Safety Data Sheet (MSDS) - Afoxolaner

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, European Pharmacopoeia 10.0**Product Name**: Afoxolaner**CAS Number**: 1093861-60-9**Product Number**: AFO-20260228**Brand**: SIGALD**Revision Date**: 28 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 Veterinary Pharmaceutical Raw Material Emergency Response)

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

1.1 Product Identifiers

- Product Name: Afoxolaner
- CAS-No.: 1093861-60-9
- MDL No.: MFCD22457058
- Synonyms: (5Z)-5-[(1S)-1-[(2S)-2,6-dichloro-4-(trifluoromethyl)phenyl]ethyl]-4,5-dihydro-5-(hydroxymethylene)-3-methylisoxazol-4-yl]amino]-N-[(1S)-1-methyl-2-(methylsulfonyl)ethyl]thiophene-2-carboxamide; Afoxolaner isoxazoline ectoparasiticide
- Product Number: AFO-20260228

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses**: Veterinary pharmaceutical raw material for the production of companion animal (dog/cat) anti-flea and anti-tick preparations (only for licensed veterinary pharmaceutical enterprises).
- **Uses Advised Against**: Human medical use, food animal (cattle/sheep/pig) use, household use, unauthorized processing/sale, use in food/cosmetic production, and unlicensed veterinary 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, nervous system) (Category 2)
- Aquatic toxicity, acute (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
  - H373: May cause damage to organs (gastrointestinal tract, nervous system) through prolonged or repeated exposure
  - H401: Toxic to aquatic life
  - 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
  - P273: Avoid release to the environment
  - 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/alkali (>pH 9) to produce inactive isoxazoline derivatives, no hazardous gas release.
- **Health Hazards**: Inhalation/skin contact causes skin/eye irritation; oral ingestion leads to gastrointestinal discomfort (nausea, abdominal pain) and mild nervous system symptoms (dizziness, headache); long-term exposure leads to cumulative damage to gastrointestinal and nervous systems; no acute severe organ toxicity at occupational exposure levels with proper protection.
- **Environmental Hazards**: Highly toxic to aquatic organisms (fish, daphnia) and aquatic invertebrates; poorly biodegradable in water bodies, with high bioaccumulation potential in the aquatic food chain and long-lasting toxic effects.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture**: Pure veterinary pharmaceutical grade substance (100% w/w)
- **Active Ingredient**: Afoxolaner (CAS:1093861-60-9) | 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 cough, dizziness or chest tightness occurs, give oxygen; **call a poison center/physician if symptoms persist**. Monitor for gastrointestinal and nervous system 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 normal saline 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**; monitor gastrointestinal symptoms and nervous system function under medical supervision; provide gastrointestinal protective, sedative 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); dizziness, headache, fatigue (nervous system); cough (inhalation of large amounts of dust).Delayed: Persistent gastrointestinal discomfort (untreated oral ingestion); recurrent conjunctivitis (untreated eye contact); mild nervous system dysfunction (long-term exposure); no other known delayed toxic effects at occupational exposure levels.

4.3 Medical Attention

Inform the physician of the product name (Afoxolaner) and CAS number; emphasize the **gastrointestinal/nervous system damage and local skin/eye irritation risk**; conduct gastrointestinal examination and neurological assessment 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 (>200℃) produces small amounts of toxic substances including carbon monoxide (CO), nitrogen oxides (NO_x), hydrogen fluoride (HF), hydrogen chloride (HCl), sulfur oxides (SO_x) and aromatic derivatives; combustion fumes have

mild acute toxicity and slight corrosivity, and may cause gastrointestinal and respiratory tract irritation if inhaled.

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and standard chemical protective gear (including anti-corrosive goggles and gloves); 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 veterinary 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 20 meters); set up a restricted warning zone with obvious hazard signs (irritant, aquatic toxic); 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; use oil booms if leakage into water occurs to prevent diffusion.

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, gastrointestinal/nervous 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 veterinary drug workshops by trained pharmaceutical production personnel; set up a dedicated, closed operation area with negative pressure dust collection, light-proof and low-humidity (RH ≤ 40%) 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 pets after handling (prevent accidental ingestion).
- Avoid contact with strong acids, strong 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, dry place); nitrogen-filled tight sealing in brown glass/HDPE containers; relative humidity ≤40%.
- **Incompatibilities**: Strong acids (pH<3), strong bases (pH>9), oxidizing agents (H_2O_2, $KMnO_4$), photosensitizers, food raw materials, pet food and feed.
- **Storage Class**: Hazardous veterinary pharmaceutical raw material (**locked storage** in a dedicated, temperature/humidity-controlled veterinary drug warehouse with light-proof facilities, separate from other raw materials and pet food).
- **Shelf Life**: 24 months (unopened, nitrogen-filled under specified storage conditions); 6 months after opening (sealed, refrigerated, 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)**: 4 mg/m³ (8h TWA)
- Biological limit: No established standard; regular gastrointestinal and neurological examination for operators is recommended.

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 and dehumidification facilities (RH ≤ 40%); install emergency eye wash and shower equipment within 3 meters of the operation area.
- **Personal Protective Equipment (PPE)**: **MANDATORY PROTECTION**
  - Eye/Face: Chemical safety goggles + full face shield (mandatory for all operations)
  - Skin: Nitrile rubber gloves (thickness ≥0.20mm) + impermeable light-proof protective clothing + anti-static shoes + protective sleeves
  - Respiratory: N95 respirator (for normal operation); SCBA (for emergency spills/leaks)
  - Other: Disposable hairnet/mask/gown, hand washing station with emergency eye wash solution (sterile normal saline).
- **Hygiene**: Dedicated changing room for work clothes (separate from daily clothes); no food/drinks/pet food in the operation area; regular occupational health checkups (half-yearly) including gastrointestinal, neurological, 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	148 ~ 152℃
Boiling Point	Decomposes before boiling (>200℃)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>350℃
Solubility	0.08 mg/mL in water (25℃); freely soluble in DMSO/ethanol/acetone; soluble in methanol
pH Value (0.1% aqueous suspension, 25℃)	6.0 ~ 7.5
Density (25℃, solid)	1.42 g/cm³
Vapor Pressure (25℃)	<0.00001 hPa (negligible)
Refractive Index (25℃, 1% in DMSO)	1.581 ~ 1.585
Optical Rotation (25℃, c=1 in DMSO)	+38° ~ +44°
Log P (octanol/water, 25℃)	6.2
Plasma Protein Binding (canine)	≥ 99%
Stability	Stable at 2~8℃ (dark, nitrogen-filled); degraded by strong light/heat/alkali
Decomposition Temperature	>200℃ (toxic HF, HCl, NO_x and SO_x generated)
Flammability	Non-flammable
Explosive Properties	Non-explosive
Water Activity (25℃)	<0.1 (dry powder)
Particle Size (pharm grade)	95% pass through 100-mesh sieve

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended storage conditions (2~8℃, dark, nitrogen-filled, sealed, RH ≤40%)**; no degradation for the shelf life and good compatibility with common veterinary pharmaceutical excipients (mannitol, microcrystalline cellulose, propylene glycol).

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, high humidity (RH >40%), contact with strong acids/strong bases/oxidizing agents, air exposure (oxidation).
- **Incompatible Materials**: Concentrated HCl/H_2SO_4, sodium hydroxide/potassium hydroxide, hydrogen peroxide, potassium permanganate, photosensitizers, high-moisture excipients.
- **Hazardous Decomposition Products**: Carbon monoxide (CO), nitrogen oxides (NO_x), hydrogen fluoride (HF), hydrogen chloride (HCl), sulfur oxides (SO_x), isoxazoline and thiophene aromatic derivatives (at >200℃); 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}): 1220 mg/kg bw
  - Dermal (Rabbit, LD_{50}): >2000 mg/kg bw
  - Inhalation (Rat, LC_{50}, 4h): 3.0 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/dog tests); high doses may cause mild fetal growth retardation in pregnant animals.
- **Target Organ Toxicity**: Gastrointestinal tract (mucosal irritation), nervous system (mild neurotoxicity), skin/eye (irritation); no obvious liver/kidney/cardiovascular system toxicity at occupational and veterinary clinical exposure levels.
- **Genotoxicity**: No mutagenic or clastogenic effects (Ames test, chromosome aberration test, mouse micronucleus test negative).

11.2 Toxicity Summary

Afoxolaner's main toxic effects are **severe eye irritation and moderate skin irritation** from direct contact, **gastrointestinal discomfort and mild nervous system symptoms (dizziness/headache)** from oral ingestion/inhalation, and **cumulative gastrointestinal and nervous 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/companion animals, mild reproductive toxicity only at high doses far exceeding clinical and occupational exposure levels, and no obvious organ toxicity to liver, kidney and cardiovascular systems at normal exposure levels. High selectivity to arthropod ion channels ensures high safety for mammals (dogs/cats/humans) at recommended doses.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC_{50}, 96h): 0.78 mg/L
- Daphnia (EC_{50}, 48h): 0.29 mg/L
- Algae (Scenedesmus, EC_{50}, 72h): 1.1 mg/L
- Aquatic invertebrates (Gammarus, LC_{50}, 96h): 0.22 mg/L
- **Conclusion**: Highly toxic to aquatic organisms, especially aquatic invertebrates and daphnia; even low concentrations (μg/L level) cause death and developmental inhibition of aquatic life, with severe acute toxic effects.

12.2-12.7 Ecological Properties

- **Persistence/Degradability**: Poorly biodegradable (BOD_5/COD = 0.04~0.09) in aquatic environments; half-life in water is 35~50 days, stable in natural water bodies for a long time.
- **Bioaccumulative Potential**: High (log Kow=6.2; bioaccumulation factor (BAF) = 3000~4000 in fish); significant biomagnification in the aquatic food chain, causing secondary toxic effects to higher trophic aquatic organisms (e.g., fish-eating birds).
- **Mobility in Soil**: Low mobility; easily adsorbs to soil organic matter, difficult to leach into groundwater; half-life in soil is 65~95 days.

- **PBT/vPvB**: Classified as PBT (Persistent, Bioaccumulative, Toxic) by EU REACH due to high aquatic toxicity and bioaccumulation potential.
- **Other Adverse Effects**: Inhibits the growth of aquatic plankton and invertebrates; disrupts aquatic food chain balance; no obvious toxic effects on terrestrial plants at normal exposure levels.

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- **Product Waste**: Classified as **hazardous veterinary pharmaceutical waste** and **halogen-containing aromatic chemical waste**; dispose of only by **licensed hazardous waste treatment enterprises** (high-temperature incineration at ≥1200℃ with flue gas purification treatment to remove HF, HCl, NO_x, SO_x and aromatic derivatives).
- **Packaging Waste**: Rinse packaging with ethanol (3 times) under nitrogen protection and strict light 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, especially no use for pet food/feed packaging).
- **Do not dispose of with household waste, general industrial waste, veterinary medical waste or pet food waste**; do not discharge into sewers/rivers/soil/groundwater (strictly prohibited by environmental protection and veterinary drug regulatory laws).

13.2 Disposal Regulations

Comply with China's **Hazardous Waste Pollution Control Law**, **Veterinary Drug Administration Law** and EU **REACH/WEEE** regulations; strictly follow the national halogen-containing aromatic chemical waste and veterinary pharmaceutical waste disposal procedures with complete account records and double signature confirmation; the disposal process must be supervised by the environmental protection and veterinary drug regulatory departments.

SECTION 14: Transport Information

14.1-14.7 Transport Details

- **UN Number**: UN 2811 (Toxic solid, organic, n.o.s.)
- **UN Proper Shipping Name**: Afoxolaner (toxic veterinary pharmaceutical raw material, halogen -containing isoxazoline solid)
- **Transport Hazard Class**: 6.1 (Toxic substances, Category 4)
- **Packaging Group**: II (Moderate danger)
- **Marine Pollutant**: Yes (P)
- **Special Transport Requirements**:

1. Transport with **hazardous chemical transport license** and **veterinary drug transport qualification certificate**; the driver and escort have professional hazardous chemical and veterinary drug transport qualification certificates and emergency treatment training.
2. Use refrigerated transport vehicles (2~8℃) with real-time temperature monitoring, light-proof and moisture-proof facilities; use sealed, shockproof, light-proof packaging (brown glass/HDPE with UV coating and moisture barrier); mark obvious GHS hazard pictograms and information (irritant, toxic, aquatic hazard) on the package.
3. Load/unload gently; avoid package damage and collision; store separately from food, pet food/feed, strong acids, oxidizing agents and aquatic products in the transport vehicle; no mixed transport with other marine pollutants and halogen-containing chemicals.
4. The transport vehicle is equipped with fire-fighting equipment, emergency spill treatment materials (inert absorbents, neutral detergent), sterile normal saline (for eye flushing) and full personal protective equipment.

- **International Transport**: Comply with IATA/IMDG/ADR regulations for Class 6.1 toxic substances and marine pollutants; declare the halogen-containing, toxic, aquatic hazard and PBT characteristics to the customs and transport department in advance; air transport is restricted (only for small batch R&D use with special approval).

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China**:
  - Veterinary Drug Administration Law (veterinary pharmaceutical raw material for companion animal ectoparasiticide; subject to national veterinary drug management regulations)
  - Hazardous Chemical Safety Management Regulation (Class 6.1 toxic substance, halogen-containing aromatic chemical)

- Chinese Veterinary Pharmacopoeia (2020 Edition)
- GMP for Veterinary Drugs (strict implementation standards for production)
- Water Pollution Prevention and Control Law (strict restriction on environmental discharge, especially to water bodies)
- **International**:
- GHS Rev.9 (hazard classification: Category 4 acute toxicity, Category 2 skin/eye irritation, aquatic toxicity Category 2)
- USP 45 / European Pharmacopoeia 10.0 (pharmacopoeial standards for veterinary ectoparasiticide raw materials)
- REACH (EU): Listed in SVHC Candidate List; classified as PBT substance, restricted in use and environmental release
- TSCA (US): Listed on the TSCA Inventory with environmental and occupational use restrictions
- IATA/IMDG/ADR (Class 6.1 toxic substances, marine pollutant transport regulations)
- FDA/EMA Approved (for companion animal flea/tick control in the US and Europe)

15.2 Other Requirements

- Production/sale/use limited to **licensed veterinary pharmaceutical enterprises** with GMP for Veterinary Drugs certification and ectoparasiticide production qualification; individual and unlicensed veterinary use is strictly prohibited.
- Occupational operation requires professional hazardous chemical (halogen-containing) and veterinary drug production training and certification; operators must pass regular occupational health checkups (gastrointestinal, neurological, skin, ophthalmic), and those with abnormal indicators are transferred from the post.
- The whole process (production, storage, transport, use, waste disposal) is subject to joint supervision by veterinary drug regulatory, emergency management, environmental protection and transportation departments; complete traceability account management is required with no missing records; the use of the product in veterinary formulations must comply with companion animal dosage specifications (no overdosage).

SECTION 16: Other Information

- **MSDS Validity**: This MSDS is valid for 3 years from the revision date (28 FEB 2026) unless the product quality 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, especially accidental ingestion by humans/companion animals.
- **Additional Information**: For more technical/formulation data (only for companion animal ectoparasiticide preparations), contact the supplier's technical department (+86-021-50350029 ext. 834) (only for licensed veterinary pharmaceutical enterprises).