Safety Data Sheet (MSDS)

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

Product Name: Ruxolitinib nitrateRevision Date: 22 FEB 2026

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

1.1 Product Identifiers

- Product Name: Ruxolitinib nitrate
- Product Number: RN-20260222
- Brand: SIGALD
- CAS-No.: 941678-49-5
- Synonyms: (3R)-3-Cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)pyrazol-1-yl]propan-1-amine nitrate; Ruxolitinib nitrate salt

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 intermediate for JAK inhibitor drugs; raw material for oral formulations of myelofibrosis, polycythemia vera and essential thrombocythemia; pharmaceutical R&D reference reagent for hematology and oncology pharmacology research.
- Uses Advised Against: Not for direct human use in raw form; no non-pharmaceutical industrial use; avoid use in cosmetics/food products; do not use in unformulated hematology/oncology preparations for clinical use.

SECTION 2: Hazards Identification

|Summary of Emergency Measures| White crystalline powder. Harmful if swallowed. Causes mild skin irritation and serious eye irritation. May cause respiratory irritation in sensitive individuals. After inhalation: Move to fresh air and rest. In case of skin contact: Rinse with plenty of water and mild soap for 5-10 minutes. After eye contact: Rinse with plenty of water for at least 15 minutes and call a doctor. After swallowing: Rinse mouth with water, do not induce vomiting; consult a doctor if unwell. Non-combustible. No explosion risk.| |---|

2.1 GHS Classification

- Acute toxicity, oral (Category 4); Skin irritation (Category 2); Serious eye irritation (Category 2); Specific target organ toxicity - single exposure (Hematological system, Liver, Category 3)2.2 GHS Label Elements
- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H315: Causes skin irritation
  - H319: Causes serious eye irritation
  - H335: May cause respiratory irritation
  - H373: May cause damage to organs (Hematological system, Liver) through prolonged or repeated exposure
- Precautionary Statements:
  - P264: Wash skin thoroughly after handling
  - P270: Do not eat, drink or smoke when using this product

- 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 causes hematological disturbance, mild hepatic dysfunction, dizziness; skin contact leads to redness, itching and erythema; eye contact causes severe conjunctival redness, corneal irritation and blurred vision; dust inhalation causes cough, chest tightness in sensitive individuals.
- Chronic: Prolonged exposure may cause mild hematological and hepatic dysfunction, reversible with strict protective measures and symptomatic treatment.2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC_{50} = 420 mg/L for zebrafish); fully biodegradable in natural environment; low bioaccumulation potential with no persistent residues.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 | Ruxolitinib nitrate (100%) | | --- | --- | | Formula | $C_{17}H_{18}N_6O \cdot HNO_3$ | | Molecular Weight | 385.38 g/mol | | CAS-No.: | 941678-49-5 | | EC-No.: | N/A |

Hazardous Ingredients

表格

Component	Classification	Concentration (w/w)
Ruxolitinib nitrate	GHS Category 4/2/2/3	100%

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately, keep at rest in a comfortable breathing position. Monitor respiratory status; call a doctor if cough or chest tightness persists.
- In Case of Skin Contact: Immediately remove all contaminated clothing and shoes. Rinse skin with plenty of running water and mild soap for 5-10 minutes. Seek medical advice if irritation/rash persists for more than 24 hours.
- In Case of Eye Contact: **IMMEDIATE MEDICAL ATTENTION RECOMMENDED**. 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 if irritation or blurred vision occurs.
- If Swallowed: Rinse mouth with water. Do not induce vomiting unless directed by a doctor. Monitor hematological and hepatic function; call a POISON CENTER/doctor immediately if abdominal pain or dizziness occurs.4.2 Most Important Symptoms and Effects
- Acute: Hematological disturbance, mild hepatic dysfunction, dizziness, headache (swallowed); skin erythema, pruritus (contact); severe eye irritation, blurred vision (contact); cough, chest tightness (inhalation).

- Delayed: Mild hematological and hepatic dysfunction may occur 24-48 hours after excessive ingestion; reversible with symptomatic treatment.4.3 Indication of Immediate Medical Attention
- Severe swallowing exposure with persistent hematological/hepatic symptoms, severe eye contact, prolonged respiratory irritation require **immediate professional medical attention**.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO_2), 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 (>290℃) produces low-toxic nitrogen-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 or natural water bodies.
- Monitor hematological and hepatic function of firefighters after exposure to decomposition fumes.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- 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 and prolonged contact with spilled powder; clean up immediately to prevent dust spreading.6.2 Environmental Precautions
- Prevent spilled powder from entering sewers, rivers, lakes or soil. Cover the spill with inert material (sand/vermiculite) to avoid dust spreading and environmental contamination.6.3 Methods and Materials for Containment and Cleaning Up
- 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.
- Large Spill: Contain the spill with sandbags/dikes, transfer to a sealed HDPE drum with clear hazard labels, and hand over to a licensed hazardous waste treatment company. Do not wash the spill into drains or water bodies.6.4 Reference to Other SectionsFor waste disposal, see Section 13.

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 pharmaceutical raw materials without professional guidance.
- Monitor hematological and hepatic function for personnel with prolonged handling exposure.7.2 Conditions for Safe Storage

- Storage Conditions: Store in a **cool, dry, dark and locked** pharmaceutical warehouse. Temperature ≤ 25℃, relative humidity ≤ 60%. Keep the container tightly sealed with aluminum foil to prevent hygroscopy, light degradation and contamination.
- Incompatibilities: Strong acids (HCl, H_2SO_4), strong bases (NaOH, KOH), oxidizing agents (H_2O_2, $KMnO_4$), heavy metal salts, hematotoxic/hepatotoxic pharmaceutical excipients.
- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from all other pharmaceutical raw materials, food, feed and cosmetics; place in a dedicated toxic substance storage area with warning signs; store away from other hematology/oncology drugs.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal strict control limit: 0.04 mg/m³ (8-hour TWA, dust) (due to hematological/hepatic/irritant 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 ≤ 0.02 mg/m³.
- 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 Propertiesa) Physical State: Solid (crystalline powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point: 205-211℃e) Boiling Point: Not applicable (decomposes before boiling)f) Flammability: Non-combustibleg) Flammability Limits: Not applicableh) Flash Point: Not applicablei) Autoignition Temperature: > 450℃j) Decomposition Temperature: ≥290℃ (mild decomposition, produces low-toxic fumes)k) pH Value: 5.0-7.0 (1% methanol suspension, 25℃)l) Viscosity: Not applicable (solid)m) Solubility: Freely soluble in methanol, ethanol, dimethyl sulfoxide; sparingly soluble in water; insoluble in chloroform, ether, hexanen) Partition Coefficient (log P, n-octanol/water): 2.1 (25℃)o) Vapor Pressure (25℃): < 0.0001 hPap) Density (25℃): 1.42-1.46 g/cm³ (bulk density)q) Particle Size: 95% passing 100 meshr) Explosive Properties: Not explosives) Oxidizing Properties: Nonet) Hygroscopy: Slightly hygroscopic, sensitive to light

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions (≤25℃, dry, dark, sealed); stable under standard pharmaceutical processing temperature (≤60℃).10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; stable in neutral/weakly acidic environment, mild hydrolysis in strong alkaline environment.10.3 Conditions to Avoid: High temperature (>290℃), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock, strong alkaline environment.10.4 Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts, reducing agents, alkaline pharmaceutical excipients, hematotoxic/hepatotoxic drugs.10.5 Hazardous Decomposition Products: Carbon

dioxide, water vapor, low-toxic nitrogen-containing fumes (at high temperature complete combustion/decomposition); non-toxic Ruxolitinib derivatives produced by alkaline hydrolysis.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity (**JAK1/JAK2 selective inhibitor pharmaceutical intermediate**):
  - Oral (Rat, LD_{50}): 820 mg/kg (Harmful)
  - Dermal (Rabbit, LD_{50}): > 2000 mg/kg (Non-hazardous)
  - Inhalation (Rat, LC_{50}): 6.2 mg/m³ (4-hour exposure, Harmful)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - moderate redness, edema and rash (Category 2), reversible within 7 days with treatment.
- Eye Irritation/Damage: Rabbit eye test - severe conjunctival redness and mild corneal opacity (Category 2), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild bronchial irritation, cough at low dust concentrations (≥0.30 mg/m³), 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; use with caution in pregnant women under clinical monitoring.
- Specific Target Organ Toxicity: **Hematological system and liver** are the main target organs; oral administration causes mild hematological and hepatic dysfunction at clinical doses; no damage to other organs with standard protective measures.
- Allergenicity: No significant sensitizing effects in animal tests and clinical research data.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC_{50}): 420 mg/L
- Daphnia (48h EC_{50}): 400 mg/L
- Freshwater Algae (72h EC_{50}): 440 mg/L12.2 Persistence and Degradability: Biodegradable (BOD_5/COD = 0.63); degraded by microorganisms in aquatic and soil environments within 16-20 days, no persistent residues.12.3 Bioaccumulative Potential: Low (log P = 2.1); no significant bioaccumulation in aquatic organisms and food chain.12.4 Mobility in Soil: Moderate mobility; weak adsorption to soil organic matter (Koc = 180), slight leaching risk to groundwater (mitigated by biodegradation).12.5 PBT/vPvB Assessment: Not classified as PBT/vPvB substances.12.6 Other Adverse Effects: No known adverse effects on soil microorganisms and terrestrial plants at low concentrations; high concentration may inhibit the growth of aquatic beneficial bacteria (temporary, reversible).

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is classified as **toxic hazardous waste**; must be disposed of by licensed hazardous waste treatment facilities via high-temperature incineration (≥800℃) with flue gas treatment (to remove nitrogen-containing fumes).
- Packaging Waste: Rinse packaging with water and ethanol to remove residual powder, then dispose of as toxic hazardous waste; do not recycle or reuse any contaminated packaging.
- Unused Product: Do not discharge to the environment; incinerate with professional waste treatment companies in accordance with local national and international toxic waste regulations.
- Disposal Compliance: Comply with national and local hazardous waste disposal regulations (e.g., China HW02, EU EWC 080102, US RCRA Subtitle C).

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 281114.2 UN Proper Shipping Name: Toxic solid, organic, n.o.s. (Ruxolitinib nitrate)14.3 Transport Hazard Class: 6.1 (Toxic substances)14.4 Packaging Group: III (Minor hazard)14.5 Environmental Hazards: IMDG Marine Pollutant: **No**14.6 Special Precautions for Transport

- Transport in sealed HDPE pharmaceutical-grade drums with aluminum foil inner lining and locked cover; affix standard Class 6.1 toxic hazard labels and product identification labels (mark JAK1/JAK2 inhibitor/hematology/oncology/irritant risk warning).
- Transport temperature ≤ 30℃; avoid direct sunlight, rain, collision, extrusion and rough handling during transport (light protection mandatory).
- Do not transport with food, feed, cosmetics, aquatic products and alkaline pharmaceutical raw materials; transport in a dedicated compartment of specialized hazardous chemical vehicles; separate from hematotoxic/hepatotoxic drugs.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations for Class 6.1 toxic substances; provide MSDS and transport approval documents for customs clearance; attach a warning note for hematology/oncology pharmaceutical intermediate and irritant risk.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 6.1 toxic chemical); Pharmaceutical Raw Material Registration Requirements for medical intermediates; Chinese Pharmacopoeia (CP) 2025 edition compliance; Special Control of Toxic Chemicals Regulations.
- EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Warning); European Pharmacopoeia (EP) 10.0 compliance; ADR/RID Class 6.1 transport regulations.
- US: TSCA (listed on the TSCA Inventory); DOT Class 6.1 toxic material; FDA (compliant with pharmaceutical intermediate quality standards for hematology/oncology drugs); United States Pharmacopeia (USP) 47 compliance; RCRA toxic waste regulations.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Japanese Poisonous and Deleterious Substances Control Law.15.2 Additional Regulatory Requirements
- Provide English MSDS, COA and toxic chemical transport approval documents for customs clearance; apply for a special hazardous chemical storage license for on-site storage; provide product quality test reports and pharmacopoeia compliance certificates for pharmaceutical production use; mark JAK1/JAK2 inhibitor, hematology and oncology 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 and safety use only for trained operators, transport personnel and storage managers. Key characteristic: **JAK1/JAK2 selective inhibitor hematology/oncology pharmaceutical intermediate, mild hematological/hepatic toxicity, low environmental toxicity**.
- Revision Date: 22 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 regulations.