

Safety Data Sheet (MSDS) - Fusidic Acid

According to: GB/T 16483, GB/T 17519, GHS Rev.9, EP 10.0, USP 45
Product Name: Fusidic Acid
CAS Number: 18592-40-0
Product Number: FA-20260222
Brand: SIGALD
Revision Date: 22 FEB 2026
Supplier: NEWAY SINOPHC TECH. LIMITED
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SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifiers

- Product Name: Fusidic Acid
- CAS-No.: 18592-40-0
- MDL No.: MFCD00072524
- Synonyms: (16 α ,17 β)-17-Hydroxy-16-methyl-3-oxo-4,17-androstadien-16-yl acetate; Fusidin
- Product Number: FA-20260222

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses:** Pharmaceutical raw material for the production of clinical topical antibacterial preparations (skin, soft tissue, ocular) (only for licensed pharmaceutical enterprises).
- **Uses Advised Against:** Systemic clinical administration (oral/injection), non-pharmaceutical use, 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)
- Specific target organ toxicity - single exposure (liver, Category 2)
- Specific target organ toxicity - repeated exposure (liver, Category 2)
- Skin irritation (Category 2)
- Serious eye irritation (Category 2)
- Aquatic toxicity, chronic (Category 3)

2.2 GHS Label Elements

- **Hazard Pictograms:** Health Hazard (), 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
 - H371: May cause damage to organs (liver) through single exposure
 - H372: May cause damage to organs (liver) through prolonged or repeated exposure
 - H315: Causes skin irritation
 - H319: Causes serious eye irritation
 - H412: Harmful 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

- **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 with inactive by-products.



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- **Health Hazards:** Inhalation/skin contact/swallowing may cause mild to moderate liver function damage; oral ingestion has acute toxicity; skin/eye contact causes irritation; long-term exposure leads to cumulative liver damage.
- **Environmental Hazards:** Harmful to aquatic organisms with long-lasting adverse effects; poorly biodegradable in water bodies with certain bioaccumulation potential in the food chain.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture:** Pure pharmaceutical grade substance (100% w/w)
- **Active Ingredient:** Fusidic Acid (CAS:18592-40-0) | 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 liver function indicators 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 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 for systemic toxic effects and liver function.
- **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 function indicators (ALT/AST) and provide liver protective supportive treatment.

4.2 Most Important Symptoms

Acute: Dizziness, nausea, vomiting, abdominal pain, skin redness/irritation, eye redness/tearing, mild elevation of liver function indicators; severe oral ingestion causes obvious liver damage. Delayed: Cumulative liver 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 (Fusidic Acid) and CAS number; emphasize the **liver damage risk**; conduct liver function tests regularly for at least 1 month after exposure; administer liver protective drugs as needed 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 (>250°C) produces small amounts of carbon monoxide (CO), carbon dioxide (CO₂) and steroid derivatives; no toxic hazardous combustion products generated.

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and full chemical protective gear; 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

- 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.
- Evacuate all non-essential personnel to a safe distance (at least 20 meters); set up a restricted warning zone with obvious hazard signs; operate in a well-ventilated area with negative pressure dust collection.

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.

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 dikes; collect with an anti-static vacuum cleaner into a sealed stainless steel drum; seal and mark the drum with hazard information; 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 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; minimize manual direct contact with the product.
- 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; 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⁺), strong light and high temperature.
- **Storage Class:** Hazardous pharmaceutical raw material (locked storage in a dedicated, temperature-controlled pharmaceutical warehouse with light-proof facilities, separate from other raw materials).
- **Shelf Life:** 24 months (unopened, nitrogen-filled, 2~8°C refrigeration); 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 (EU):** 1 mg/m³ (8h TWA)
- **OEL (China):** 2 mg/m³ (8h TWA)
- **Biological limit:** Monitor liver function indicators (ALT/AST) for operators; no specific biological exposure limit established.

8.2 Exposure Controls

- **Engineering Controls:** Closed operation system, negative pressure dust collection (air exchange rate ≥ 12 times/h), local exhaust ventilation, GMP workshop air filtration (HEPA filter), light-proof operation facilities.
- **Personal Protective Equipment (PPE):**
 - Eye/Face: Chemical safety goggles + full face shield (mandatory for all operations)
 - Skin: Nitrile rubber gloves (thickness ≥0.18mm) + impermeable protective clothing + anti-static shoes
 - Respiratory: N95 respirator (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 function tests.

SECTION 9: Physical and Chemical Properties

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Property

Value

Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	190 ~ 194°C
Boiling Point	Decomposes before boiling (>250°C)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>350°C
Solubility	Practically insoluble in water; freely soluble in ethanol/methanol/acetone; soluble in DMSO
pH Value (1% aqueous suspension, 25°C)	5.0 ~ 7.0
Density (25°C, solid)	1.19 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% ethanol solution)	1.542 ~ 1.546
Stability	Stable at 2~8°C (dark, nitrogen-filled); degraded by strong light/heat/alkali
Decomposition Temperature	>250°C (inactive steroid derivatives generated)

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 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.
- **Hazardous Decomposition Products:** Carbon monoxide (CO), carbon dioxide (CO₂), inactive steroid derivatives (at >250°C); photodegradation products (inactive) 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): 2300 mg/kg bw
 - Dermal (Rabbit, LD₅₀): >5000 mg/kg bw
 - Inhalation (Rat, LC₅₀, 4h): 3.5 mg/m³ (dust)
- **Skin Irritation (Rabbit):** Moderate irritation (4h exposure, erythema and slight edema; reversible within 48h)
- **Eye Irritation (Rabbit):** Severe irritation (24h exposure, conjunctivitis and corneal redness; reversible within 72h)
- **Sensitization:** No skin/respiratory sensitization (Guinea pig test)
- **Carcinogenicity:** IARC Class 3 (Not classifiable as to its carcinogenicity to humans)
- **Reproductive Toxicity:** No teratogenic/fertility damage effects at clinical relevant doses (rat/mouse tests); high doses may cause mild fetal growth retardation.
- **Target Organ Toxicity:** Liver (mild to moderate function damage), skin/eye (irritation); no other organ toxicity at occupational exposure levels.

11.2 Toxicity Summary

Fusidic Acid's main toxic effect is **liver function damage** caused by oral ingestion or large-scale skin/inhalation exposure; the damage is reversible with symptomatic treatment in mild to moderate cases. Local effects include moderate skin irritation and serious eye irritation. No carcinogenicity or obvious reproductive toxicity at occupational exposure levels with proper protection; all acute effects are reversible with timely intervention and supportive treatment.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC₅₀, 96h): 32 mg/L
- Daphnia (EC₅₀, 48h): 18 mg/L
- Algae (EC₅₀, 72h): 45 mg/L
- **Conclusion:** Harmful to aquatic organisms; fatal to aquatic invertebrates at low concentrations with long-lasting adverse effects.

12.2-12.7 Ecological Properties

- **Persistence/Degradability:** Poorly biodegradable (BOD₅/COD = 0.15~0.25) in aquatic environments; remains stable in water for more than 4 months.
- **Bioaccumulative Potential:** Moderate (log Kow=4.8; bioaccumulation factor (BAF) = 400~600 in fish); certain biomagnification in the aquatic food chain.
- **Mobility in Soil:** Low (strongly adsorbs to soil organic matter; no leaching to groundwater)
- **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; no eutrophication risk.

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- **Product Waste:** Classified as **hazardous pharmaceutical waste** and **toxic chemical waste**; dispose of only by **licensed hazardous waste treatment enterprises** (incineration at >1000°C with flue gas purification treatment).
- **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 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 chemical waste disposal procedures with complete account records and double signature confirmation.

SECTION 14: Transport Information

14.1-14.7 Transport Details

- **UN Number:** UN 3077 (Environmentally hazardous substance, solid, n.o.s.)
- **UN Proper Shipping Name:** Fusidic Acid (toxic pharmaceutical raw material, solid)
- **Transport Hazard Class:** 9 (Miscellaneous dangerous goods) + 6.1 (Toxic substances)
- **Packaging Group:** III
- **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.
 2. Use sealed, light-proof, shockproof and moisture-proof packaging (brown glass/stainless steel); mark obvious hazard signs (toxic, environmental hazard) on the package.
 3. Load/unload gently; avoid package damage; store separately from food, feed, strong acids/alkalis, oxidizing agents and other drugs in the transport vehicle; no mixed transport with other hazardous goods.
 4. The transport vehicle is equipped with fire-fighting equipment, emergency spill treatment materials and 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 9 and 6.1 toxic substances; apply for international hazardous chemical transport approval in advance; declare the hazard characteristics to the customs and transport department.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China:**
 - Pharmaceutical Administration Law (pharmaceutical raw material for topical use only)

- Hazardous Chemical Safety Management Regulation (Class 6.1 toxic substance, Class 9 miscellaneous dangerous goods)
- Chinese Pharmacopoeia (2025 Edition)
- GMP for Pharmaceutical Raw Materials (strict implementation standards)
- Occupational Disease Prevention and Control Law (special occupational protection for operators)
- **International:**
 - GHS Rev.9 (hazard classification: Category 2 target organ toxicity)
 - EP 10.0 / USP 45 (pharmacopoeial standards, topical use only)
 - REACH (EU) (registered; listed in SVHC Candidate List due to aquatic toxicity)
 - TSCA (US) (listed on the TSCA Inventory with use restrictions)
 - IATA/IMDG/ADR (Class 9 + 6.1 transport regulations)

15.2 Other Requirements

- Production/sale/use limited to **licensed pharmaceutical enterprises** with GMP certification; systemic administration (oral/injection) is not recommended due to liver damage risk.
- Occupational operation requires professional hazardous chemical and pharmaceutical production training and certification; operators must pass regular liver function tests, and be transferred from the post if abnormal indicators are found.
- The whole process (production, storage, transport, use, waste disposal) is subject to supervision by drug regulatory, emergency management and environmental protection 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 (22 FEB 2026) unless the product formula or hazard information changes.
- **Disclaimer:** This MSDS is based on current scientific and technical knowledge; the supplier is not liable for any damage caused by improper use, non-compliance with regulations, or unauthorized handling of the product.
- **Additional Information:** For more technical/formulation data (only for topical formulations), contact the supplier's technical department (+86-021-50350029 ext. 815) (only for licensed pharmaceutical enterprises).
- **Key Reminder:** This product is a **pharmaceutical raw material with liver damage risk and aquatic toxicity**; any illegal production/sale/use/transport/disposal will be subject to legal liability in accordance with national and international laws.