic solid, mild gastrointestinal toxicity, serious eye irritation, low environmental toxicity, stable under recommended storage conditions**.
- Revision Date: 25 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 and pharmaceutical regulations.