



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
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Safety Data Sheet (MSDS) - Ofloxacin

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0 **Product Name:** Ofloxacin **CAS Number:** 82419-36-1 **Product Number:** OF-20260225 **Brand:** SIGALD **Revision Date:** 25 FEB 2026 **Supplier:** NEWAY SINOPHC TECH. LIMITED **Address:** RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE **Telephone/Fax:** +86-021-50350029 **Emergency Telephone:** +86-021-50350029 (24h Pharmaceutical Raw Material Emergency Response)

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

1.1 Product Identifiers

- Product Name: Ofloxacin
- CAS-No.: 82419-36-1
- MDL No.: MFCD00079626
- Synonyms: (±)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid; Floxin
- Product Number: OF-20260225

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses:** Pharmaceutical raw material for the production of clinical antibacterial preparations (oral, injectable, topical) (only for licensed pharmaceutical enterprises).
- **Uses Advised Against:** Non-pharmaceutical use, direct clinical administration (raw material only), household use, unauthorized processing/sale, use in food/cosmetic production, and unlicensed clinical use.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 4)
- Acute toxicity, dermal (Category 5)
- Acute toxicity, inhalation (dust/mist, Category 4)
- Serious eye irritation (Category 2)
- Skin irritation (Category 2)
- Specific target organ toxicity - single exposure (central nervous system, gastrointestinal tract, Category 2)
- Specific target organ toxicity - repeated exposure (liver/kidney, Category 2)
- Aquatic toxicity, chronic (Category 2)

2.2 GHS Label Elements

- **Hazard Pictograms:** Exclamation mark (!)
- **Signal Word:** Warning
- **Hazard Statements:**
 - H302: Harmful if swallowed
 - H313: May be harmful in contact with skin
 - H332: May be harmful if inhaled
 - H315: Causes skin irritation
 - H319: Causes serious eye irritation
 - H371: May cause damage to organs (CNS, gastrointestinal tract) through single exposure
 - H372: May cause damage to organs (liver, kidney) through prolonged or repeated exposure
 - H411: Toxic to aquatic life with long-lasting effects
- **Precautionary Statements:**
 - P260: Do not breathe dust/fume/gas/mist/vapors/spray
 - P270: Do not eat, drink or smoke when using this product
 - P280: Wear protective gloves/eye protection/face protection/respiratory protection
 - P301+P312: If swallowed: Call a POISON CENTER/doctor if you feel unwell
 - P302+P352: If on skin: Wash with plenty of soap and water
 - 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/doctor if you feel unwell
 - P405: Store locked up
 - P501: Dispose of contents/container in accordance with local/national/international regulations

2.3-2.6 Hazards Summary



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- **Physical/Chemical Hazards:** Non-flammable, non-explosive, non-oxidizing under normal use; stable at recommended storage temperature (2~8°C), degraded by strong light/heat/alkali to produce inactive fluorinated derivatives, no hazardous gas release.
- **Health Hazards:** Inhalation/skin contact/swallowing causes skin/eye irritation, gastrointestinal discomfort and mild central nervous system reactions; long-term exposure leads to cumulative liver and kidney function damage; oral ingestion has moderate acute toxicity.
- **Environmental Hazards:** Toxic to aquatic organisms with long-lasting adverse effects; poorly biodegradable in water bodies with certain bioaccumulation potential in the aquatic food chain.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture:** Pure pharmaceutical grade substance (100% w/w)
- **Active Ingredient:** Ofloxacin (CAS:82419-36-1) | Hazard classification: see Section 2
- **No other ingredients/additives**

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- **Inhaled:** Immediately remove victim to fresh air; keep respiratory tract open. If breathing is difficult, give oxygen; **call a poison center/physician if discomfort persists.** Monitor for dizziness, headache and other CNS symptoms, and provide symptomatic treatment.
- **Skin Contact:** Immediately remove contaminated clothing and shoes; rinse skin with plenty of soap and running water for 15-20 minutes. **Apply mild emollient if irritation occurs;** monitor for systemic absorption and liver/kidney function if contact is extensive.
- **Eye Contact:** Immediately rinse eyes thoroughly with plenty of sterile water for injection for 15-20 minutes (lift upper/lower eyelids); remove contact lenses if worn. **Consult an ophthalmologist immediately;** continue to monitor eye redness, swelling and vision until symptoms disappear.
- **Swallowed:** Do not induce vomiting; rinse mouth with water. **Call a poison center/doctor at once;** perform gastric lavage under medical supervision if necessary; check liver/kidney function indicators (ALT/AST, creatinine) and provide gastrointestinal and organ protective treatment.

4.2 Most Important Symptoms

Acute: Dizziness, headache, nausea, vomiting, abdominal pain, skin redness/erythema, eye redness/tearing and blurred vision; severe oral ingestion causes convulsions and abnormal liver/kidney function. Delayed: Cumulative liver/kidney function damage, persistent elevation of transaminase, chronic skin irritation, recurrent conjunctivitis (long-term exposure).

4.3 Medical Attention

Inform the physician of the product name (Ofloxacin) and CAS number; emphasize the **CNS/organ damage and local irritation risk;** conduct liver/kidney function and blood routine tests regularly for at least 1 month after exposure; administer symptomatic and organ protective treatment for abnormal indicators.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable:** Dry powder, carbon dioxide (CO₂), foam; water spray (for cooling fire-exposed containers).
- **Unsuitable:** Direct high-pressure water on bulk powder (to prevent dust spread and inhalation by firefighters).

5.2 Special Hazards

Thermal decomposition at high temperature (>260°C) produces toxic and corrosive substances including carbon monoxide (CO), nitrogen oxides (NO_x), hydrogen fluoride (HF) and pyridine derivatives; combustion fumes have strong acute toxicity and corrosivity.

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and full chemical protective gear (acid-resistant); fight fire from upwind; cool containers with water spray until fire is out; prevent fire water from entering water bodies/soil (avoid environmental contamination); collect and dispose of fire debris as hazardous pharmaceutical waste.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions



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- Wear full level C PPE (nitrile rubber gloves, chemical safety goggles, full face shield, N95+ respirator, impermeable protective clothing); avoid any contact with spilled material (even trace amounts).
- Evacuate all non-essential personnel to a safe distance (at least 30 meters); set up a restricted warning zone with obvious hazard signs; operate in a well-ventilated area with negative pressure dust collection and light-proof facilities.

6.2 Environmental Precautions

Prevent spilled powder/leachate from entering sewers, rivers, lakes, soil and groundwater; use inert absorbents (sand/diatomite) to cover and contain spilled material to avoid aquatic organism poisoning and environmental contamination; do not flush with water directly.

6.3 Containment and Cleaning Up

- **Small Spill:** Cover with inert absorbent (sand/diatomite); collect into a sealed GMP-compliant hazardous waste container with a clear hazard label; dispose of by licensed hazardous waste treatment enterprises.
- **Large Spill:** Contain with acid-resistant dikes; collect with an anti-static vacuum cleaner into a sealed stainless steel drum; seal and mark the drum with hazard information (toxic, corrosive); do not store with other materials; dispose of by professional hazardous waste treatment teams.
- Do not reuse contaminated absorbents; do not wash spilled material into drainage systems; decontaminate the spill area with neutral detergent and rinse with a small amount of water; collect the rinse water for hazardous waste treatment.

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate only in GMP-certified workshops by trained pharmaceutical production personnel; set up a dedicated, closed operation area with negative pressure dust collection and light-proof facilities.
- Use closed feeding and mixing equipment to avoid dust generation/inhalation; no manual direct contact with the product (even with gloves).
- Do not eat, drink or smoke during handling; wash hands/face thoroughly with soap and water for at least 5 minutes after operation; take a shower if the body is contaminated.
- Avoid contact with strong acids, strong bases, oxidizing agents and high temperature (>25°C) to prevent degradation and toxic by-product generation; record all operation processes in detail for traceability.

7.2 Safe Storage

- **Storage Conditions:** 2 ~ 8°C (refrigerated, dark place); nitrogen-filled tight sealing in brown glass/stainless steel containers; relative humidity ≤60%.
- **Incompatibilities:** Strong acids (pH<3), strong bases (pH>9), oxidizing agents (H₂O₂, KMnO₄), heavy metal salts (Fe³⁺, Cu²⁺), photosensitizers, strong reducing agents.
- **Storage Class:** Hazardous pharmaceutical raw material (locked storage in a dedicated, temperature-controlled pharmaceutical warehouse with light-proof and acid-resistant facilities, separate from other raw materials).
- **Shelf Life:** 24 months (unopened, nitrogen-filled, under specified storage conditions); 6 months after opening (sealed, refrigerated, and used up as soon as possible with strict record).

SECTION 8: Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits

- **OEL (China):** 2 mg/m³ (8h TWA)
- **OEL (US OSHA):** 5 mg/m³ (8h TWA)
- Biological limit: Monitor liver/kidney function indicators (ALT/AST, creatinine) and blood routine for operators; no specific biological exposure limit established.

8.2 Exposure Controls

- **Engineering Controls:** Closed operation system, negative pressure dust collection (air exchange rate ≥ 15 times/h), local exhaust ventilation, GMP workshop air filtration (HEPA filter), light-proof operation facilities; set up acid-resistant drainage and waste collection systems.
- **Personal Protective Equipment (PPE):**
 - Eye/Face: Chemical safety goggles + full acid-resistant face shield (mandatory for all operations)
 - Skin: Nitrile rubber gloves (thickness ≥0.18mm) + impermeable/acid-resistant protective clothing + anti-static shoes

- Respiratory: N95 respirator + organic vapor/acid gas cartridge (for normal operation); SCBA (for emergency spills/leaks)
- Other: Disposable hairnet/mask/gown, hand washing station with emergency eye wash/shower equipment (within 5 meters of operation area).
- **Hygiene:** Dedicated changing room for work clothes (separate from daily clothes); no food/drinks in the operation area; regular occupational health checkups (quarterly) including liver/kidney function, blood routine and ophthalmic examination.

SECTION 9: Physical and Chemical Properties

表格

Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	250 ~ 255°C (decomposition)
Boiling Point	Decomposes before boiling (>260°C)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>350°C
Solubility	Sparingly soluble in water; freely soluble in glacial acetic acid/DMSO; soluble in methanol/ethanol
pH Value (0.1% aqueous suspension, 25°C)	6.0 ~ 8.0
Density (25°C, solid)	1.46 g/cm ³
Vapor Pressure (25°C)	<0.0001 hPa (negligible)
Particle Size	95% pass through 100-mesh sieve (pharmaceutical grade)
Refractive Index (25°C, 1% in glacial acetic acid)	1.578 ~ 1.582
Stability	Stable at 2~8°C (dark, nitrogen-filled); degraded by strong light/heat/alkali
Decomposition Temperature	>260°C (toxic fluorinated derivatives generated)
Viscosity	Not applicable (solid)
Flammability	Non-flammable

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended storage conditions (2~8°C, dark, nitrogen-filled, sealed)**; no degradation for the shelf life and good compatibility with common pharmaceutical excipients for oral, injectable and topical formulations.

10.2-10.5 Reactivity Summary

- No hazardous reactions under normal use/handling conditions (with strict protection).
- **Conditions to Avoid:** High temperature (>25°C), direct strong light, moisture, contact with strong acids/alkalis/oxidizing agents/heavy metal ions, air exposure (oxidation).
- **Incompatible Materials:** Concentrated HCl/H₂SO₄, NaOH/KOH, hydrogen peroxide, potassium permanganate, iron(III) chloride, copper sulfate, photosensitizers.
- **Hazardous Decomposition Products:** Carbon monoxide (CO), nitrogen oxides (NO_x), hydrogen fluoride (HF), pyridine and benzoxazine derivatives (at >260°C); photodegradation products (inactive and slightly toxic) under strong light.
- No polymerization under normal storage and use conditions.

SECTION 11: Toxicological Information

11.1 Key Toxicological Data

- **Acute Toxicity:**
 - Oral (Rat, LD₅₀): 1450 mg/kg bw
 - Dermal (Rabbit, LD₅₀): >2000 mg/kg bw
 - Inhalation (Rat, LC₅₀, 4h): 3.2 mg/m³ (dust)
- **Skin Irritation (Rabbit):** Moderate irritation (4h exposure, erythema and edema; reversible within 72h)
- **Eye Irritation (Rabbit):** Severe irritation (24h exposure, conjunctivitis, corneal damage and blurred vision; reversible within 7 days)



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- **Sensitization:** No skin/respiratory sensitization (Guinea pig test)
- **Carcinogenicity:** IARC Class 3 (Not classifiable as to its carcinogenicity to humans)
- **Reproductive Toxicity:** No obvious teratogenic/fertility damage effects at clinical relevant doses (rat/mouse tests); high doses may cause mild fetal growth retardation and bone development abnormalities.
- **Target Organ Toxicity:** Central nervous system (dizziness, convulsions), gastrointestinal tract (irritation), liver/kidney (cumulative damage), skin/eye (local irritation); no other organ toxicity at occupational exposure levels.

11.2 Toxicity Summary

Ofloxacin's main toxic effects are **skin/eye severe irritation** from direct contact, **gastrointestinal and central nervous system reactions** from oral ingestion/inhalation, and **cumulative liver/kidney function damage** from long-term exposure; the toxic effects are reversible with symptomatic and organ protective treatment at occupational exposure levels with proper protection. It has low acute dermal toxicity and moderate acute oral/inhalation toxicity, no confirmed carcinogenicity to humans, and mild reproductive toxicity only at high doses.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC₅₀, 96h): 9.8 mg/L
- Daphnia (EC₅₀, 48h): 5.6 mg/L
- Algae (EC₅₀, 72h): 12.5 mg/L
- **Conclusion:** Toxic to aquatic organisms (especially invertebrates); fatal to aquatic life at low concentrations with long-lasting adverse effects.

12.2-12.7 Ecological Properties

- **Persistence/Degradability:** Poorly biodegradable (BOD₅/COD = 0.05~0.15) in aquatic environments; remains stable in water for more than 6 months.
- **Bioaccumulative Potential:** Moderate to high (log Kow=0.78; bioaccumulation factor (BAF) = 800~1200 in fish); obvious biomagnification in the aquatic food chain.
- **Mobility in Soil:** Moderate (partial leaching to groundwater; persistent in soil for more than 12 months).
- **PBT/vPvB:** Classified as vP (very Persistent) and T (Toxic) to aquatic organisms.
- **Other Adverse Effects:** Inhibits the growth and reproduction of aquatic microorganisms and plankton; causes liver/kidney damage to aquatic vertebrates (similar to human toxic effects); no eutrophication risk.

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- **Product Waste:** Classified as **hazardous pharmaceutical waste** and **toxic/fluorinated chemical waste**; dispose of only by **licensed hazardous waste treatment enterprises** (incineration at >1200°C with acid gas purification treatment to remove HF and NO_x).
- **Packaging Waste:** Rinse packaging with ethanol (3 times) under nitrogen protection; collect the rinse solution and incinerate with the product waste; decontaminate the clean packaging with neutral detergent and dispose of as hazardous waste (no recycling, no secondary use).
- **Do not dispose of with household waste, general industrial waste or medical waste;** do not discharge into sewers/rivers/soil/groundwater (strictly prohibited by environmental protection and drug regulatory laws).

13.2 Disposal Regulations

Comply with China's **Hazardous Waste Pollution Control Law, Pharmaceutical Waste Disposal Standards** and EU **REACH/WEEE** regulations; strictly follow the national toxic/fluorinated chemical waste disposal procedures with complete account records and double signature confirmation; the incineration process must meet the national acid gas emission standards.

SECTION 14: Transport Information

14.1-14.7 Transport Details

- **UN Number:** UN 2811 (Toxic solid, organic, n.o.s.)
- **UN Proper Shipping Name:** Ofloxacin (toxic pharmaceutical raw material, fluorinated solid)
- **Transport Hazard Class:** 6.1 (Toxic substances, Category 4)
- **Packaging Group:** II (Dangerous)
- **Marine Pollutant:** Yes (P)

- **Special Transport Requirements:**

1. Transport with **hazardous chemical transport license** issued by emergency management department; use temperature-controlled refrigerated transport vehicles (2~8°C) with real-time temperature monitoring and light-proof facilities.
 2. Use sealed, light-proof, shockproof and acid-resistant packaging (brown glass/stainless steel); mark obvious hazard signs (toxic, environmental hazard, corrosive) on the package.
 3. Load/unload gently; avoid package damage and collision; store separately from food, feed, strong acids/alkalis, oxidizing agents and other drugs in the transport vehicle; no mixed transport with other hazardous goods (especially acid/alkali materials).
 4. The transport vehicle is equipped with fire-fighting equipment, acid-resistant emergency spill treatment materials and full personal protective equipment; the driver and escort have professional hazardous chemical transport qualification certificates and first-aid training.
- **International Transport:** Comply with IATA/IMDG/ADR regulations for Class 6.1 toxic substances; apply for international hazardous chemical transport approval in advance; declare the fluorinated and toxic characteristics to the customs and transport department.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China:**

- Pharmaceutical Administration Law (pharmaceutical raw material for clinical antibacterial use; subject to national antimicrobial drug management regulations)
- Hazardous Chemical Safety Management Regulation (Class 6.1 toxic substance, fluorinated chemical)
- Chinese Pharmacopoeia (2025 Edition)
- GMP for Pharmaceutical Raw Materials (strict implementation standards)
- Occupational Disease Prevention and Control Law (special occupational protection for operators)
- Water Pollution Prevention and Control Law (strict restriction on environmental discharge)

- **International:**

- GHS Rev.9 (hazard classification: Category 4 acute toxicity, Category 2 target organ toxicity)
- USP 45 / EP 10.0 (pharmacopoeial standards for clinical antibacterial use)
- REACH (EU) (registered; listed in SVHC Candidate List due to aquatic toxicity and fluorinated characteristics)
- TSCA (US) (listed on the TSCA Inventory with strict use and environmental discharge restrictions)
- IATA/IMDG/ADR (Class 6.1 toxic substances transport regulations)

15.2 Other Requirements

- Production/sale/use limited to **licensed pharmaceutical enterprises** with GMP certification; production and operation must comply with national antimicrobial drug management regulations and fluorinated chemical management requirements.
- Occupational operation requires professional hazardous chemical (fluorinated) and pharmaceutical production training and certification; operators must pass regular occupational health checkups (focus on liver/kidney function, ophthalmic and respiratory system), and be transferred from the post if abnormal indicators are found.
- The whole process (production, storage, transport, use, waste disposal) is subject to joint supervision by drug regulatory, emergency management, environmental protection and chemical industry departments; complete traceability account management is required with no missing records.

SECTION 16: Other Information

- **MSDS Validity:** This MSDS is valid for 3 years from the revision date (25 FEB 2026) unless the product formula or hazard information changes.
- **Disclaimer:** This MSDS is based on current scientific and technical knowledge and complies with national and international relevant standards; the supplier is not liable for any damage caused by improper use, non-compliance with safety precautions or unauthorized handling of the product.
- **Additional Information:** For more technical/formulation data (only for clinical antibacterial preparations), contact the supplier's technical department (+86-021-50350029 ext. 817) (only for licensed pharmaceutical enterprises).



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- **Key Reminder:** This product is a **toxic fluorinated pharmaceutical raw material with aquatic toxicity and organ damage risk**; any illegal production/sale/use/transport/disposal will be subject to severe legal liability in accordance with national and international laws.



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