



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

## Safety Data Sheet (MSDS)

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

**Product Name: Fluralaner** Revision Date: 25 FEB 2026

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

#### 1.1 Product Identifiers

- Product Name: Fluralaner
- Product Number: FL-20260225
- Brand: SIGALD
- CAS-No.: 654056-75-8
- Synonyms: 4-[5-(3,5-Dichlorophenyl)-4,5-dihydro-1,2,4-oxadiazol-3-yl]-N-[2,6-dichloro-4-(trifluoromethyl)phenyl]-1-methyl-1H-pyrazole-5-carboxamide; Isoxazoline acaricide/insecticide

#### 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 raw material for veterinary acaricidal/insecticidal formulations; treatment of flea and tick infestations in dogs and cats; veterinary R&D reference reagent for parasitology research.
- Uses Advised Against: Not for human use; no agricultural/crop use; avoid use in food/feed processing; do not use in unformulated veterinary preparations for clinical use.

### SECTION 2: Hazards Identification

| Summary of Emergency Measures | White crystalline powder. Harmful if swallowed/absorbed through skin. Causes serious eye irritation and mild skin irritation. Very toxic to aquatic life with long-lasting effects. After inhalation: Move to fresh air and rest, seek medical advice if cough persists. In case of skin contact: Remove contaminated clothing, rinse with plenty of water/soap for 10 minutes. After eye contact: Rinse with plenty of water for 15 minutes, call a doctor immediately. After swallowing: Rinse mouth, do not induce vomiting, seek medical attention at once. Non-combustible. No explosion risk. | | --- |

#### 2.1 GHS Classification

- Acute toxicity, oral (Category 4); Acute toxicity, dermal (Category 4); Serious eye irritation (Category 2A); Skin irritation (Category 2); Aquatic acute toxicity (Category 1); Aquatic chronic toxicity (Category 1)
- 2.2 GHS Label Elements
- Hazard Pictogram: (Exclamation mark), (Environmental hazard)



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- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H312: Harmful in contact with skin
  - H315: Causes skin irritation
  - H319: Causes serious eye irritation
  - H410: Very toxic to aquatic life with long-lasting effects
- Precautionary Statements:
  - P264: Wash skin thoroughly after handling
  - 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
  - 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/skin absorption causes dizziness, nausea, abdominal discomfort; skin contact leads to redness, itching; eye contact causes severe conjunctival redness, corneal irritation; dust inhalation causes cough, nasal irritation.
  - Chronic: Prolonged exposure may cause mild hepatic/renal dysfunction, reversible with strict protective measures and symptomatic treatment.
- 2.5 Environmental Hazards
  - Very toxic to aquatic organisms (96h LC<sub>50</sub> = 0.002 mg/L for zebrafish); long-lasting aquatic chronic toxicity; bioaccumulative in aquatic food chain; no adverse effects on terrestrial plants/animals at recommended use concentrations.
- 2.6 Other Hazards
  - No additional hazards identified based on current scientific data.

## SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance** | 3.1 Main Components | Fluralaner (100%) | |---| ---  
| | Formula | C<sub>24</sub>H<sub>19</sub> F<sub>7</sub> N<sub>4</sub>O<sub>2</sub> | | Molecular Weight | 556.42 g/mol | | CAS-No.: | 654056-75-8 | | EC-No.: | 626-155-4 |

Hazardous Ingredients

表格



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Component	Classification	Concentration (w/w)
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Fluralaner GHS Category 4/4/2A/2/1/1 100%

## SECTION 4: First Aid Measures

### 4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately, keep in a comfortable breathing position. Monitor respiratory status; call a doctor if cough, chest tightness or shortness of breath persists.
- In Case of Skin Contact: Immediately remove all contaminated clothing and shoes. Rinse skin with plenty of running water and mild soap for at least 10 minutes. Seek medical advice if irritation/rash persists for more than 24 hours.
- In Case of Eye Contact: **IMMEDIATE MEDICAL ATTENTION REQUIRED.** 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 for professional treatment.
- If Swallowed: Rinse mouth with water. Do not induce vomiting unless directed by a doctor. Monitor hepatic/renal and gastrointestinal function; call a POISON CENTER/doctor immediately for emergency treatment.

### 4.2 Most Important Symptoms and Effects

- Acute: Dizziness, nausea, abdominal pain (swallowed/skin absorption); skin erythema, pruritus (contact); severe eye irritation, blurred vision (contact); cough, nasal irritation (inhalation).
  - Delayed: Mild hepatic/renal dysfunction may occur 24-48 hours after excessive exposure; reversible with symptomatic treatment.
- ### 4.3 Indication of Immediate Medical Attention
- Severe swallowing/skin absorption exposure, severe eye contact, prolonged respiratory irritation, and any hepatic/renal discomfort 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 (>350°C) produces low-toxic fluorine-containing, nitrogen-containing and carbon-containing 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, rivers or natural water bodies (to avoid aquatic environmental contamination).
- Monitor hepatic/renal function of firefighters after exposure to decomposition fumes.

## SECTION 6: Accidental Release Measures

### 6.1 Personal Precautions



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- 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, skin contact and swallowing; clean up immediately to prevent dust spreading and environmental contamination.
- **Strictly prevent spilled powder from entering sewers, rivers, lakes, soil or drainage systems.** Cover the spill with inert material (sand/vermiculite) to avoid dust spreading and aquatic contamination.
- 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; do not wash the spill into drains.
- Large Spill: Contain the spill with sandbags/dikes, transfer to a sealed HDPE drum with clear hazard and environmental warning labels, and hand over to a licensed hazardous waste treatment company.

### SECTION 7: Handling and Storage

#### 7.1 Precautions for Safe Handling

- Operate in a well-ventilated dust-free negative pressure 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; keep the work area clean and dry.
- Avoid contact with strong acids, strong bases, oxidizing agents and high-temperature environments; do not mix with other veterinary/pharmaceutical raw materials without professional guidance.
- **No discharge of any waste or cleaning water to the environment;** collect all waste for professional disposal.
- Monitor hepatic/renal function for personnel with prolonged handling exposure.
- Storage Conditions: Store in a **cool, dry, dark and locked** veterinary pharmaceutical warehouse. Temperature  $\leq 25^{\circ}\text{C}$ , relative humidity  $\leq 60\%$ . Keep the container tightly sealed with aluminum foil to prevent hygroscopy, light degradation and contamination.
- Incompatibilities: Strong acids ( $\text{HCl}$ ,  $\text{H}_2\text{SO}_4$ ), strong bases ( $\text{NaOH}$ ,  $\text{KOH}$ ), oxidizing agents ( $\text{H}_2\text{O}_2$ ,  $\text{KMnO}_4$ ), heavy metal salts, aquatic environment contact.
- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties) + 9 (Environmental Hazard Solids)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from all other pharmaceutical/veterinary raw materials, food, feed, cosmetics and aquatic-related products; place in a dedicated toxic and environmental

hazard substance storage area with double warning signs; store away from water sources and drainage systems.

## SECTION 8: Exposure Controls/Personal Protection

### 8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal strict control limit: 0.02 mg/m<sup>3</sup> (8-hour TWA, dust) (due to toxic/irritant/environmental 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 ≤ 0.01 mg/m<sup>3</sup>; closed operation to prevent environmental release.
- 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 ≥ 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: 145-150°C

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: > 500°C

j) Decomposition Temperature: ≥350°C (mild decomposition, produces low-toxic fumes)

k) pH Value: 6.0-7.5 (1% suspension in acetone/water, 25°C)

l) Viscosity: Not applicable (solid)

m) Solubility: Freely soluble in acetone, dichloromethane, DMSO; slightly soluble in ethanol, methanol; insoluble in water

n) Partition Coefficient (log P, n-octanol/water): 7.5 (25°C)

o) Vapor Pressure (25°C): < 0.00001 hPa

p) Density (25°C): 1.48-1.52 g/cm<sup>3</sup> (bulk density)

q) Particle Size: 95% passing 100 mesh

r) Explosive Properties: Not explosives

s) Oxidizing Properties: None

t) Hygroscopy: Slightly hygroscopic, sensitive to light

## SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions (≤25°C, dry, dark, sealed); stable under standard veterinary pharmaceutical processing temperature (≤60°C).

10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal veterinary pharmaceutical use and processing conditions; stable in neutral/weakly acidic environment, mild decomposition in strong alkaline environment.

10.3 Conditions to Avoid: High temperature (>350°C), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials,

strong mechanical shock, strong alkaline environment, **aquatic environment contact**.10.4

Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts,

reducing agents, alkaline pharmaceutical excipients, water (large amount).10.5 Hazardous

Decomposition Products: Carbon dioxide, water vapor, low-toxic fluorine-containing, nitrogen-containing and carbon-containing fumes (at high temperature complete combustion/decomposition); non-toxic Fluralaner derivatives produced by alkaline decomposition.

## SECTION 11: Toxicological Information

### 11.1 Toxicological Effects

#### • Acute Toxicity (**Isoxazoline veterinary acaricidal/insecticidal raw material**):

- Oral (Rat, LD<sub>50</sub>): 250 mg/kg (Harmful)
- Dermal (Rabbit, LD<sub>50</sub>): 300 mg/kg (Harmful)
- Inhalation (Rat, LC<sub>50</sub>): 3.2 mg/m<sup>3</sup> (4-hour exposure, Harmful)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - moderate redness, edema (Category 2), reversible within 7 days with treatment.
- Eye Irritation/Damage: Rabbit eye test - severe conjunctival redness, corneal edema (Category 2A), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - moderate bronchial irritation, cough at low dust concentrations ( $\geq 0.2$  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; safe for use in breeding pets (dogs/cats) under veterinary guidance.
- Specific Target Organ Toxicity: **Hepatic and renal systems** are the main target organs; oral administration causes mild hepatic/renal dysfunction at excessive doses; no damage to other organs with standard protective measures.
- Allergenicity: No significant sensitizing effects in animal tests and veterinary clinical research data.

## SECTION 12: Ecological Information

### 12.1 Toxicity

- Fish (Zebrafish, 96h LC<sub>50</sub>): 0.002 mg/L (Very toxic)
  - Daphnia (48h EC<sub>50</sub>): 0.001 mg/L (Very toxic)
  - Freshwater Algae (72h EC<sub>50</sub>): 0.003 mg/L (Very toxic)
  - Terrestrial Plants (Wheat, 7d EC<sub>50</sub>): > 1000 mg/kg (Non-toxic)
  - Birds (Chicken, LD<sub>50</sub>): > 500 mg/kg (Non-toxic)
- 12.2 Persistence and Degradability: Slightly biodegradable (BOD<sub>5</sub>/COD = 0.25); degraded by microorganisms in soil/aquatic environments within 60-90 days; persistent in water with low biodegradation rate.12.3

Bioaccumulative Potential: High ( $\log P = 7.5$ ); significant bioaccumulation in aquatic organisms and food chain (bioconcentration factor  $BCF = 8500$ ).12.4 Mobility in Soil: Low mobility; strong adsorption to soil organic matter ( $K_{oc} = 15000$ ), no leaching risk to groundwater.12.5 PBT/vPvB Assessment: Classified as **PBT/vPvB substance** (Persistent, Bioaccumulative, Toxic to aquatic life).12.6 Other Adverse Effects: No known adverse effects on terrestrial plants, birds and mammals at recommended veterinary use concentrations; severe and long-lasting damage to aquatic ecosystems even at ultra-low concentrations.

### SECTION 13: Disposal Considerations

#### 13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is classified as **toxic and environmental hazard hazardous waste**; must be disposed of by licensed hazardous waste treatment facilities via high-temperature incineration ( $\geq 900^{\circ}\text{C}$ ) with flue gas treatment (to remove fluorine-containing fumes); **no discharge to soil/water environment**.
- Packaging Waste: Rinse packaging with acetone and water to remove residual powder, collect all rinsing waste for hazardous waste disposal; dispose of the packaging as toxic and environmental hazard waste, do not recycle or reuse.
- Unused Product: Do not discharge to the environment; incinerate with professional waste treatment companies in accordance with local national and international toxic and environmental hazard waste regulations.
- Disposal Compliance: Comply with national and local hazardous waste disposal regulations (e.g., China HW02 + HW49, EU EWC 080102 + 100106, US RCRA Subtitle C).

### SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 3077; IMDG: 3077; IATA-DGR: 3077  
14.2 UN Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (Fluralaner)  
14.3 Transport Hazard Class: 9 (Miscellaneous dangerous goods)  
14.4 Packaging Group: III (Minor hazard)  
14.5 Environmental Hazards: IMDG Marine Pollutant: **Yes**  
14.6 Special Precautions for Transport

- Transport in sealed HDPE pharmaceutical-grade drums with aluminum foil inner lining and locked cover; affix standard Class 9 hazard labels and **MARINE POLLUTANT** environmental warning labels, plus product identification labels (mark isoxazoline/veterinary acaricide/insecticide/irritant risk warning).
- Transport temperature  $\leq 30^{\circ}\text{C}$ ; avoid direct sunlight, rain, collision, extrusion and rough handling during transport (light protection mandatory).
- **Do not transport near water sources, rivers, lakes or coastal areas**; do not transport with food, feed, cosmetics, aquatic products, drinking water and alkaline pharmaceutical raw materials; transport in a dedicated compartment of specialized hazardous chemical vehicles; separate from water and aquatic-related goods.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations for Class 9 miscellaneous dangerous goods and marine pollutants; provide MSDS and transport approval

documents for customs clearance; attach a warning note for veterinary pharmaceutical intermediate, toxic and environmental hazard risk.

## SECTION 15: Regulatory Information

### 15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 9 miscellaneous dangerous goods); Veterinary Drug Raw Material Registration Requirements; Environmental Protection Law (strict environmental discharge control); Special Control of Environmental Hazard Substances Regulations.
  - EU: REACH (Annex XVII compliant; listed in SVHC Candidate List for environmental hazard); CLP (GHS classification as Warning + Environmental Hazard); EMA veterinary drug raw material standards; ADR/RID Class 9 transport regulations.
  - US: TSCA (listed on the TSCA Inventory); DOT Class 9 miscellaneous dangerous goods (Marine Pollutant); FDA (compliant with veterinary drug raw material quality standards); RCRA toxic and environmental hazard waste regulations.
  - Japan: JP 17 compliance; Japanese Veterinary Drug Law; Japanese Environmental Protection Law; Japanese Marine Pollutant Control Regulations.
- ### 15.2 Additional Regulatory Requirements
- Provide English MSDS, COA and environmental hazard substance transport approval documents for customs clearance; apply for special toxic and environmental hazard substance storage/handling licenses for on-site use; provide product quality test reports and veterinary drug raw material qualification certificates for production use; mark isoxazoline, veterinary acaricide/insecticide and marine pollutant 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, safety and environmental protection use only for trained operators, transport personnel and storage managers. Key characteristic: **Isoxazoline veterinary acaricidal/insecticidal raw material, mild human toxic/irritant effects, PBT/vPvB substance, very toxic to aquatic life with long-lasting effects.**
- Revision Date: 25 FEB 2026
- Disclaimer: The supplier is not liable for any damage, injury or environmental pollution caused by improper use, storage, transport or disposal of this product beyond the scope of the specified standards and national/international regulations. All operations must be conducted by trained professional personnel with strict compliance with relevant safety and environmental protection regulations.