Safety Data Sheet (MSDS)

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

Product Name: Pulvis Cholestyramini (Cholestyramine Powder)Revision Date: 28 FEB 2026

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

1.1 Product Identifiers

- Product Name: Pulvis Cholestyramini; Cholestyramine Powder
- Product Number: PC-20260228
- Brand: SIGALD
- CAS-No.: 11041-12-6
- Synonyms: Cholestyramine resin; Poly(styrene-co-divinylbenzene) quaternary ammonium chloride; Anion exchange resin for lipid-lowering

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 for lipid-lowering oral formulations; treatment of hypercholesterolemia and bile acid malabsorption; pharmaceutical R&D reference reagent for cardiovascular pharmacology research.
- Uses Advised Against: Not for injection; avoid use in cosmetic/food products; do not use as industrial ion exchange resin for non-pharmaceutical purposes.

SECTION 2: Hazards Identification

|Summary of Emergency Measures|White free-flowing powder. May cause mild respiratory irritation if inhaled; mild skin irritation with prolonged contact; mild eye irritation if splashed. After inhalation: Move to fresh air and rest, cough gently to expel dust. In case of skin contact: Rinse with plenty of water and soap. After eye contact: Rinse with plenty of water for 10-15 minutes. After swallowing: Rinse mouth with water, drink a glass of water; no induced vomiting. Non-combustible. No explosion risk.| |---|

2.1 GHS Classification

- Eye irritation (Category 2A); Skin irritation (Category 2); Respiratory tract irritation (Category 2)2.2 GHS Label Elements
- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H315: Causes skin irritation

- H319: Causes serious eye irritation
- H335: May cause respiratory irritation
- Precautionary Statements:
- P264: Wash skin thoroughly after handling
- P271: Use only outdoors or in a well-ventilated area
- P280: Wear protective gloves/eye protection/face protection
- P302+P352: If on skin: Wash with plenty of water and soap
- P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing
- P312: Call a POISON CENTER or doctor/physician if you feel unwell
- P332+P313: If skin irritation occurs: Get medical advice/attention
- P337+P313: If eye irritation persists: Get medical advice/attention

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: Inhalation causes mild cough, nasal irritation; skin contact with prolonged exposure leads to dryness, redness; eye splashing causes mild conjunctival redness, tearing. No acute oral toxicity (low bioavailability, non-absorbable).
- Chronic: No known chronic toxic effects with standard protective measures; prolonged inhalation may cause mild respiratory tract irritation.2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC_{50} = 850 mg/L for zebrafish); non-biodegradable but non-bioaccumulative; no adverse effects on soil and water environment with proper disposal.2.6 Other Hazards
- May form dust clouds in dry conditions; no dust explosion risk (low combustibility).

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance (Polymeric Resin)** | 3.1 Main Components | Cholestyramine (100%) | | --- | --- | | Formula | $(C_{27}H_{46}NO)_n \cdot Cl_n$ | | Molecular Weight | ≈40000-50000 g/mol (average) | | CAS-No.: | 11041-12-6 | | EC-No.: | 234-291-5 |

Hazardous Ingredients

表格

Component	Classification	Concentration (w/w)
Cholestyramine	GHS Category 2/2A/2	100%

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately, keep in a comfortable breathing position. Encourage gentle coughing to expel dust; no special treatment if no discomfort, consult a doctor if cough persists.

- In Case of Skin Contact: Immediately remove contaminated clothing. Rinse skin with plenty of running water and mild soap for 5-10 minutes; apply moisturizer if skin dryness occurs.
- In Case of Eye Contact: **Hold eyelids open** and rinse thoroughly with plenty of running water for 10-15 minutes. Remove contact lenses if present and easy to do. Consult an ophthalmologist if irritation, redness or tearing persists.
- If Swallowed: Rinse mouth with water and drink a glass of clean water (200-300 mL). Do not induce vomiting (non-absorbable resin, no systemic toxicity). Consult a doctor only if gastrointestinal discomfort (abdominal distension, constipation) occurs.4.2 Most Important Symptoms and Effects
- Acute: Mild respiratory/nasal irritation (inhalation); skin dryness/redness (contact); eye redness/tearing (splashing). No systemic toxic symptoms due to non-oral absorption.
- Delayed: No known delayed toxic effects based on current scientific data.4.3 Indication of Immediate Medical Attention
- Severe eye irritation with persistent blurred vision; severe respiratory irritation with chest tightness; severe gastrointestinal discomfort after massive ingestion.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, carbon dioxide (CO_2), dry chemical powder, foam.
- Unsuitable Extinguishing Media: No limitations of extinguishing agents.5.2 Special Hazards Arising from the Substance
- Non-combustible; no hazardous combustion gases generated; slight dust cloud formation if heated in dry conditions, no explosion risk.5.3 Advice for Firefighters
- Wear standard fire-fighting gear and self-contained breathing apparatus (SCBA) if dust cloud forms.
- Prevent fire-extinguishing water from entering municipal sewers or natural water bodies (no environmental hazard, just for general protection).

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear N95 dust mask, nitrile rubber gloves, safety goggles and disposable lab coat. Ensure good ventilation at the spill site; evacuate non-essential personnel to avoid dust inhalation.6.2 Environmental Precautions
- Prevent spilled powder from entering sewers, rivers or soil; sweep up spilled powder to avoid dust spreading.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 reuse or disposal. Do not blow or vacuum the powder to avoid dust inhalation.
- Large Spill: Contain the spill with sandbags/dikes, transfer to a sealed HDPE drum with clear labels using a dust-free shovel; hand over to professional waste treatment company if contaminated.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 area or fume hood; use dust-free operation tools (anti-static) to avoid dust cloud formation during weighing and mixing.
- Wear the specified PPE for all handling operations; no eating, drinking or smoking in the work area.
- Wash hands, face and exposed skin thoroughly with soap and water after handling; clean the work area regularly to avoid dust accumulation.
- Avoid contact with strong oxidizing agents 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, well-ventilated and locked** pharmaceutical warehouse. Temperature ≤ 25℃, relative humidity ≤ 60%. Keep the container tightly sealed to prevent moisture absorption and caking.
- Incompatibilities: Strong oxidizing agents (H_2O_2, $KMnO_4$), strong acids, organic solvents (acetone, chloroform).
- Storage Class (TRGS 510): 11 (Non-hazardous Powders)
- Shelf Life: 24 months (unopened, under the specified storage conditions).
- Segregation: Store separately from other pharmaceutical raw materials, food, feed and cosmetics; place in a dedicated resin raw material storage area with warning signs; avoid storage with lipid-lowering drug excipients that may interact with bile acids.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal strict control limit: 1.0 mg/m³ (8-hour TWA, dust) (due to respiratory/irritant 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 ≤ 0.5 mg/m³.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical-resistant safety goggles (mandatory for all operations); full face shield for large-scale handling to prevent splashing/dust.
  - Skin Protection: Chemical-resistant nitrile rubber gloves (thickness ≥ 0.20 mm), impermeable anti-chemical lab coat, protective shoe 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 (free-flowing powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point: Not applicable (decomposes before melting)e) Boiling Point: Not applicable (polymeric resin, no boiling)f) Flammability: Non-combustibleg) Flammability Limits: Not applicableh) Flash Point: Not applicablei) Autoignition Temperature: > 500℃j) Decomposition Temperature: ≥200℃ (mild decomposition, no hazardous fumes)k) pH Value: 4.0-6.0 (5% aqueous suspension, 25℃)l) Viscosity: Not applicable (solid powder)m) Solubility: Insoluble in water, methanol, ethanol, organic solvents; swells in water/aqueous solutionsn) Partition Coefficient (log P, n-octanol/water): Not applicableo) Vapor Pressure (25℃): < 0.0001 hPap) Bulk Density: 0.35-0.45 g/cm³ (25℃)q) Particle Size: 90% passing 150 μmr) Explosive Properties: Not explosive (no dust explosion risk)s) Oxidizing Properties: Nonet) Hygroscopy: Slightly hygroscopic, prone to caking if exposed to high humidity

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions (≤25℃, dry, sealed); stable in neutral/weakly acidic aqueous suspension, suitable for pharmaceutical formulation processing.10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; does not react with common pharmaceutical excipients (lactose, microcrystalline cellulose).10.3 Conditions to Avoid: High temperature (>200℃), high humidity (>60%), direct contact with strong oxidizing agents/strong acids/organic solvents, strong mechanical shock.10.4 Incompatible Materials: Strong oxidizing agents, concentrated mineral acids, ketones, halogenated hydrocarbons, strong alkaline solutions.10.5 Hazardous Decomposition Products: Carbon dioxide, water vapor, low-toxic nitrogen-containing fumes (at high temperature complete combustion); no toxic decomposition products under normal use conditions.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity (**Anion exchange resin, lipid-lowering pharmaceutical raw material**):
  - Oral (Rat, LD_{50}): > 20000 mg/kg (Non-toxic, non-absorbable)
  - Dermal (Rabbit, LD_{50}): > 10000 mg/kg (Non-hazardous)
  - Inhalation (Rat, LC_{50}): > 10 mg/m³ (4-hour exposure, mild respiratory irritation only)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - mild redness, no edema (Category 2), reversible within 48 hours without treatment.
- Eye Irritation/Damage: Rabbit eye test - mild conjunctival redness, tearing (Category 2A), reversible within 24 hours with flushing.
- Respiratory Irritation: Rat inhalation test - mild nasal/cough irritation at high dust concentrations (≥5 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 high doses; safe for use in pregnant women under clinical monitoring (for hypercholesterolemia).
- Specific Target Organ Toxicity: No target organ toxicity (non-absorbable, acts only in gastrointestinal tract); mild gastrointestinal discomfort (constipation) may occur with oral administration (pharmaceutical formulation-related).
- Allergenicity: No significant sensitizing effects in animal tests and clinical research data.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC_{50}): 850 mg/L
- Daphnia (48h EC_{50}): 900 mg/L
- Freshwater Algae (72h EC_{50}): 880 mg/L12.2 Persistence and Degradability: Non-biodegradable (polymeric resin); no microbial degradation in natural environment, but no bioaccumulation and no persistent toxic effects.12.3 Bioaccumulative Potential: None (high molecular weight, insoluble in water/organic solvents, cannot cross biological membranes).12.4 Mobility in Soil: No mobility (insoluble in water, adsorbs to soil particles completely).12.5 PBT/vPvB Assessment: Not classified as PBT/vPvB substances (no bioaccumulation, no toxic effects).12.6 Other Adverse Effects: No known adverse effects on soil microorganisms, aquatic organisms and terrestrial plants at normal disposal concentrations.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Uncontaminated expired product can be recycled for R&D use; contaminated product is classified as **non-hazardous pharmaceutical waste**; dispose of by licensed waste treatment facilities via high-temperature incineration (≥800℃) with flue gas treatment.
- Packaging Waste: Rinse packaging with water to remove residual powder, then dispose of as non-hazardous plastic waste; can be recycled if not contaminated.
- Unused Product: Do not discharge to the environment; incinerate with professional waste treatment companies in accordance with local pharmaceutical waste regulations.
- Disposal Compliance: Comply with national and local non-hazardous waste disposal regulations (e.g., China GB 18484, EU EWC 070201, US RCRA Subtitle D).

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: -; IMDG: -; IATA-DGR: -14.2 UN Proper Shipping Name: ADR/RID: Not dangerous goods; IMDG: Not dangerous goods; IATA-DGR: Not dangerous goods14.3 Transport Hazard Class(es): ADR/RID: -; IMDG: -; IATA-DGR: -14.4 Packaging Group: ADR/RID: -; IMDG: -; IATA-DGR: -14.5 Environmental Hazards: IMDG Marine Pollutant: **No**14.6 Special Precautions for Transport

- Transport in sealed HDPE pharmaceutical-grade drums with inner plastic lining and locked cover; affix product identification labels (mark anion exchange resin/lipid-lowering pharmaceutical raw material/dust irritation warning).
- Transport temperature ≤ 30℃, relative humidity ≤ 60%; avoid direct sunlight, rain, collision and rough handling during transport to prevent caking and package damage.
- Do not transport with strong oxidizing agents, strong acids, organic solvents and food/feed/cosmetics; transport in a dedicated compartment of ordinary pharmaceutical transport vehicles with dust-proof measures.
- Comply with international non-dangerous goods transport regulations (ADR/RID, IMDG Code, IATA-DGR); provide MSDS and COA for customs clearance if needed.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- China: Pharmaceutical Raw Material Registration Requirements; Chinese Pharmacopoeia (CP) 2025 edition compliance; Hazardous Chemicals Safety Management Regulation (**Non-hazardous classification**); Good Manufacturing Practice (GMP) for pharmaceuticals.
- EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Warning); European Pharmacopoeia (EP) 10.0 compliance; EMA pharmaceutical raw material standards.
- US: TSCA (listed on the TSCA Inventory); FDA (compliant with pharmaceutical excipient/raw material standards for lipid-lowering drugs); United States Pharmacopeia (USP) 47 compliance; cGMP for pharmaceuticals.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; PMDA pharmaceutical raw material registration standards.15.2 Additional Regulatory Requirements
- Provide English MSDS, COA and pharmaceutical raw material qualification documents for customs clearance; comply with GMP production and quality control requirements for pharmaceutical use; mark anion exchange resin and lipid-lowering drug raw material 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: **Anion exchange resin, non-absorbable lipid-lowering pharmaceutical raw material, mild irritant, non-toxic, non-hazardous for transport**.
- Revision Date: 28 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.