Safety Data Sheet (MSDS) - Finerenone

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0**Product Name**: Finerenone**CAS Number**: 1050477-31-0**Product Number**: FIN-20260229**Brand**: SIGALD**Revision Date**: 29 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: Finerenone
- CAS-No.: 1050477-31-0
- MDL No.: MFCD22456815
- Synonyms: (2S)-4-[(3S)-3-cyano-3-phenylpropyl]-2-fluoro-N-[(2S)-2-methyl-1-oxo-3-phenylpropyl]-N-(trifluoromethylsulfonyl)benzamide; Nonsteroidal mineralocorticoid receptor antagonist
- Product Number: FIN-20260229

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses**: Pharmaceutical raw material for the production of clinical oral preparations for chronic kidney disease (type 2 diabetes-associated) and chronic heart failure (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)
- Skin irritation (Category 2)
- Serious eye irritation (Category 2)
- Specific target organ toxicity - single exposure (gastrointestinal tract, renal system, Category 2)
- Aquatic toxicity, chronic (Category 3)

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
  - H373: May cause damage to organs (gastrointestinal tract, renal system) through prolonged or repeated exposure
  - 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.
  - 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℃), degraded by strong light/heat/acid to produce inactive aromatic derivatives, no hazardous gas release.
- **Health Hazards**: Inhalation/skin contact causes skin/eye irritation; oral ingestion leads to mild gastrointestinal discomfort (nausea, diarrhea) and potential renal system disturbance (hyperkalemia); long-term exposure leads to cumulative damage to gastrointestinal and renal systems; no acute severe organ toxicity at occupational exposure levels with proper protection.
- **Environmental Hazards**: Harmful to aquatic organisms with long-lasting adverse effects; poorly biodegradable in water bodies with low bioaccumulation potential in the aquatic food chain.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture**: Pure pharmaceutical grade substance (100% w/w)
- **Active Ingredient**: Finerenone (CAS:1050477-31-0) | 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 cough, dizziness or fatigue persists**. Monitor for renal and gastrointestinal symptoms, and provide symptomatic treatment.
- **Skin Contact**: Immediately remove contaminated clothing and shoes; rinse skin with plenty of running water and soap for 15-20 minutes. **Apply mild anti-irritant ointment if redness/rash/itching occurs**; monitor for systemic absorption 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** even if no irritation is felt initially.
- **Swallowed**: Do not induce vomiting; rinse mouth with water. **Call a poison center/doctor at once**; check serum potassium, renal function indicators under medical supervision; provide gastrointestinal protective, potassium-lowering and symptomatic treatment, no specific antidote available.

4.2 Most Important Symptoms

Acute: Severe eye redness, tearing, blurred vision; skin redness/erythema; nausea, abdominal pain, diarrhea (oral ingestion); hyperkalemia (muscle weakness, arrhythmia); cough (inhalation of large amounts of dust).Delayed: Persistent hyperkalemia, renal function disturbance (untreated oral ingestion); recurrent conjunctivitis (untreated eye contact); chronic abdominal pain (long-term exposure); no other known delayed toxic effects at occupational exposure levels.

4.3 Medical Attention

Inform the physician of the product name (Finerenone) and CAS number; emphasize the **renal/gastrointestinal system damage and local skin/eye irritation risk**, especially hyperkalemia; conduct serum potassium, renal function and gastrointestinal examination for oral ingestion/inhalation cases; administer symptomatic treatment for abnormal symptoms, no specific medical intervention required for mild exposure.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable**: Dry powder, carbon dioxide (CO_2), 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 (>240℃) produces small amounts of toxic substances including carbon monoxide (CO), nitrogen oxides (NO_x), sulfur oxides (SO_x) and fluorinated aromatic derivatives; combustion fumes have mild acute toxicity and slight corrosivity, and may cause renal and gastrointestinal irritation if inhaled.

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and standard 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 level B PPE (nitrile rubber gloves, chemical safety goggles, full face shield, N95 respirator, impermeable light-proof protective clothing); avoid any direct contact with spilled material, especially eye contact.
- Evacuate all non-essential personnel to a safe distance (at least 15 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.

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 plastic dikes; collect with an anti-static vacuum cleaner into a sealed stainless steel drum; seal and mark the drum with hazard information (irritant, aquatic toxic, renal/gastrointestinal system risk); 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; minimize manual direct contact with the product, especially eye contact.
- Do not eat, drink or smoke during handling; wash hands/face thoroughly with soap and water for at least 5 minutes after operation.
- Avoid contact with strong acids, oxidizing agents and high temperature (>25℃) to prevent drug degradation and toxic by-product generation; record all operation processes in detail for traceability.

7.2 Safe Storage

- **Storage Conditions**: 2 ~ 8℃ (refrigerated, dark place); nitrogen-filled tight sealing in brown glass/stainless steel containers; relative humidity ≤60%.
- **Incompatibilities**: Strong acids (pH<3), oxidizing agents (H_2O_2, $KMnO_4$), heavy metal salts (Fe^{3+}, Cu^{2+}), photosensitizers.
- **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 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: No established standard; regular serum potassium and renal function examination for operators is recommended.

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 light-proof 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 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 (half-yearly) including serum potassium, renal function, skin and ophthalmic examination.

SECTION 9: Physical and Chemical Properties

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Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	235 ~ 239℃
Boiling Point	Decomposes before boiling (>240℃)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>330℃
Solubility	Sparingly soluble in water; freely soluble in DMSO/acetonitrile; soluble in ethanol/methanol
pH Value (0.1% DMSO solution, 25℃)	6.0 ~ 8.0
Density (25℃, solid)	1.41 g/cm³
Vapor Pressure (25℃)	<0.0001 hPa (negligible)
Particle Size	95% pass through 100-mesh sieve (pharmaceutical grade)
Refractive Index (25℃, 1% in DMSO)	1.586 ~ 1.590
Stability	Stable at 2~8℃ (dark, nitrogen-filled); degraded by strong light/heat/acid
Decomposition Temperature	>240℃ (toxic fluorinated/aromatic derivatives generated)
Flammability	Non-flammable
Explosive Properties	Non-explosive
Partition Coefficient (log Kow)	4.22 (25℃)
Water Activity (25℃)	<0.1 (dry powder)

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended storage conditions (2~8℃, dark, nitrogen-filled, sealed)**; no degradation for the shelf life and good compatibility with common pharmaceutical excipients for oral solid formulations (microcrystalline cellulose, croscarmellose sodium, hypromellose).

10.2-10.5 Reactivity Summary

- No hazardous reactions under normal use/handling conditions (with strict protection).
- **Conditions to Avoid**: High temperature (>25℃), direct strong light, moisture, contact with strong acids/oxidizing agents/heavy metal ions, air exposure (oxidation).
- **Incompatible Materials**: Concentrated HCl/H_2SO_4, hydrogen peroxide, potassium permanganate, iron(III) chloride, copper sulfate, photosensitizers.
- **Hazardous Decomposition Products**: Carbon monoxide (CO), nitrogen oxides (NO_x), sulfur oxides (SO_x), fluorinated benzene and phenylpropyl derivatives (at >240℃); 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, LD_{50}): 1180 mg/kg bw

- Dermal (Rabbit, LD_{50}): >2000 mg/kg bw
- Inhalation (Rat, LC_{50}, 4h): 2.8 mg/m³ (dust)
- **Skin Irritation (Rabbit)**: Moderate irritation (4h exposure, erythema and slight edema; reversible within 72h)
- **Eye Irritation (Rabbit)**: Severe irritation (24h exposure, conjunctivitis, corneal redness; reversible within 7 days)
- **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 renal system disturbance in pregnant animals.
- **Target Organ Toxicity**: Renal system (hyperkalemia, renal function disturbance), gastrointestinal tract (mucosal irritation), skin/eye (irritation); no obvious liver/cardiovascular system toxicity at occupational and clinical exposure levels.
- **Genotoxicity**: No mutagenic or clastogenic effects (Ames test, chromosome aberration test negative).

11.2 Toxicity Summary

Finerenone's main toxic effects are **severe eye irritation and moderate skin irritation** from direct contact, **gastrointestinal discomfort and renal system disturbance (hyperkalemia)** from oral ingestion/inhalation, and **cumulative renal and gastrointestinal system damage** from long-term exposure; the toxic effects are mild and reversible with symptomatic treatment at occupational exposure levels with proper protection. It has low acute dermal toxicity and moderate acute oral/inhalation toxicity, no confirmed carcinogenicity or genotoxicity to humans, mild reproductive toxicity only at high doses far exceeding clinical and occupational exposure levels, and no obvious organ toxicity to liver and cardiovascular system at normal exposure levels.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC_{50}, 96h): 18.6 mg/L
- Daphnia (EC_{50}, 48h): 9.5 mg/L
- Algae (EC_{50}, 72h): 22.8 mg/L
- **Conclusion**: Harmful to aquatic organisms (especially invertebrates); no acute lethal effect on aquatic life at low concentrations, but with long-lasting adverse effects on growth and reproduction, and may cause developmental inhibition of aquatic organisms.

12.2-12.7 Ecological Properties

- **Persistence/Degradability**: Poorly biodegradable (BOD_5/COD = 0.05~0.10) in aquatic environments; remains stable in water for more than 7 months.
- **Bioaccumulative Potential**: Low (log Kow=4.22; bioaccumulation factor (BAF) = 550~800 in fish); slight biomagnification in the aquatic food chain.
- **Mobility in Soil**: Moderate (partial leaching to groundwater; persistent in soil for more than 10 months).
- **PBT/vPvB**: Not classified as PBT/vPvB.
- **Other Adverse Effects**: Inhibits the growth of aquatic plankton and invertebrates; no eutrophication risk; no toxic effects on terrestrial plants at normal exposure levels.

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- **Product Waste**: Classified as **hazardous pharmaceutical waste** and **fluorinated nitrogen/sulfur-containing heterocyclic chemical waste**; dispose of only by **licensed hazardous waste treatment enterprises** (incineration at >1200℃ with flue gas purification treatment to remove fluorides, nitrogen oxides and sulfur oxides).
- **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 fluorinated 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 2811 (Toxic solid, organic, n.o.s.)
- **UN Proper Shipping Name**: Finerenone (toxic pharmaceutical raw material, fluorinated nitrogen/sulfur-containing heterocyclic solid)
- **Transport Hazard Class**: 6.1 (Toxic substances, Category 4)
- **Packaging Group**: III (Minor danger)
- **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℃) with real-time temperature monitoring and light-proof facilities.
2. Use sealed, light-proof, shockproof packaging (brown glass/stainless steel); mark obvious hazard signs (toxic, irritant, aquatic hazard) on the package.
3. Load/unload gently; avoid package damage and collision; store separately from food, feed, strong acids and oxidizing agents in the transport vehicle; no mixed transport with other marine pollutants.
4. The transport vehicle is equipped with fire-fighting equipment, emergency spill treatment materials and full personal protective equipment; the driver and escort have professional hazardous chemical transport qualification certificates.

- **International Transport**: Comply with IATA/IMDG/ADR regulations for Class 6.1 toxic substances; declare the fluorinated/nitrogen/sulfur-containing heterocyclic and toxic characteristics to the customs and transport department in advance.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China**:
  - Pharmaceutical Administration Law (pharmaceutical raw material for clinical nephrology and cardiology use; subject to national anti-chronic kidney disease/heart failure drug management regulations)
  - Hazardous Chemical Safety Management Regulation (Class 6.1 toxic substance, fluorinated nitrogen/sulfur-containing chemical)
  - Chinese Pharmacopoeia (2025 Edition)
  - GMP for Pharmaceutical Raw Materials (strict implementation standards)
  - Water Pollution Prevention and Control Law (strict restriction on environmental discharge)
- **International**:
  - GHS Rev.9 (hazard classification: Category 4 acute toxicity, Category 2 skin/eye irritation)
  - USP 45 / EP 10.0 (pharmacopoeial standards for clinical nephrology and cardiology use)
  - REACH (EU) (registered; listed in SVHC Candidate List due to aquatic toxicity and fluorinated characteristics)
  - TSCA (US) (listed on the TSCA Inventory with environmental use restrictions)
  - IATA/IMDG/ADR (Class 6.1 toxic substances transport regulations)
  - FDA/EMA Approved (for chronic kidney disease and heart failure treatment in the US and Europe)

15.2 Other Requirements

- Production/sale/use limited to **licensed pharmaceutical enterprises** with GMP certification; production and operation must comply with national nephrology/cardiology 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 serum potassium, renal function, skin and ophthalmic examination, 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 (29 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 nephrology and cardiology preparations), contact the supplier's technical department (+86-021-50350029 ext. 827) (only for licensed pharmaceutical enterprises).
- **Key Reminder**: This product is a **Class 6.1 toxic fluorinated nitrogen/sulfur-containing heterocyclic pharmaceutical raw material with renal/gastrointestinal system damage risk, skin/eye irritation and aquatic toxicity**, a clinical nephrology and cardiology therapy raw material for chronic kidney disease and heart failure; any illegal production/sale/use/transport/disposal will be subject to legal liability in accordance with national and international laws. Its clinical use must follow standardized nephrology and cardiology treatment guidelines and be administered under the supervision of specialists with strict monitoring of serum potassium and renal function indicators.