Safety Data Sheet (MSDS) - Ozagrel Sodium

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0**Product Name**: Ozagrel Sodium**CAS Number**: 82571-53-7**Product Number**: OS-20260226**Brand**: SIGALD**Revision Date**: 26 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: Ozagrel Sodium
- CAS-No.: 82571-53-7
- MDL No.: MFCD00072015
- Synonyms: Sodium (E)-3-(4-(1H-imidazol-1-yl)phenyl)acrylate; Ozagrel monosodium salt
- Product Number: OS-20260226

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses**: Pharmaceutical raw material for the production of clinical anti-thrombotic preparations (injection, oral tablets, oral liquid) for cerebral infarction and myocardial infarction (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, blood system, 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, blood system) through prolonged or repeated exposure
  - 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
  - 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 imidazole derivatives, no hazardous gas release.

- **Health Hazards**: Inhalation/skin contact/swallowing causes skin/eye irritation and mild gastrointestinal discomfort (nausea, abdominal pain); single high-dose exposure may cause blood system damage (bleeding tendency, thrombocytopenia); long-term exposure leads to cumulative gastrointestinal and blood system damage; oral ingestion has moderate acute toxicity.
- **Environmental Hazards**: Toxic to aquatic organisms with long-lasting adverse effects; poorly biodegradable in water bodies with certain bioaccumulation potential in the aquatic food chain.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture**: Pure pharmaceutical grade substance (100% w/w)
- **Active Ingredient**: Ozagrel Sodium (CAS:82571-53-7) | 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 bleeding from nasal/oral mucosa persists**. Monitor for blood system 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 emollient if redness/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**; continue to monitor eye redness, swelling and vision until symptoms disappear.
- **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 blood routine, coagulation function indicators, and provide hemostatic, gastrointestinal protective and symptomatic treatment.

4.2 Most Important Symptoms

Acute: Nausea, abdominal pain, melena, skin redness/erythema, eye redness/tearing and blurred vision; severe oral ingestion causes thrombocytopenia, prolonged coagulation time and gastrointestinal bleeding.Delayed: Cumulative blood system damage (persistent bleeding tendency, thrombocytopenia), chronic gastrointestinal mucosal damage (recurrent abdominal pain, erosion), recurrent skin irritation (long-term exposure); no obvious liver/kidney function damage with prolonged contact.

4.3 Medical Attention

Inform the physician of the product name (Ozagrel Sodium) and CAS number; emphasize the **blood/gastrointestinal system damage and local skin/eye irritation risk**; conduct blood routine, coagulation function and gastrointestinal endoscopy if necessary; administer hemostatic drugs, platelet growth factors and gastrointestinal mucosal protective agents for abnormal indicators, no specific antidote available.

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 (>230℃) produces toxic and corrosive substances including carbon monoxide (CO), nitrogen oxides (NO_x) and imidazole aromatic derivatives; combustion fumes have strong acute toxicity and corrosivity, and may cause bleeding tendency if inhaled.

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and full acid-resistant 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 light-proof protective clothing); avoid any contact with spilled material (even trace amounts), especially for injection grade raw materials (sterile PPE required).
- 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 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; do not flush with water directly.

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 acid-resistant dikes; collect with an anti-static vacuum cleaner into a sealed stainless steel drum; seal and mark the drum with hazard information (toxic, corrosive, bleeding 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; sterile clean room (Class 10000) for injection grade raw material operation.
- Use closed feeding and mixing equipment to avoid dust generation/inhalation; minimize manual direct contact with the product, especially injection grade raw materials (strict sterile operation).
- 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; sterile hand disinfection for injection grade operation.
- Avoid contact with strong acids, oxidizing agents and high temperature (>25℃) to prevent degradation and toxic by-product generation; record all operation processes in detail for traceability (complete sterile operation records for injection grade).

7.2 Safe Storage

- **Storage Conditions**: 2 ~ 8℃ (refrigerated, dark place); nitrogen-filled tight sealing in brown glass/stainless steel containers; relative humidity ≤60%; sterile sealed packaging for injection grade raw materials.
- **Incompatibilities**: Strong acids (pH<3), oxidizing agents (H_2O_2, $KMnO_4$), heavy metal salts (Fe^{3+}, Cu^{2+}), photosensitizers, strong reducing agents.
- **Storage Class**: Hazardous pharmaceutical raw material (locked storage in a dedicated, temperature-controlled pharmaceutical warehouse with light-proof and acid-resistant facilities, separate from other raw materials; sterile cold storage for injection grade).
- **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; 3 months for opened injection grade).

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: Monitor blood routine and coagulation function indicators for operators; no specific biological exposure limit established.

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 operation facilities; Class 10000 clean room with laminar flow for injection grade raw materials, sterile air filtration system.
- **Personal Protective Equipment (PPE)**:
  - Eye/Face: Chemical safety goggles + full acid-resistant face shield (mandatory for all operations); sterile goggles for injection grade.
  - Skin: Nitrile rubber gloves (thickness ≥0.18mm) + impermeable/acid-resistant light-proof protective clothing + anti-static shoes; sterile latex gloves + sterile protective clothing for injection grade.
  - Respiratory: N95 respirator + organic vapor/acid gas cartridge (for normal operation); SCBA (for emergency spills/leaks); sterile respiratory mask for injection grade clean room.
  - Other: Disposable hairnet/mask/gown, hand washing station with emergency eye wash/shower equipment (within 5 meters of operation area); sterile hand washing and disinfection station for injection grade.
- **Hygiene**: Dedicated changing room for work clothes (separate from daily clothes); no food/drinks in the operation area; regular occupational health checkups (quarterly) including blood routine, coagulation function, skin examination and ophthalmic examination; transfer from post if abnormal blood indicators are found.

SECTION 9: Physical and Chemical Properties

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Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	223 ~ 227℃
Boiling Point	Decomposes before boiling (>230℃)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>320℃
Solubility	Freely soluble in water; slightly soluble in methanol/ethanol; insoluble in acetone/ether
pH Value (1% aqueous solution, 25℃)	7.0 ~ 8.5
Density (25℃, solid)	1.35 g/cm³
Vapor Pressure (25℃)	<0.0001 hPa (negligible)
Particle Size	95% pass through 100-mesh sieve (pharmaceutical grade)
Refractive Index (25℃, 1% in H_2O)	1.592 ~ 1.596
Stability	Stable at 2~8℃ (dark, nitrogen-filled); degraded by strong light/heat/acid
Decomposition Temperature	>230℃ (toxic imidazole/aromatic derivatives generated)
Flammability	Non-flammable
Explosive Properties	Non-explosive
Partition Coefficient (log Kow)	1.28 (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 injection and oral solid formulations (mannitol, sodium citrate for injection; microcrystalline cellulose, crospovidone for oral).

10.2-10.5 Reactivity Summary

- No hazardous reactions under normal use/handling conditions (with strict protection and sterile operation for injection grade).
- **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), 4-imidazolylbenzene and acrylic acid derivatives (at >230℃); photodegradation products (inactive and slightly toxic) 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}): 1250 mg/kg bw
  - Dermal (Rabbit, LD_{50}): >2000 mg/kg bw
  - Inhalation (Rat, LC_{50}, 4h): 3.5 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 bleeding tendency in pregnant animals.
- **Target Organ Toxicity**: Blood system (thrombocytopenia, prolonged coagulation time), gastrointestinal tract (mucosal irritation, bleeding), skin/eye (local irritation); no obvious liver/kidney/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

Ozagrel Sodium's main toxic effects are **severe eye irritation and moderate skin irritation** from direct contact, **mild gastrointestinal discomfort and bleeding tendency** from oral ingestion/inhalation, and **cumulative blood and gastrointestinal system damage** from long-term exposure; the toxic effects are mild and reversible with symptomatic and protective 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, kidney and cardiovascular system at normal exposure levels.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC_{50}, 96h): 9.8 mg/L
- Daphnia (EC_{50}, 48h): 5.2 mg/L
- Algae (EC_{50}, 72h): 15.6 mg/L
- **Conclusion**: Toxic to aquatic organisms (especially invertebrates); fatal to aquatic life at low concentrations with long-lasting adverse effects on growth and reproduction, and may cause blood system damage to 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 8 months.
- **Bioaccumulative Potential**: Moderate (log Kow=1.28; bioaccumulation factor (BAF) = 650~950 in fish); obvious biomagnification in the aquatic food chain.
- **Mobility in Soil**: Moderate (partial leaching to groundwater; persistent in soil for more than 12 months).
- **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; 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 **toxic nitrogen-containing chemical waste**; dispose of only by **licensed hazardous waste treatment enterprises** (incineration at >1200℃ with acid gas and nitrogen oxide purification treatment to remove NO_x and imidazole derivatives).
- **Packaging Waste**: Rinse packaging with ethanol (3 times) under nitrogen protection (sterile water for injection grade packaging); 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; sterile packaging is disposed of as medical sterile waste).
- **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 nitrogen-containing chemical waste disposal procedures with complete account records and double signature confirmation; the incineration process must meet the national acid gas and nitrogen oxide emission standards; sterile waste from injection grade raw materials is disposed of in accordance with medical sterile waste regulations.

SECTION 14: Transport Information

14.1-14.7 Transport Details

- **UN Number**: UN 2811 (Toxic solid, organic, n.o.s.)
- **UN Proper Shipping Name**: Ozagrel Sodium (toxic pharmaceutical raw material, nitrogen-containing solid)
- **Transport Hazard Class**: 6.1 (Toxic substances, Category 4)
- **Packaging Group**: II (Dangerous)
- **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; sterile cold chain transport for injection grade raw materials.
2. Use sealed, light-proof, shockproof and acid-resistant packaging (brown glass/stainless steel); sterile sealed packaging for injection grade; mark obvious hazard signs (toxic, environmental hazard, bleeding risk) on the package.
3. Load/unload gently; avoid package damage and collision; store separately from food, feed, strong acids/oxidizing agents and other drugs in the transport vehicle; no mixed transport with other hazardous goods (especially acid materials); sterile isolation for injection grade raw materials during transport.
4. The transport vehicle is equipped with fire-fighting equipment, acid-resistant emergency spill treatment materials and full personal protective equipment; the driver and escort have professional hazardous chemical transport qualification certificates and first-aid training; sterile operation for loading/unloading of injection grade raw materials.

- **International Transport**: Comply with IATA/IMDG/ADR regulations for Class 6.1 toxic substances; apply for international hazardous chemical transport approval in advance; declare the nitrogen-containing and toxic characteristics to the customs and transport department; sterile cold chain transport for international shipment of injection grade raw materials.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China**:
  - Pharmaceutical Administration Law (pharmaceutical raw material for clinical anti-thrombotic use; injection grade as sterile pharmaceutical raw material, subject to national sterile drug management regulations)

- Hazardous Chemical Safety Management Regulation (Class 6.1 toxic substance, nitrogen-containing chemical)
- Chinese Pharmacopoeia (2025 Edition)
- GMP for Pharmaceutical Raw Materials (strict implementation standards; Class 10000 clean room for injection grade production)
- Occupational Disease Prevention and Control Law (special occupational protection for operators, focus on blood system protection)
- 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 anti-thrombotic use)
- REACH (EU) (registered; listed in SVHC Candidate List due to aquatic toxicity and nitrogen-containing characteristics)
- TSCA (US) (listed on the TSCA Inventory with strict use and environmental discharge restrictions)
- IATA/IMDG/ADR (Class 6.1 toxic substances transport regulations)
- FDA/EMA Approved (for acute cerebral infarction and myocardial infarction treatment in the US and Europe)

15.2 Other Requirements

- Production/sale/use limited to **licensed pharmaceutical enterprises** with GMP certification; injection grade raw materials are only supplied to enterprises with sterile drug production qualification; production and operation must comply with national anti-thrombotic drug management regulations and nitrogen-containing chemical management requirements.
- Occupational operation requires professional hazardous chemical (nitrogen-containing) and pharmaceutical production training and certification; sterile operation training for injection grade raw material handlers; operators must pass regular occupational health checkups (focus on blood routine, coagulation function, skin and ophthalmic system), and be transferred from the post if abnormal blood 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 (including sterile operation and cold chain transport records for injection grade).

SECTION 16: Other Information

- **MSDS Validity**: This MSDS is valid for 3 years from the revision date (26 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, especially the injection grade raw materials (strict sterile operation is required).
- **Additional Information**: For more technical/formulation data (only for clinical anti-thrombotic preparations), contact the supplier's technical department (+86-021-50350029 ext. 825) (only for licensed pharmaceutical enterprises with sterile drug production qualification).
- **Key Reminder**: This product is a **toxic nitrogen-containing anti-thrombotic pharmaceutical raw material with blood/gastrointestinal system damage risk, skin/eye irritation and aquatic toxicity**; any illegal production/sale/use/transport/disposal will be subject to severe legal liability in accordance with national and international laws. Its clinical use must follow standardized anti-thrombotic treatment guidelines and be administered under the supervision of neurologists and cardiologists, with strict monitoring of coagulation function during medication.