



# 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

**Product Name:** Polymyxin B (Sulfate) **CAS-No.:** 1404-26-8 **Product Number:** PMB-20260226 **Brand:** SIGALD **Revision Date:** 26 FEB 2026

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

#### 1.1 Product Identifiers

- Synonyms: Polymyxin B sulfate; Aerosporin; Cyclic polypeptide antibiotic B

#### 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:** +86-021-50350029 (CHEMTREC)

#### 1.4 Identified Uses & Uses Advised Against

- Identified Uses: Pharmaceutical raw material (systemic/topical antibiotic); veterinary medicine; laboratory antimicrobial reagent; industrial biocide (low-concentration).
- Uses Advised Against: No unapproved use in food/feed; avoid overuse to prevent antibiotic resistance; avoid use in polymyxin-allergic individuals.

### SECTION 2: Hazards Identification

2.1 **GHS Classification:** Acute oral toxicity, Category 3 (H301); Acute dermal toxicity, Category 4 (H312); Eye irritation, Category 2 (H319); Specific target organ toxicity (single exposure), Category 3 (Kidney) (H373) 2.2 **GHS Label Elements**

- Hazard Pictogram: (Warning)
- Signal Word: **Warning**
- Hazard Statements: H301 - Toxic if swallowed; H312 - Harmful in contact with skin; H319 - Causes serious eye irritation; H373 - May cause damage to kidneys through prolonged or repeated exposure
- Precautionary Statements: P260, P264, P270, P280, P301+P310, P305+P351+P338, P314 2.3

**Physical and Chemical Hazards:** No physical/chemical hazards; non-combustible; highly hygroscopic

2.4 **Health Hazards:** Toxic if swallowed; harmful via skin contact; causes serious eye irritation; kidney damage via prolonged/repeated systemic exposure; gastrointestinal upset on ingestion; neurotoxicity at high doses (systemic use) 2.5 **Environmental Hazards:** Highly toxic to aquatic organisms; moderately biodegradable; low environmental persistence.

2.6 **Other Hazards:** Antibiotic resistance risk with overuse; no additional hazards identified.

### SECTION 3: Composition/Information on Ingredients

- **Substance / Mixture:** Pure cyclic polypeptide antibiotic (sulfate salt)



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- **Active Component:** Polymyxin B (CAS:1404-26-8) | Concentration: ≥95.0% (as sulfate) | Classification: Acute oral toxicity Cat.3; Acute dermal toxicity Cat.4; Eye irritation Cat.2; Target organ toxicity (Kidney) Cat.3

## SECTION 4: First Aid Measures

### 4.1 First-Aid Measures

- Inhaled: Move to fresh air; administer oxygen if breathing is difficult; **immediately consult a doctor.**
  - Skin Contact: Rinse skin with running water and mild soap for 15 mins; remove contaminated clothing; wash clothing before reuse; consult a doctor if irritation/dizziness occurs.
  - Eye Contact: Rinse eyes thoroughly with sterile water for 20-30 mins (hold eyelids open); remove contact lenses; **immediately consult an ophthalmologist.**
  - Swallowed: Rinse mouth with water; **do not induce vomiting**; call a poison control center/consult a doctor at once; monitor kidney/neurological function.
- 4.2 Symptoms:** Nausea/vomiting/diarrhea (ingestion); skin redness/burning; eye severe burning/tearing; dizziness/ataxia (neurotoxicity); kidney dysfunction (prolonged exposure).
- 4.3 Medical Attention:** Symptomatic treatment; supportive care for kidney/neurological damage; no specific antidote; monitor serum creatinine/BUN for kidney injury.
- 4.4 Notes to Physician:** Inform of product composition (polymyxin B sulfate) and exposure route/amount; assess for antibiotic allergy; monitor renal/neurological function.

## SECTION 5: Firefighting Measures

- 5.1 Extinguishing Media:** Water spray, foam, CO<sub>2</sub>, dry powder (all suitable)
- 5.2 Special Hazards:** Non-combustible; decomposes at >180°C into non-toxic amino acids; no toxic combustion/decomposition fumes generated.
- 5.3 Firefighter Advice:** Wear standard fire-fighting gear (SCBA recommended for large fires); cool containers with water spray to prevent thermal degradation/hygroscopic absorption; no toxic fume inhalation risk.

## SECTION 6: Accidental Release Measures

- 6.1 Personal Precautions:** Wear N95 dust mask, chemical safety goggles, nitrile gloves, impermeable lab coat and face shield; operate in well-ventilated area; avoid dust inhalation/skin contact.
- 6.2 Environmental Precautions:** Strictly contain spilled powder to prevent runoff into water bodies/soil; use absorbent material to avoid environmental contamination.
- 6.3 Clean Up Methods**
- Small Spill: Sweep up with dry clean spatula; transfer to sealed moisture-proof container for disposal.
  - Large Spill: Contain with inert material (anhydrous silica gel/sand); collect into sealed vacuum container; do not rinse with water (hygroscopic); dispose of collected material as hazardous waste.
- 6.4 Reference:** See Section 13 for disposal details.

## SECTION 7: Handling and Storage

### 7.1 Safe Handling

- Operate in well-ventilated, low-humidity (RH  $\leq$ 40%) area; avoid dust generation/inhalation and skin/eye contact; use dry sterile equipment.
- Do not eat/drink/smoke in the work area; wash hands thoroughly with water after handling; use double gloves for large-scale handling.
- Identify antibiotic-allergic personnel and avoid exposure; limit prolonged/repeated contact to prevent kidney damage.

## 7.2 Safe Storage

- Storage Conditions: **2-8°C (refrigerated)**, dry, dark, **hermetically sealed**; secondary packaging with anhydrous desiccant; avoid temperature fluctuation/repeated freeze-thaw.
- Incompatibilities: Strong acids/bases, oxidizing agents, heavy metal ions, other antibiotics (cephalosporins), proteolytic enzymes.
- Storage Class (TRGS 510): 10 (Toxic Solids, Non-combustible)
- Shelf Life: 36 months (unopened, 2-8°C storage); 1 month (room temperature, after opening)
- Storage Segregation: Store separately from food/feed, pharmaceuticals, strong acids/bases; store in dedicated locked antibiotic storage area; keep away from aquatic environment.

## SECTION 8: Exposure Controls/Personal Protection

### 8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national limit; recommended TWA: 0.1 mg/m<sup>3</sup> (inhalable dust)

### 8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) for dust-generating operations; low-humidity air supply (RH  $\leq$ 40%); negative pressure work area.
- Personal Protective Equipment (PPE)
  - Eye/Face: Chemical safety goggles + face shield (mandatory)
  - Skin: Powder-free nitrile rubber gloves ( $\geq$ 0.2mm, double-layer); impermeable lab coat; shoe covers
  - Respiratory: N95/P95 dust mask for routine handling; PAPR with full facepiece for large-scale powder handling
  - Hand: Powder-free nitrile gloves (no latex, double-layer)
- Hygiene: Change all contaminated PPE immediately; perform hand hygiene with water/soap after handling; no direct skin contact with the product; regular medical monitoring for renal function (prolonged exposure).

## SECTION 9: Physical and Chemical Properties

- Physical State: Hygroscopic powder
- Color: White to pale pink
- Odor: Odorless
- Melting Point: Decomposes ( $>$ 180°C)
- Boiling Point: N/A (decomposes before boiling)
- Flammability: Non-combustible
- Flash Point: N/A



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- Autoignition Temperature: >300°C
- Solubility: Soluble in water, methanol; slightly soluble in ethanol; insoluble in ether, chloroform
- Density (25°C): 1.28 g/cm<sup>3</sup>
- Particle Size: 200-300 mesh (pharmaceutical grade)
- Explosive Properties: Non-explosive
- Oxidizing Properties: None
- pH Value: 5.0-7.5 (1% aqueous solution, 25°C)
- Hygroscopy: High (absorbs moisture at RH >40%)
- Vapor Pressure (25°C): < 0.1 hPa
- Sulfate Content: 10.0-14.0% (as H<sub>2</sub>SO<sub>4</sub>)

### SECTION 10: Stability and Reactivity

10.1 **Chemical Stability:** Stable at 2-8°C hermetically sealed storage; stable for 1 month at room temperature (≤25°C); degrades rapidly at high temperature (>40°C) or high humidity.10.2

**Hazardous Reactions:** No hazardous reactions; hydrolyzes in strong acids/bases to amino acids; degrades via enzymatic breakdown; forms insoluble complexes with heavy metal ions.10.3

**Conditions to Avoid:** High temperature (>40°C), direct sunlight, high humidity (RH >40%), strong acids/bases, oxidizing agents, heavy metal ions.10.4

**Incompatible Materials:** Concentrated HCl/H<sub>2</sub>SO<sub>4</sub>, NaOH/KOH, hydrogen peroxide, copper/iron/zinc ions, cephalosporins, trypsin/pepsin.10.5

**Decomposition Products:** Non-toxic amino acids, sulfate ions; no hazardous decomposition products.

### SECTION 11: Toxicological Information

#### 11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD<sub>50</sub>) = 180 mg/kg; Dermal (Rabbit, LD<sub>50</sub>) = 850 mg/kg; Inhalation (Rat, LC<sub>50</sub>) = 0.5 mg/m<sup>3</sup> (4h)
- Skin Irritation/Corrosion: Mild irritation (Rabbit, 24h exposure); reversible.
- Eye Irritation/Damage: Severe irritation (Rabbit, 24h exposure); reversible with prompt treatment.
- Skin Sensitization: Low potential (human/animal tests); minimal antibiotic allergy cross-reactivity.
- Mutagenicity: No mutagenic effects (Ames test, chromosome aberration test).
- Carcinogenicity: Not classified as carcinogenic by IARC/EPA/NTP.
- Reproductive Toxicity: No adverse reproductive effects at therapeutic dosages; avoid high-dose exposure during pregnancy/lactation (renal risk).
- Target Organ Toxicity: Kidneys (prolonged/repeated systemic exposure); nervous system (high-dose systemic use); gastrointestinal tract (ingestion); eyes/skin (direct contact).
- Chronic Toxicity: Renal tubular damage with prolonged systemic exposure; reversible with dose cessation.

### SECTION 12: Ecological Information

12.1 **Toxicity:** Fish (Zebrafish,  $LC_{50}$ ) = 0.5 mg/L (96h); Daphnia ( $EC_{50}$ ) = 0.2 mg/L (48h); Algae ( $EC_{50}$ ) = 0.8 mg/L (72h); **highly toxic to aquatic life.** 12.2 **Persistence and Degradability:** Moderately biodegradable (40-60% degradation in 7 days) by soil/aquatic microorganisms; low environmental persistence (half-life = 3-5 days). 12.3 **Bioaccumulative Potential:** Low ( $\log K_{oc}$  = 0.8); no significant bioaccumulation in food chains. 12.4 **Mobility in Soil:** Moderate mobility (water-soluble); binds weakly to soil organic matter; potential leaching risk to groundwater (avoid soil contamination). 12.5 **PBT/vPvB:** Not classified as PBT/vPvB; low persistence, low bioaccumulation, high aquatic toxicity. 12.6 **Other Effects:** May inhibit aquatic/soil microbial growth at low concentrations; antibiotic resistance risk in environmental bacteria with overuse; no long-term ecological impacts at controlled use levels.

## SECTION 13: Disposal Considerations

13.1 **Waste Treatment:** All waste (powder/solution) is **hazardous waste**; incinerate at  $>900^{\circ}\text{C}$  via licensed hazardous waste facilities with gas treatment; no discharge to water/soil/sewage system; do not dispose of with ordinary waste. 13.2 **Packaging Waste:** Decontaminate with dilute disinfectant; rinse with water; dry thoroughly; dispose as hazardous plastic/glass waste via licensed facilities.

## SECTION 14: Transport Information

14.1 **UN Number:** ADR/RID/IMDG/IATA: 2811 14.2 **UN Proper Shipping Name:** Toxic solids, organic, n.o.s. (Polymyxin B sulfate) 14.3 **Transport Hazard Class:** 6.1 (Toxic substances) 14.4 **Packaging Group:** II 14.5 **Environmental Hazards:** IMDG: Marine pollutant (Yes) 14.6 **Special Precautions:** **Refrigerated transport (2-8°C)**; hermetically sealed packaging with anhydrous desiccant; shock-proof packaging; mark "**Keep Refrigerated**", "**Toxic**", "**Marine Pollutant**"; no transport with food/feed/aquatic products; avoid transport near water bodies; licensed hazardous chemical transport only. 14.7 **Incompatible Materials:** Avoid transport with strong acids/bases, oxidizing agents, food/feed, pharmaceuticals, heavy metal salts.

## SECTION 15: Regulatory Information

### 15.1 National & International Regulations

- China: CP compliant; Hazardous Chemical Safety Management Regulation (Class 6.1); Pharmaceutical Raw Material Management Regulation (GMP grade); Veterinary Drug Regulation; Environmental Protection Law (aquatic toxicity control).
- International: GHS (Rev.9) Cat.3 Acute oral toxicity; REACH (EU) Registered; TSCA (US) Listed; USP/EP/FDA compliant; FDA-approved for systemic/topical pharmaceutical use; IMO MARPOL Annex V (marine pollutant). 15.2 **Other:** Comply with local antibiotic import/export (controlled antibiotic), refrigerated transport and hazardous chemical regulations; comply with antibiotic resistance control guidelines; mark for renal toxicity and aquatic hazard risk.

## SECTION 16: Other Information

- This MSDS is based on current scientific research and complies with GB/T 16483, GB/T 17519 and GHS international standards.



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- Supplier is not liable for damage caused by improper use, non-refrigerated storage/transport, environmental contamination or non-compliance with safety precautions.
- Pharmaceutical grade Polymyxin B sulfate meets global pharmacopoeia standards; for pharmaceutical/veterinary use only (GMP conditions); avoid overuse to prevent antibiotic resistance.
- For further technical/safety information, contact the supplier's antibiotic R&D/EHS department (refrigerated storage and environmental safety guidance provided).

