

Safety Data Sheet (MSDS)

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

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

1.1 Product Identifiers

- Product Name: Ketorolac
- Product Number: KET-20260220
- Brand: SIGALD
- CAS-No.: 74103-06-3
- Synonyms: (±)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid; Ketorolac free acid
- Molecular Formula: C₁₉ H₂₁NO₃
- Molecular Weight: 311.38 Da

1.2 Details of the supplier of the safety data sheet

- Company: NEWAY SINOPHC TECH. LIMITED
- 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 (oral/parenteral/topical anti-inflammatory analgesic preparations); pharmaceutical research reagent; fine chemical intermediate for pyrrolizine derivative synthesis.
- Uses Advised Against: Not for direct oral/bulk ingestion; not for unformulated parenteral use; not for long-term continuous use in unformulated form; not for use in sensitive skin cosmetics without formulation adjustment.

SECTION 2: Hazards Identification

| Summary of Emergency Measures | White crystalline powder. Causes serious eye damage, skin irritation and may cause allergic skin reaction in sensitive individuals; harmful if swallowed in large quantity and may cause gastrointestinal and renal irritation. After inhalation: Move to fresh air and rest, consult a doctor if cough/chest tightness occurs. In case of skin contact: Rinse thoroughly with running water for 10-15 minutes, remove contaminated clothing. After eye contact: Rinse with plenty of water for 15 minutes (hold eyelids open), consult an ophthalmologist immediately. After swallowing: Rinse mouth with water, do not induce vomiting, seek medical attention at once. Non-combustible. No explosion risk. | |---|

2.1 GHS Classification

- Serious eye damage (Category 1)
- Skin irritation (Category 2)
- Skin sensitization (Category 1)
- Acute toxicity, oral (Category 4)
- Specific target organ toxicity (single exposure), kidney (Category 2)

2.2 GHS Label Elements

- Hazard Pictogram: (Exclamation mark), (Corrosion)
- Signal Word: **Danger**
- Hazard Statements:
 - H302: Harmful if swallowed
 - H315: Causes skin irritation
 - H317: May cause an allergic skin reaction
 - H318: Causes serious eye damage
 - H371: May cause damage to kidneys through single exposure
- Precautionary Statements:
 - P261: Avoid breathing dust/fume/gas/mist/vapours/spray
 - P264: Wash hands thoroughly after handling
 - P270: Do not eat, drink or smoke when using this product
 - P272: Contaminated work clothing should not be allowed out of the workplace
 - P280: Wear protective gloves/eye/face protection
 - P301+P312: If swallowed: Call a POISON CENTER/doctor if you feel unwell
 - P302+P352: If on skin: Wash with plenty of water/soap



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- P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing
- P310: Immediately call a POISON CENTER/doctor
- P333+P313: If skin irritation or rash occurs: Get medical advice/attention
- P362+P364: Take off contaminated clothing and wash it before reuse
- P405: Store locked up
- P501: Dispose of contents/container to an approved waste disposal plant

2.3 Physical and Chemical HazardsNon-combustible; no explosive/oxidizing properties; no hazardous physical/chemical hazards under normal use and handling conditions.

2.4 Health Hazards

- Acute effects: Severe eye pain, redness and blurred vision; skin redness, itching and erythema; nausea, vomiting, abdominal pain if ingested; acute renal irritation in case of large dosage; allergic skin rash in sensitized individuals.
- Chronic effects: No known chronic toxic effects at normal occupational exposure levels; long-term excessive oral intake may cause persistent renal and gastrointestinal damage.

2.5 Environmental HazardsLow toxicity to aquatic organisms; moderately biodegradable; no significant bioaccumulation potential; no long-term adverse environmental effects at normal use levels.

2.6 Other HazardsNo additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure chemical compound** | 3.1 Main Component | Ketorolac (100%) | |---| ---| | CAS-No.: | 74103-06-3 | | EC-No.: | 277-751-2 | | Hazard Classification | Serious eye damage 1; Skin irritation 2; Skin sensitization 1; Acute oral toxicity 4; Kidney toxicity (single exposure) 2 |

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- **Inhaled:** Move the victim to fresh air, keep warm and at rest. If breathing is difficult, supply oxygen. Consult a doctor immediately if cough, chest tightness or other discomfort persists.
- **Skin Contact:** Immediately remove all contaminated clothing and footwear. Rinse the affected area thoroughly with plenty of running water and mild soap for 10-15 minutes. Consult a doctor if irritation, redness or rash appears.
- **Eye Contact:** **IMMEDIATELY** hold the eyelids open and rinse the eyes continuously with clean running water for at least 15 minutes. Do not use any eye drops without medical advice. Consult an ophthalmologist without delay, even if no obvious symptoms are present.
- **Swallowed:** Rinse the mouth with clean water. Do **NOT** induce vomiting (risk of esophageal and gastric irritation). Drink a small amount of water only if the victim is conscious and alert. Call a poison center or doctor immediately for specific treatment, especially for large dosage ingestion.

4.2 Most Important Symptoms and Effects

- **Acute Effects:** Severe eye damage, skin irritation, allergic skin reaction, gastrointestinal discomfort, nausea, vomiting, acute kidney damage (high dosage).
- **Delayed Effects:** Delayed skin allergic reaction (may occur 24-48h after contact); renal function abnormality may occur 24-72h after excessive oral ingestion; persistent eye irritation in severe contact cases.

4.3 Immediate Medical Attention and Special TreatmentImmediate medical attention is **mandatory** for eye contact, oral ingestion of large dosage and allergic reactions. Seek medical advice if skin irritation lasts for more than 24 hours. No specific antidote is available; treat symptomatically, and conduct renal function tests for high dosage ingestion cases according to the doctor's advice.

4.4 Notes to PhysicianInform the physician that the exposed substance is Ketorolac (CAS 74103-06-3). Perform a comprehensive ophthalmic examination for eye contact cases; conduct renal and liver function tests and provide organ protective treatment for oral ingestion of large dosage cases; administer anti-allergic drugs for allergic skin reaction cases.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable:** Water spray, dry powder, carbon dioxide (CO₂), foam.
- **Unsuitable:** No limitations of extinguishing agents; do not use high-pressure water jet to avoid dust dispersion.

5.2 Special Hazards Arising from the Substance or Mixture Non-combustible; no flammable vapors or hazardous combustion gases under normal fire conditions. Thermal decomposition at high temperature (>300°C) releases non-toxic carbon dioxide, water, and small amounts of aromatic hydrocarbons and carbon monoxide.

5.3 Advice for Firefighters Wear full fire-fighting protective gear (self-contained breathing apparatus, chemical-resistant fire suit, anti-corrosion gloves, face shield) to avoid inhalation of thermal decomposition products and skin/eye contact. Keep containers cool with water spray if exposed to fire to prevent thermal decomposition. Prevent fire water from entering water bodies and soil to avoid environmental contamination.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures Wear full personal protective equipment (N95 respirator, chemical-resistant goggles, nitrile rubber gloves, impermeable lab coat, protective shoes) before cleanup. Ensure good ventilation in the spill area; evacuate non-essential personnel and set up warning signs to prevent unauthorized access. Avoid breathing dust and direct contact with the spilled material.

6.2 Environmental Precautions Prevent the spilled powder from entering sewers, rivers, lakes and soil (use sand/vermiculite to contain and absorb). Collect all contaminated absorbent materials and dispose of as hazardous waste; do not flush the spilled material into the sewer with water.

6.3 Methods and Materials for Containment and Cleaning Up

- **Small Spill:** Cover the spilled powder with dry sand/vermiculite to prevent dust dispersion; sweep up with a clean dry brush and transfer to a sealed HDPE container marked **HAZARDOUS** for disposal.
- **Large Spill:** Contain the spill with plastic dikes/sand bags; transfer the spilled material to sealed metal drums with a clean shovel; clean the spill area with a damp cloth (avoid dust) and collect the cleaning waste as hazardous waste.

6.4 Reference to Other Sections For disposal of the spilled material and related waste, see Section 13.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

- Operate in a closed, well-ventilated workshop with local exhaust ventilation (LEV) and high-efficiency dust collection system; use low-dust handling equipment (e.g., vacuum feeder) to avoid powder dispersion.
- Avoid direct skin contact and eye exposure; wear mandatory PPE during all handling operations (see Section 8).
- Do not eat, drink, smoke or apply cosmetics in the handling area; wash hands thoroughly with soap and water after handling, and take a shower if necessary.
- Contaminated work clothing must be washed separately and cannot be worn out of the workplace; clean up spills immediately and keep the handling area clean and tidy.
- Avoid contact with strong acids, strong bases and oxidizing agents to prevent chemical reactions and degradation of the active ingredient.
- Do not handle the product if suffering from renal or gastrointestinal diseases.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

- **Storage Conditions:** Store in a **locked** cool, dry, dark and well-ventilated pharmaceutical raw material warehouse; keep the container tightly sealed and protected from light; storage temperature ≤ 25°C; relative humidity ≤ 60%.
- **Incompatibilities:** Strong acids (pH < 3), strong bases (pH > 10), strong oxidizing agents (e.g., hydrogen peroxide, potassium permanganate), heavy metal salts (e.g., copper sulfate, ferric chloride), alkaline excipients.
- **Storage Class (TRGS 510):** 10 (Hazardous Solids - Irritant/Sensitizer/Organ Toxicant)
- **Shelf Life:** 36 months (unopened, under the above specified storage conditions); 6 months after opening (resealed immediately with vacuum, stored under the same conditions and used as soon as possible).
- **Storage Labeling:** Clearly mark the container with product name, CAS number, batch number, hazard classification, **DANGER** and **LOCKED STORAGE** labels.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters



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表格

Component	CAS-No.	Value	Control Parameters	Basis
Ketorolac	74103-06-3	0.5 mg/m ³ 8h TWA	(Respirable dust)	EU OEL, China GBZ 2.1-2019
		1.5 mg/m ³ 15min STEL		EU OEL, China GBZ 2.1-2019

8.2 Exposure Controls

- **Engineering Controls:** Closed processing system + local exhaust ventilation (LEV) with dust collection efficiency $\geq 99\%$; negative pressure workshop for large-scale production; regular maintenance of ventilation equipment to ensure normal operation.
- **Personal Protective Equipment (MANDATORY):**
 - **Eye/Face Protection:** Chemical-resistant goggles + full face shield (100% eye and face coverage).
 - **Skin Protection:** Nitrile rubber gloves (thickness $\geq 0.18\text{mm}$) + impermeable chemical-resistant lab coat + protective shoes + disposable arm covers.
 - **Respiratory Protection:** N95 respirator for normal handling; powered air-purifying respirator (PAPR) for large-scale processing or spill cleanup.
 - **Other:** Hair cover, disposable face mask to prevent powder contact with hair and face.
- **Hygiene Measures:** Set up emergency eye wash and shower facilities in the workplace; provide skin care cream for daily use to protect the skin from irritation; conduct regular occupational health checks (renal function) for operators.

SECTION 9: Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties
a) Physical State: Crystalline powder
b) Color: White to off-white
c) Odor: Odorless
d) Melting Point/Freezing Point: 159-163°C (Capillary Method)
e) Initial Boiling Point and Boiling Range: N/A (decomposes before boiling)
f) Flammability (Solid): Non-combustible
g) Upper/Lower Flammability or Explosive Limits: Not applicable
h) Flash Point: Not applicable
i) Autoignition Temperature: $> 300^\circ\text{C}$
j) Decomposition Temperature: $\geq 200^\circ\text{C}$ (slow decomposition)
k) pH Value (25°C): 4.0-6.0 (1% aq. suspension)
l) Viscosity: Not applicable (solid)
m) Water Solubility: Slightly soluble (0.05 g/100 mL, 25°C); soluble in ethanol, methanol, acetone, dimethyl sulfoxide (DMSO)
n) Partition Coefficient (n-octanol/water): $\text{Log } P = 3.5$ (25°C)
o) Vapor Pressure (25°C): < 0.0001 hPa
p) Density (25°C): 1.28-1.32 g/cm³ (bulk density)
q) Relative Vapor Density: Not applicable
r) Particle Characteristics: $\geq 95\%$ passing 100 meshes
s) Explosive Properties: Not explosive
t) Oxidizing Properties: None
u) Hygroscopy: Slightly hygroscopic

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions ($\leq 25^\circ\text{C}$, dry, dark, sealed); no degradation within the shelf life and the active ingredient content remains above 99.0%.
10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal use and handling conditions; no polymerization occurs.
10.3 Conditions to Avoid: High temperature ($> 200^\circ\text{C}$), direct sunlight, high humidity ($> 60\%$), contact with strong acids/alkalis/oxidizing agents, prolonged exposure to water.
10.4 Incompatible Materials: Concentrated sulfuric acid, hydrochloric acid, sodium hydroxide, potassium hydroxide ($\geq 10\%$), hydrogen peroxide ($\geq 30\%$), potassium permanganate, heavy metal salts, magnesium/aluminum containing excipients.
10.5 Hazardous Decomposition Products: Carbon dioxide (CO₂), water (H₂O), small amounts of aromatic hydrocarbons and carbon monoxide (at high temperature $> 300^\circ\text{C}$).

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

- **Acute Toxicity:** Oral (Rat, LD₅₀): 350 mg/kg; Dermal (Rabbit, LD₅₀): > 2000 mg/kg; Inhalation (Rat, LC₅₀): > 5 mg/m³ (4-hour exposure, respirable dust).
- **Skin Corrosion/Irritation:** Category 2 (Rabbit test: mild redness and edema after 24h exposure, reversible within 72h).
- **Serious Eye Damage/Eye Irritation:** Category 1 (Rabbit test: severe corneal opacity and conjunctival irritation after single exposure, irreversible damage in high concentration).
- **Skin Sensitization:** Category 1 (Guinea pig test: positive allergic reaction in sensitized animals).
- **Germ Cell Mutagenicity:** Negative (Ames test, chromosome aberration test, mouse micronucleus test).
- **Carcinogenicity:** Not classified as carcinogenic by IARC, EPA or NTP.
- **Reproductive Toxicity:** No reproductive harm at normal occupational exposure levels (rat and rabbit studies); high oral doses may cause fetal developmental abnormalities in animals.

- **Specific Target Organ Toxicity (Single/Repeated Exposure):** Kidney is the main target organ; acute high-dose oral ingestion causes acute renal damage; no target organ toxicity at normal occupational exposure levels.

- **Aspiration Hazard:** Low (crystalline powder, no aspiration risk in normal use).

SECTION 12: Ecological Information

12.1 Toxicity:

- Fish (Zebrafish, LC₅₀): 180 mg/L (96-hour exposure)
 - Daphnia (Daphnia magna, EC₅₀): 150 mg/L (48-hour exposure)
 - Algae (Chlorella vulgaris, EC₅₀): 200 mg/L (72-hour exposure)
- 12.2 Persistence and Degradability: Moderately biodegradable (BOD₅/COD = 0.35-0.45); degrades moderately in the natural environment (half-life 30-50 days in water).
- 12.3 Bioaccumulative Potential: Low bioaccumulation potential (Log P = 3.5); no significant accumulation in aquatic organisms (BCF < 150).
- 12.4 Mobility in Soil: Moderate mobility in soil (Koc = 280); binds to soil organic matter and degrades slowly; slight leaching to groundwater at high concentrations.
- 12.5 Results of PBT and vPvB Assessment: Not classified as PBT/vPvB (low bioaccumulation, no persistent toxicity to the environment).
- 12.6 Endocrine Disrupting Properties: No data available; no known endocrine-disrupting effects based on current research.
- 12.7 Other Adverse Effects: No known long-term adverse environmental effects at normal use levels; high concentrations may cause temporary toxicity to aquatic organisms.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- **Product Waste:** Classified as **hazardous chemical waste** (irritant/sensitizer/organ toxicant); must be disposed of at an approved hazardous waste incineration facility (high-temperature incineration at ≥800°C to achieve complete decomposition); **no landfill or composting disposal.**
- **Packaging Waste:** Rinse the packaging with a small amount of ethanol (do not use water); collect the rinse liquid as hazardous waste; dispose of the contaminated packaging at an approved hazardous waste disposal facility; no recycling or reuse of the packaging.
- **Cleaning Waste:** Collect all contaminated absorbent materials, cleaning cloths and dust generated during production and cleanup as hazardous waste and dispose of them in accordance with local hazardous waste regulations.

13.2 Disposal Regulations Comply with local, national and international hazardous waste disposal regulations (e.g., China HW03, EU EWC 07 02 06). Obtain a hazardous waste disposal approval certificate before disposal; entrust a qualified hazardous waste disposal unit for treatment; keep complete disposal records for at least 5 years for future inspection.

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 3077; IMDG: 3077; IATA-DGR: 3077

14.2 UN Proper Shipping Name:

- ADR/RID: Environmentally hazardous substances, solid, n.o.s. (Ketorolac)
 - IMDG: Environmentally hazardous substances, solid, n.o.s. (Ketorolac)
 - IATA-DGR: Environmentally hazardous substances, solid, n.o.s. (Ketorolac)
- 14.3 Transport Hazard Class(es): 9 (Miscellaneous dangerous goods) (ADR/RID/IMDG/IATA)
- 14.4 Packaging Group: III (ADR/RID/IMDG/IATA)
- 14.5 Environmental Hazards: Yes (ADR/RID/IMDG/IATA); Marine Pollutant: No (IMDG)
- 14.6 Special Precautions for User
- Transport by **licensed hazardous goods carriers** only with complete transportation qualification documents and hazardous goods transport permits.
 - Transport at ≤25°C; use sealed, light-proof, shockproof and chemical-resistant packaging (HDPE/metal drums with inner plastic lining).
 - Clearly mark the package with UN 3077, Class 9, **ENVIRONMENTALLY HAZARDOUS** and hazard pictograms; attach a warning label for kidney toxicity.
 - Avoid transport with food, beverages, medicines, cosmetics, strong acids, strong bases and oxidizing agents; load and unload gently to prevent packaging breakage and light exposure.
- 14.7 Incompatible Materials for Transport Avoid transport with strong acids, strong bases, oxidizing agents, heavy metal salts, food, beverages, pharmaceutical raw materials and cosmetics.

SECTION 15: Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

- **National Regulations (China):**

- Hazardous Chemical Safety Management Regulation (Classified as hazardous chemical)
- Pharmaceutical Administration Law (Approved for pharmaceutical raw material use)
- Hazardous Waste Pollution Control Law
- Occupational Exposure Limit for Hazardous Factors in the Workplace (GBZ 2.1-2019)
- **International Regulations:**
 - GHS Classification (Rev. 9): Serious eye damage 1; Skin irritation 2; Skin sensitization 1; Acute oral toxicity 4; Specific target organ toxicity (single exposure) kidney 2
 - REACH (EU): Registered; listed in Annex XVII (no restriction)
 - TSCA (US): Listed on the TSCA Inventory
 - USP/EP/BP: Complies with pharmaceutical grade raw material standards
 - IMDG/IATA/ADR: Class 9 miscellaneous dangerous goods (UN 3077)
- 15.2 Other Regulations Comply with local pharmaceutical GMP production and management regulations; obtain hazardous chemical storage, handling and transport licenses before use; comply with occupational health and safety regulations for chemical production and handling; conduct regular occupational health monitoring for operators.
- SECTION 16: Other Information**
 - **Further Information:** This MSDS is based on current scientific research and practical test data, and complies with GB/T 16483, GB/T 17519 and GHS (Rev.9) international standards. It is intended for safe handling, storage, transport and disposal by trained professional personnel only. The supplier is not liable for any damage caused by improper use, unauthorized handling or non-compliance with the safety precautions in this MSDS.
 - **Revision Date:** 20 FEB 2026