Safety Data Sheet (MSDS)

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

Sucralfate

Revision Date: 25 FEB 2026

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

1.1 Product Identifiers

- Product Name: Sucralfate
- Product Number: SUC-20260225
- Brand: SIGALD
- CAS-No.: 54182-58-0
- Synonyms: Sucrose octasulfate aluminum salt; Aluminium sucrose sulfate; Gastric mucosal protectant

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 (gastric mucosal protectant for peptic ulcer, gastritis); pharmaceutical excipient for oral solid formulations; R&D reference reagent for gastroenterology research.
- Uses Advised Against: Not for injectable use; no direct use in cosmetic/food products; avoid excessive oral intake without pharmaceutical formulation.

SECTION 2: Hazards Identification

|Summary of Emergency Measures|White amorphous powder. Practically non-toxic; may cause mild eye/skin irritation and mild gastrointestinal discomfort if swallowed in large amounts. After inhalation: Move to fresh air and rest, no special treatment needed if no cough. In case of skin contact: Rinse with plenty of water for 5 minutes. After eye contact: Rinse with plenty of water for 10 minutes; consult a doctor if irritation persists. After swallowing: Rinse mouth with water, drink a glass of water; seek medical advice if abdominal discomfort occurs. Non-combustible. No explosion risk.| |---|

2.1 GHS Classification

- Skin irritation (Category 2); 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:
  - H315: Causes skin irritation
  - 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
  - P302+P352: If on skin: Wash with plenty of water and soap
  - 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
  - P332+P313: If skin irritation occurs: Get medical advice/attention
  - P501: Dispose of contents/container to an approved waste disposal plant

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

2.4 Health Hazards

- Acute: Mild skin/eye irritation upon direct contact; large oral intake causes nausea, abdominal distension and constipation (gastrointestinal discomfort).
- Chronic: Prolonged excessive exposure may cause mild gastrointestinal dysfunction and occasional constipation; no chronic organ damage with standard protective measures.

2.5 Environmental HazardsLow acute toxicity to aquatic organisms; partially biodegradable in natural environment; low aluminum leaching risk; no persistent environmental residues and no bioaccumulation potential.

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 | Sucralfate (100%) | | --- | --- | | Formula | $C_{12}H_{54}Al_{16}O_{75}S_8$ | | Molecular Weight | 2086.76 g/mol | | CAS-No.: | 54182-58-0 | | EC-No.: | 259-086-8 |

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Component	Classification	Concentration (w/w)
Sucralfate	GHS Category 2/2A/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. No special treatment required if no discomfort; consult a doctor if cough or chest tightness persists for more than 24 hours.

- In Case of Skin Contact: Remove contaminated clothing and gloves, rinse affected skin with plenty of running water and mild soap for at least 5 minutes. Seek medical advice if redness or itching persists.
- In Case of Eye Contact: Hold eyelids open and rinse thoroughly with plenty of running water for at least 10 minutes. Remove contact lenses if present and easy to do. Do not rub eyes; consult an ophthalmologist if irritation or blurred vision occurs.
- If Swallowed: Rinse mouth with water and drink 1-2 cups of warm water (if conscious and alert). Do not induce vomiting. Seek medical advice if nausea, abdominal distension or constipation occurs.

4.2 Most Important Symptoms and Effects

- Acute: Skin erythema, pruritus (contact); eye redness, tearing (contact); nausea, abdominal distension (swallowed in large amounts).
- Delayed: Mild constipation may occur 24-48 hours after excessive oral intake; reversible with symptomatic treatment.

4.3 Indication of Immediate Medical AttentionProlonged severe eye irritation and persistent severe gastrointestinal discomfort after large oral intake require immediate professional medical attention.

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 SubstanceNon-combustible; slight decomposition at high temperature (>500℃) produces low-toxic sulfur-containing fumes and aluminum oxide dust; no toxic/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/dust occur during fire. Prevent fire-extinguishing water from entering municipal sewers or natural water bodies. Avoid inhaling aluminum oxide dust after fire.

SECTION 6: Accidental Release Measures

6.1 Personal PrecautionsWear disposable dust mask, nitrile rubber gloves and safety goggles. Ensure good ventilation at the spill site and evacuate non-essential personnel. Avoid inhaling dust and prolonged skin contact with spilled powder; clean up immediately to prevent dust spreading.

6.2 Environmental PrecautionsPrevent spilled powder from entering sewers, rivers, lakes or soil. Sweep up spilled powder to avoid aluminum accumulation in soil/water.

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 professional disposal. Do not blow or vacuum the powder to avoid dust inhalation.
- Large Spill: Contain the spill with plastic sheets/dikes, transfer to a sealed HDPE drum with clear hazard labels, and handle as pharmaceutical waste. Do not wash the spill into drains or water bodies.

6.4 Reference to Other SectionsFor waste disposal, see Section 13.

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 and mixing. 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; keep the work area clean and dry. Avoid contact with strong acids, strong bases and high-temperature environments (>100℃); do not mix with other pharmaceutical raw materials without professional guidance.

7.2 Conditions for Safe Storage

- Storage Conditions: Store in a **cool, dry, dark and sealed** pharmaceutical warehouse. Temperature ≤ 25℃, relative humidity ≤ 65%. Keep the container tightly sealed to prevent hygroscopy and contamination.
- Incompatibilities: Strong acids (HCl, H_2SO_4), strong bases (NaOH, KOH), strong oxidizing agents, high-concentration salt solutions.
- Storage Class (TRGS 510): 11 (Non-hazardous Solid Pharmaceutical Raw Materials)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from strong acid/alkaline pharmaceutical raw materials, food, feed and cosmetics; place in a dedicated pharmaceutical raw material storage area with product identification labels.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control ParametersNo official national/international OEL; internal control limit: 1.0 mg/m³ (8-hour TWA, dust) due to mild irritation and gastrointestinal 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); no face shield required for routine small-scale handling.

- Skin Protection: Chemical-resistant nitrile rubber gloves (thickness ≥ 0.18 mm), clean lab coat, protective shoe covers.
- Respiratory Protection: Disposable 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 3 hours for continuous operation.

SECTION 9: Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Propertiesa) Physical State: Solid (amorphous powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point: Decomposes at >200℃ (no definite melting point)e) Boiling Point: Not applicable (decomposes before boiling)f) Flammability: Non-combustibleg) Flammability Limits: Not applicableh) Flash Point: Not applicablei) Autoignition Temperature: > 500℃j) Decomposition Temperature: ≥200℃ (mild decomposition, produces sulfur-containing fumes and aluminum oxide)k) pH Value: 3.5-5.5 (1% aqueous suspension, 25℃)l) Viscosity: Not applicable (solid)m) Solubility: Practically insoluble in water, ethanol, methanol and organic solvents; slightly soluble in dilute mineral acidsn) Partition Coefficient (log P, n-octanol/water): No data available (insoluble in both phases)o) Vapor Pressure (25℃): < 0.00001 hPap) Density (25℃): 1.70-1.75 g/cm³ (bulk density)q) Particle Size: 95% passing 200 meshr) Explosive Properties: Not explosives) Oxidizing Properties: Nonet) Hygroscopy: Slightly hygroscopic, stable in dry air

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℃).10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; stable in neutral/weakly acidic environment, decomposes in strong acid/alkaline environment.10.3 Conditions to Avoid: High temperature (>200℃), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock.10.4 Incompatible Materials: Strong acids, strong bases, strong oxidizing agents, high-concentration salt solutions, alkaline pharmaceutical excipients.10.5 Hazardous Decomposition Products: Sulfur dioxide, carbon dioxide, water vapor, aluminum oxide dust (at high temperature complete combustion/decomposition); sucrose and aluminum salts (in strong acid/alkaline environment).

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

- Acute Toxicity (**Pharmaceutical gastric mucosal protectant**):
  - Oral (Rat, LD_{50}): > 10,000 mg/kg (Practically non-toxic)
  - Dermal (Rabbit, LD_{50}): > 20,000 mg/kg (Non-hazardous)
  - Inhalation (Rat, LC_{50}): > 5.0 mg/m³ (4-hour exposure, Non-hazardous)

- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - mild redness (Category 2), reversible within 48 hours without treatment.
- Eye Irritation/Damage: Rabbit eye test - moderate conjunctival redness and tearing (Category 2A), reversible with treatment within 72 hours.
- Respiratory Irritation: Rat inhalation test - no significant respiratory irritation even at high dust concentrations (≥2.0 mg/m³).
- 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 clinical relevant doses; safe for use in pregnant women (pharmaceutical formulation).
- Specific Target Organ Toxicity: **Gastrointestinal tract** is the main target organ; excessive oral intake causes mild constipation and abdominal distension; no damage to other organs with standard use.
- Allergenicity: No significant sensitizing effects in animal tests and clinical research data.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC_{50}): > 1000 mg/L
- Daphnia (48h EC_{50}): > 800 mg/L
- Freshwater Algae (72h EC_{50}): > 1000 mg/L12.2 Persistence and Degradability: Partially biodegradable (BOD_5 /COD = 0.35); the organic component is degraded by microorganisms in aquatic and soil environments within 30-40 days; aluminum oxide is inert and non-toxic in natural environment.12.3 Bioaccumulative Potential: None (insoluble in water and organic solvents, log P unavailable); no bioaccumulation in aquatic organisms and food chain.12.4 Mobility in Soil: Low mobility; strongly adsorbs to soil organic matter and mineral particles, no leaching risk to groundwater.12.5 PBT/vPvB Assessment: Not classified as PBT/vPvB substances.12.6 Other Adverse Effects: No known adverse effects on soil microorganisms and terrestrial plants at normal concentrations; high concentration may slightly inhibit the growth of aquatic beneficial bacteria (temporary, reversible).

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Expired/contaminated product is classified as **non-hazardous pharmaceutical waste**; can be disposed of by licensed waste treatment facilities via high-temperature incineration (≥800℃) or landfill (after solidification).
- Packaging Waste: Rinse packaging with water to remove residual powder, then dispose of as non-hazardous plastic waste; recycle clean and uncontaminated packaging.

- Unused Product: Can be reused if stored in compliance with conditions; do not discharge to the environment; dispose of in accordance with local pharmaceutical waste regulations if expired.
- Disposal Compliance: Comply with national and local pharmaceutical waste disposal regulations (e.g., China Pharmaceutical Waste Disposal Standard, EU EWC 070101, US RCRA Non-hazardous Waste).

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: 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 TransportTransport in sealed HDPE pharmaceutical-grade drums with plastic inner lining and sealed cover; affix product identification labels (mark pharmaceutical raw material/gastric mucosal protectant). Transport temperature ≤ 30℃; avoid direct sunlight, rain, collision, extrusion and rough handling during transport. Do not transport with strong acid/alkaline raw materials, food, feed and cosmetics; transport in a dedicated compartment of pharmaceutical raw material transport vehicles. Comply with international pharmaceutical raw material transport regulations; provide MSDS and COA for customs clearance; no special transport approval required (non-hazardous goods).

SECTION 15: Regulatory Information

15.1 National/International Regulations

- China: Pharmaceutical Raw Material Registration Requirements; Chinese Pharmacopoeia (CP) 2025 edition compliance; Non-hazardous Chemicals Classification (GB 30000).
- 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 raw material quality standards for oral gastrointestinal drugs); United States Pharmacopeia (USP) 47 compliance.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Non-hazardous Chemicals Control Law.15.2 Additional Regulatory RequirementsProvide English MSDS, COA and pharmaceutical raw material qualification documents for customs clearance; comply with GMP standards for pharmaceutical production use; mark gastric mucosal protectant, oral pharmaceutical 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: **Oral pharmaceutical raw material (gastric mucosal protectant), practically non-toxic, mild skin/eye irritation, non-hazardous for transport**.

- 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 regulations.

纳维盈医化科技
NEWAY SINOPHC TECH