

## Safety Data Sheet (MSDS)

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

**Product Name: Fosufloxacin Hydrochloride** Revision Date: 20 FEB 2026

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

#### 1.1 Product Identifiers

- Product Name: Fosufloxacin Hydrochloride
- Product Number: FH-20260220
- Brand: SIGALD
- CAS-No.: 112811-71-9
- Synonyms: (±)-7-[(2-Amino-4-thiazolyl)(methoxyimino)acetylamino]-3-fluoromethyl-3-cephem-4-carboxylic acid hydrochloride; Fosufloxacin HCl

#### 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 intermediate for cephalosporin antibacterial drugs; raw material for oral/injectable antibacterial formulations; pharmaceutical R&D reference reagent for antibacterial pharmacology research.
- Uses Advised Against: Not for direct human use in raw form; no non-pharmaceutical industrial use; avoid use in cosmetics/food products; do not use in unformulated antibacterial preparations for clinical use.

### SECTION 2: Hazards Identification

| Summary of Emergency Measures | White crystalline powder. Harmful if swallowed. Causes skin irritation and serious eye irritation. May cause respiratory irritation in sensitive individuals. After inhalation: Move to fresh air and rest. In case of skin contact: Rinse with plenty of water and soap for 10-15 minutes. After eye contact: Rinse with plenty of water for at least 15 minutes and call a doctor. After swallowing: Rinse mouth with water, do not induce vomiting; consult a doctor if unwell. Non-combustible. No explosion risk. | |---|

#### 2.1 GHS Classification

- Acute toxicity, oral (Category 4); Skin irritation (Category 2); Serious eye irritation (Category 2); Specific target organ toxicity - single exposure (Gastrointestinal system, Category 3); Specific target organ toxicity - single exposure (Ocular system, Category 3)

#### 2.2 GHS Label Elements

- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H315: Causes skin irritation
  - H319: Causes serious eye irritation
  - H335: May cause respiratory irritation
  - H373: May cause damage to organs (Gastrointestinal, Ocular) 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/face protection

- P301+P312: If swallowed: Call a POISON CENTER or doctor/physician if you feel unwell
  - 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
  - P405: Store locked up
  - P501: Dispose of contents/container to an approved waste disposal plant
- 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: Swallowing causes nausea, abdominal pain, diarrhea; skin contact leads to redness, itching and erythema; eye contact causes severe conjunctival redness and corneal irritation; dust inhalation causes cough, throat dryness in sensitive individuals.
  - Chronic: Prolonged exposure may cause mild gastrointestinal mucosal damage and ocular surface irritation, reversible with strict protective measures and symptomatic treatment.
- 2.5 Environmental Hazards

- Low acute toxicity to aquatic organisms (96h LC<sub>50</sub> = 420 mg/L for zebrafish); fully biodegradable in natural environment; low bioaccumulation potential with no persistent residues.
- 2.6 Other Hazards
- May cause mild photosensitivity in exposed personnel; avoid direct sunlight after skin contact with the powder.

### SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance** | 3.1 Main Components | Fosufloxacin Hydrochloride (100%) | --- | --- | Formula | C<sub>19</sub> H<sub>20</sub> FN<sub>3</sub>O<sub>6</sub> S · HCl | Molecular Weight | 457.90 g/mol | CAS-No.: | 112811-71-9 | EC-No.: | N/A | Hazardous Ingredients

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Component	Classification	Concentration (w/w)
Fosufloxacin Hydrochloride	GHS Category 4/2/2/3	100%

### SECTION 4: First Aid Measures

#### 4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately, keep at rest in a comfortable breathing position. If cough or throat irritation persists, call a POISON CENTER/doctor.
  - In Case of Skin Contact: Immediately remove all contaminated clothing and shoes. Rinse skin with plenty of running water and mild soap for 10-15 minutes. Seek medical advice if irritation/rash persists for more than 24 hours; avoid sunlight for 24 hours to prevent photosensitivity.
  - In Case of Eye Contact: **IMMEDIATE MEDICAL ATTENTION RECOMMENDED.** Hold eyelids open and rinse thoroughly with plenty of running water for at least 15 minutes. Remove contact lenses if present. Do not rub eyes. Call a POISON CENTER/ophthalmologist if irritation or blurred vision occurs.
  - If Swallowed: Rinse mouth with water. Do not induce vomiting unless directed by a doctor. Monitor gastrointestinal status (nausea, abdominal pain). Call a POISON CENTER/doctor immediately if severe gastrointestinal symptoms occur.
- 4.2 Most Important Symptoms and Effects
- Acute: Nausea, abdominal pain, diarrhea (swallowed); skin erythema, pruritus (contact); severe eye irritation, blurred vision (contact); cough, throat dryness (inhalation).

- Delayed: Mild gastrointestinal mucosal damage and ocular irritation may occur 24-48 hours after excessive exposure; mild photosensitivity rash may appear after sunlight exposure, reversible with treatment.
- 4.3 Indication of Immediate Medical Attention
- Severe swallowing exposure with persistent gastrointestinal symptoms, severe eye contact, prolonged respiratory irritation, photosensitivity reactions require **immediate professional medical attention**.

## SECTION 5: Firefighting Measures

### 5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO<sub>2</sub>), dry chemical powder.
- Unsuitable Extinguishing Media: No limitations of extinguishing agents.
- 5.2 Special Hazards Arising from the Substance
- Non-combustible; slight decomposition at high temperature (>270°C) produces low-toxic fluorinated, sulfur-containing and amine fumes; no toxic/explosive gases released under normal fire conditions.
- 5.3 Advice for Firefighters
- Wear self-contained breathing apparatus (SCBA) and full chemical-resistant fire-fighting protective gear if decomposition fumes occur during fire.
- Keep a safe distance from the fire scene; prevent fire-extinguishing water from entering municipal sewers or natural water bodies.

## SECTION 6: Accidental Release Measures

### 6.1 Personal Precautions

- Wear N95 dust mask, chemical-resistant nitrile gloves, safety goggles and impermeable lab coat. Ensure good ventilation at the spill site and evacuate all non-essential personnel.
- Avoid inhaling dust and prolonged contact with spilled powder; avoid direct sunlight after skin contact to prevent photosensitivity.
- 6.2 Environmental Precautions

- Prevent spilled powder from entering sewers, rivers, lakes or soil. Cover the spill with inert material (sand/vermiculite) to avoid dust spreading and 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 or vacuum the powder.
- Large Spill: Contain the spill with sandbags/dikes, transfer to a sealed HDPE drum with clear hazard labels, and hand over to a licensed hazardous waste treatment company. Do not wash the spill into drains or water bodies.
- 6.4 Reference to Other Sections For waste disposal, see Section 13.

## SECTION 7: Handling and Storage

### 7.1 Precautions for Safe Handling

- Operate 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; avoid direct sunlight for 24 hours after skin contact to prevent photosensitivity.
- Avoid contact with strong acids, strong bases, 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, dark and locked** pharmaceutical warehouse. Temperature ≤ 25°C, relative humidity ≤ 60%. Keep the container tightly sealed to prevent hygroscopy, light degradation and contamination.
- Incompatibilities: Strong bases (NaOH, KOH), oxidizing agents (H<sub>2</sub>O<sub>2</sub>, KMnO<sub>4</sub>), heavy metal salts, alkaline pharmaceutical excipients, metal ions (Fe<sup>3+</sup>, Al<sup>3+</sup>).

- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from all other pharmaceutical raw materials, food, feed and cosmetics; place in a dedicated toxic substance storage area with warning signs.

## SECTION 8: Exposure Controls/Personal Protection

### 8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal strict control limit: 0.06 mg/m<sup>3</sup> (8-hour TWA, dust) (due to gastrointestinal/ocular/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  $\leq$  0.02 mg/m<sup>3</sup>.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical-resistant safety goggles (mandatory for all operations); full face shield for large-scale handling.
  - Skin Protection: Chemical-resistant nitrile rubber gloves (thickness  $\geq$  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 Properties  
a) Physical State: Solid (crystalline powder)  
b) Color: White to off-white  
c) Odor: Practically odorless  
d) Melting Point/Freezing Point: 225-231 °C (decomposes slightly)  
e) Boiling Point: Not applicable (decomposes before boiling)  
f) Flammability: Non-combustible  
g) Flammability Limits: Not applicable  
h) Flash Point: Not applicable  
i) Autoignition Temperature:  $>$  450 °C  
j) Decomposition Temperature:  $\geq$  270 °C (mild decomposition, produces low-toxic fumes)  
k) pH Value: 3.5-5.5 (1% aqueous suspension, 25 °C)  
l) Viscosity: Not applicable (solid)  
m) Solubility: Freely soluble in water; soluble in methanol, ethanol; slightly soluble in acetonitrile; insoluble in chloroform, ethern  
n) Partition Coefficient (log P, n-octanol/water): 1.2 (25 °C)  
o) Vapor Pressure (25 °C):  $<$  0.0001 hPa  
p) Density (25 °C): 1.55-1.60 g/cm<sup>3</sup> (bulk density)  
q) Particle Size: 95% passing 100 mesh  
r) Explosive Properties: Not explosives  
s) Oxidizing Properties: Nonet  
t) Hygroscopy: Slightly hygroscopic, sensitive to light

## SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions ( $\leq$  25 °C, dry, dark, sealed); stable under standard pharmaceutical processing temperature ( $\leq$  60 °C).  
10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; mild hydrolysis may occur in moist and alkaline environment to produce non-toxic cephalosporin derivatives.  
10.3 Conditions to Avoid: High temperature ( $>$  270 °C), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock, alkaline environment.  
10.4 Incompatible Materials: Strong bases, oxidizing agents, heavy metal salts, reducing agents, alkaline pharmaceutical excipients, metal ions (Fe<sup>3+</sup>, Al<sup>3+</sup>).  
10.5 Hazardous Decomposition Products: Carbon dioxide, water vapor, low-toxic fluorinated, sulfur-containing and amine fumes (at high temperature complete combustion/decomposition); non-toxic fosfloxacin derivatives produced by alkaline hydrolysis.

## SECTION 11: Toxicological Information

### 11.1 Toxicological Effects

- Acute Toxicity (**cephalosporin antibacterial agent, broad-spectrum bactericidal**):
  - Oral (Rat, LD<sub>50</sub>): 1350 mg/kg (Harmful)

- Dermal (Rabbit, LD<sub>50</sub>): > 2000 mg/kg (Non-hazardous)
- Inhalation (Rat, LC<sub>50</sub>): 7.2 mg/m<sup>3</sup> (4-hour exposure, Harmful)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - moderate redness, edema and rash (Category 2), reversible within 7 days with treatment.
- Eye Irritation/Damage: Rabbit eye test - severe conjunctival redness and mild corneal opacity (Category 2), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild bronchial irritation, cough at low dust concentrations (≥0.40 mg/m<sup>3</sup>), 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 clinical relevant doses; use with caution in pregnant women under clinical monitoring.
- Specific Target Organ Toxicity: **Gastrointestinal and ocular systems** are the main target organs; mild irritation at clinical doses; no damage to other organs with standard protective measures; mild photosensitivity in animal tests (high-dose long-term exposure).
- Allergenicity: No significant sensitizing effects in animal tests and clinical data.

## SECTION 12: Ecological Information

### 12.1 Toxicity

- Fish (Zebrafish, 96h LC<sub>50</sub>): 420 mg/L
- Daphnia (48h EC<sub>50</sub>): 400 mg/L
- Freshwater Algae (72h EC<sub>50</sub>): 440 mg/L
- 12.2 Persistence and Degradability: Biodegradable (BOD<sub>5</sub>/COD = 0.65); degraded by microorganisms in aquatic and soil environments within 18-25 days, no persistent residues.
- 12.3 Bioaccumulative Potential: Low (log P = 1.2); no significant bioaccumulation in aquatic organisms and food chain.
- 12.4 Mobility in Soil: Low mobility; strongly adsorbs to soil organic matter (K<sub>oc</sub> = 550), 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 low concentrations; high concentration may inhibit the growth of aquatic beneficial bacteria (temporary, reversible).

## SECTION 13: Disposal Considerations

### 13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is classified as **toxic hazardous waste**; must be disposed of by licensed hazardous waste treatment facilities via high-temperature incineration (≥800°C) with flue gas treatment (to remove fluorinated, sulfur-containing and amine fumes).
- Packaging Waste: Rinse packaging with water and ethanol to remove residual powder, then dispose of as toxic hazardous waste; do not recycle or reuse any contaminated packaging.
- Unused Product: Do not discharge to the environment; incinerate with professional waste treatment companies in accordance with local national and international toxic waste regulations.
- Disposal Compliance: Comply with national and local hazardous waste disposal regulations (e.g., China HW02, EU EWC 080102, US RCRA Subtitle C).

## SECTION 14: Transport Information

- 14.1 UN Number: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 2811
- 14.2 UN Proper Shipping Name: Toxic solid, organic, n.o.s. (Fosufloxacin Hydrochloride)
- 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 Transport
- Transport in sealed HDPE pharmaceutical-grade drums with aluminum foil inner lining and locked cover; affix standard Class 6.1 toxic hazard labels and product identification labels (mark cephalosporin/antibacterial/photosensitivity risk warning).



## NEWAY SINOPHC TECH. LIMITED

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- Transport temperature  $\leq 30^{\circ}\text{C}$ ; avoid direct sunlight, rain, collision, extrusion and rough handling during transport (light protection mandatory).
- Do not transport with food, feed, cosmetics, aquatic products and alkaline pharmaceutical raw materials; transport in a dedicated compartment of specialized hazardous chemical vehicles.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations for Class 6.1 toxic substances; provide MSDS and 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 chemical); Pharmaceutical Raw Material Registration Requirements for medical intermediates; Chinese Pharmacopoeia (CP) 2025 edition compliance; Special Control of Toxic Chemicals Regulations.
  - EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Warning); European Pharmacopoeia (EP) 10.0 compliance; ADR/RID Class 6.1 transport regulations.
  - US: TSCA (listed on the TSCA Inventory); DOT Class 6.1 toxic material; FDA (compliant with pharmaceutical intermediate quality standards for antibacterial agents); United States Pharmacopoeia (USP) 47 compliance; RCRA toxic waste regulations.
  - Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Japanese Poisonous and Deleterious Substances Control Law.
- #### 15.2 Additional Regulatory Requirements
- Provide English MSDS, COA and toxic chemical transport approval documents for customs clearance; apply for a special hazardous chemical storage license for on-site storage; provide product quality test reports and pharmacopoeia compliance certificates for pharmaceutical production use; mark cephalosporin antibacterial, photosensitivity and irritant 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: **broad-spectrum cephalosporin antibacterial agent, mild gastrointestinal/ocular irritation, photosensitivity risk, low environmental toxicity.**
- Revision Date: 20 FEB 2026