



# 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)

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

#### 1.1 Product Identifiers

- Product Name: Diclofenac Sodium
- Product Number: DS-20260205
- Brand: SIGALD
- CAS-No.: 15307-79-6
- Synonyms: Sodium 2-[(2,6-dichlorophenyl)amino]benzoate; Diclofenac sodium salt
- Molecular Formula:  $C_{14}H_{10}Cl_2NNaO_2$
- Molecular Weight: 318.13 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/topical/injectable anti-inflammatory analgesic preparations); pharmaceutical research reagent; fine chemical intermediate for diclofenac derivatives.
- Uses Advised Against: Not for direct oral/bulk ingestion; not for unformulated injectable use in humans/animals; not for use in infant products without professional approval; 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; harmful if swallowed in large quantity; may cause gastrointestinal irritation if ingested. 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)



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- Acute toxicity, oral (Category 4)
- 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
- 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
  - 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/blurred vision; skin redness/itching/erythema; nausea/vomiting/abdominal pain if ingested; allergic rash in sensitized individuals.
  - Chronic effects: No known chronic toxic effects at normal occupational exposure; long-term skin contact may cause persistent irritation.
- 2.5 Environmental HazardsLow toxicity to aquatic organisms; not readily 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



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- Substance / Mixture: **Pure chemical compound** | 3.1 Main Component | Diclofenac Sodium (100%) | |---|---| | CAS-No.: | 15307-79-6 | | EC-No.: | 239-349-9 | | Hazard Classification | Serious eye damage 1; Skin irritation 2; Skin sensitization 1; Acute oral toxicity 4 |

## SECTION 4: First Aid Measures

### 4.1 First-Aid Measures

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

### 4.2 Most Important Symptoms

- Acute: Severe eye damage, skin irritation, allergic skin reaction, gastrointestinal discomfort, nausea, vomiting.
- Delayed: Delayed skin allergic reaction (24-48h after contact), persistent eye irritation (severe cases).

### 4.3 Immediate Medical Attention Mandatory medical attention for **eye contact** and **oral ingestion**; seek medical advice for skin irritation/rash lasting more than 24h.

4.4 Notes to Physician Inform the physician the exposed substance is diclofenac sodium (CAS 15307-79-6); perform ophthalmic examination for eye contact; provide gastrointestinal protectant for oral ingestion (symptomatic treatment only, no specific antidote).

## SECTION 5: Firefighting Measures

### 5.1 Extinguishing Media

- **Suitable:** Water spray, dry powder, carbon dioxide (CO<sub>2</sub>), foam.
- **Unsuitable:** No limitations; do not use high-pressure water jet (avoids dust dispersion).

5.2 Special Hazards Non-combustible; no flammable vapors. Thermal decomposition at >300°C releases non-toxic CO<sub>2</sub>, water, and small amounts of hydrogen chloride (HCl) gas, sodium oxide and aromatic amines.

5.3 Advice for Firefighters Wear full fire-fighting PPE (self-contained breathing apparatus, chemical-resistant suit, gloves); keep containers cool with water spray if exposed to fire; prevent fire water from entering water bodies/soil.

## SECTION 6: Accidental Release Measures



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6.1 Personal PrecautionsWear full PPE (N95 respirator, chemical-resistant goggles, nitrile gloves, impermeable lab coat); evacuate non-essential personnel; ensure good ventilation; avoid breathing dust and direct contact.

6.2 Environmental PrecautionsPrevent spilled powder from entering sewers/rivers/soil (contain with sand/vermiculite); do not flush with water (avoids groundwater contamination).

### 6.3 Cleaning Up

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

## SECTION 7: Handling and Storage

### 7.1 Safe Handling

- Operate in a closed, well-ventilated workshop with local exhaust ventilation (LEV) and dust collection; use low-dust equipment (vacuum feeder) to avoid powder dispersion.
- Wear mandatory PPE during all operations (see Section 8); no eating/drinking/smoking in the handling area; wash hands/shower after handling.
- Contaminated clothing must be washed separately and not worn outside the workplace; clean up spills **immediately**.
- Avoid contact with strong acids, strong bases and oxidizing agents to prevent chemical reactions.

### 7.2 Safe Storage

- **Conditions:** Store in a **locked**, cool, dry, dark and well-ventilated pharmaceutical warehouse; tightly sealed, light-proof; storage temperature  $\leq 25^{\circ}\text{C}$ ; relative humidity  $\leq 60\%$ .
- **Incompatibilities:** Strong acids ( $\text{pH} < 3$ ), strong bases ( $\text{pH} > 10$ ), oxidizing agents ( $\text{H}_2\text{O}_2$ ,  $\text{KMnO}_4$ ), heavy metal salts.
- **Storage Class (TRGS 510):** 10 (Hazardous Solids - Irritant/Sensitizer)
- **Shelf Life:** 36 months (unopened, specified conditions); 6 months after opening (resealed vacuum/light-proof).
- **Labeling:** Clearly mark with product name, CAS, batch number, hazard classification, **DANGER** and **LOCKED STORAGE** labels.

## SECTION 8: Exposure Controls/Personal Protection

### 8.1 Control Parameters

表格

Component	CAS-No.	Value	Control Parameters	Basis
Diclofenac Sodium	15307-79-6	0.5 mg/m <sup>3</sup> 8h TWA	(Respirable dust)	EU OEL, China GBZ 2.1-2019
		1.5 mg/m <sup>3</sup> 15min STEL		EU OEL, China GBZ 2.1-2019

### 8.2 Exposure Controls



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- **Engineering Controls:** Closed processing system + LEV (dust collection efficiency  $\geq 99\%$ ); negative pressure workshop for large-scale production.
- **Personal Protective Equipment (MANDATORY):**
  - Eye/Face: Chemical-resistant goggles + full face shield (100% coverage).
  - Skin: Nitrile rubber gloves ( $\geq 0.18\text{mm}$ ) + impermeable lab coat + protective shoes + disposable arm covers.
  - Respiratory: N95 respirator (normal handling); powered air-purifying respirator (PAPR) for spills/large-scale processing.
  - Other: Hair cover, disposable face mask (prevent powder contact).
- **Hygiene:** Equip workplace with emergency eye wash/shower; provide skin care cream for daily use.

## SECTION 9: Physical and Chemical Properties

9.1 Basic Properties  
a) Physical State: Crystalline powder  
b) Color: White to off-white  
c) Odor: Odorless  
d) Melting Point:  $283\text{-}285^\circ\text{C}$  (Capillary Method)  
e) Flammability: Non-combustible  
f) Flash Point: Not applicable  
g) Decomposition Temperature:  $\geq 200^\circ\text{C}$  (slow decomposition)  
h) pH Value ( $25^\circ\text{C}$ ):  $7.0\text{-}8.5$  (1% aq. solution)  
i) Water Solubility: **Freely soluble** (50 g/100 mL,  $25^\circ\text{C}$ ); soluble in ethanol, methanol, slightly soluble in acetone  
j) Partition Coefficient (Log P): 3.9 ( $25^\circ\text{C}$ )  
k) Vapor Pressure ( $25^\circ\text{C}$ ):  $< 0.0001$  hPa  
l) Bulk Density:  $1.40\text{-}1.45$  g/cm<sup>3</sup>  
m) Particle Size:  $\geq 95\%$  passing 100 mesh  
n) Hygroscopy: Slightly hygroscopic  
o) Explosive/Oxidizing Properties: None

## 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 shelf life.  
10.2 Hazardous Reactions: No hazardous reactions under normal use; no polymerization occurs.  
10.3 Conditions to Avoid: High temperature ( $> 200^\circ\text{C}$ ), direct sunlight, high humidity ( $> 60\%$ ), strong acids/alkalis/oxidizing agents.  
10.4 Incompatible Materials: Concentrated  $\text{H}_2\text{SO}_4/\text{HCl}$ ,  $\text{NaOH}/\text{KOH}$  ( $\geq 10\%$ ),  $\text{H}_2\text{O}_2$  ( $\geq 30\%$ ),  $\text{KMnO}_4$ , copper sulfate/ferric chloride.  
10.5 Decomposition Products:  $\text{CO}_2$ ,  $\text{H}_2\text{O}$ , small amounts of HCl gas, sodium oxide and aromatic amines (at  $> 300^\circ\text{C}$ ).

## SECTION 11: Toxicological Information

### 11.1 Toxicological Effects

- **Acute Toxicity:** Oral (Rat,  $\text{LD}_{50}$ ): 150 mg/kg; Dermal (Rabbit,  $\text{LD}_{50}$ ):  $> 2000$  mg/kg; Inhalation (Rat,  $\text{LC}_{50}$ ):  $> 5$  mg/m<sup>3</sup> (4h).
- **Skin Irritation:** Category 2 (mild redness/edema, reversible within 72h).
- **Eye Damage:** Category 1 (severe corneal opacity, irreversible damage in high concentration).
- **Skin Sensitization:** Category 1 (positive allergic reaction in guinea pig tests).
- **Mutagenicity:** Negative (Ames test, chromosome aberration test).
- **Carcinogenicity:** Not classified by IARC/EPA/NTP.
- **Reproductive Toxicity:** No harm at normal exposure; high oral doses may cause fetal developmental abnormalities in animals.



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- **Target Organ Toxicity:** No target organ toxicity at normal exposure; long-term high-dose oral use may cause liver/kidney damage in animals.

### SECTION 12: Ecological Information

12.1 Toxicity: Zebrafish LC<sub>50</sub> : 100 mg/L (96h); Daphnia EC<sub>50</sub> : 85 mg/L (48h); Algae EC<sub>50</sub> : 135 mg/L (72h).12.2 Persistence: Not readily biodegradable (BOD<sub>5</sub> /COD <0.2); half-life >60 days in water.12.3 Bioaccumulation: Low potential (Log P=3.9, BCF <100); no accumulation in aquatic organisms.12.4 Soil Mobility: Moderate (Koc=290); binds to soil organic matter, no leaching to groundwater.12.5 PBT/vPvB: Not classified (low bioaccumulation, no persistent toxicity).12.6 Other: No known long-term adverse environmental effects at normal use levels.

### SECTION 13: Disposal Considerations

#### 13.1 Waste Treatment

- **Product Waste:** Classified as **hazardous chemical waste**; dispose at approved hazardous waste incineration facilities (≥800°C for complete decomposition); **no landfill/composting**.
- **Packaging Waste:** Rinse with small amount of ethanol (no water); collect rinse liquid as hazardous waste; dispose contaminated packaging at approved facilities (no recycling/reuse).
- **Cleaning Waste:** Collect all absorbent materials/cloths/dust as hazardous waste and dispose per local regulations.

13.2 Disposal Regulations Comply with local/national/international hazardous waste regulations (China HW03, EU EWC 07 02 06); entrust qualified disposal units; keep records for at least 5 years.

### SECTION 14: Transport Information

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

- Transport by **licensed hazardous goods carriers** with complete qualification documents.
- Transport at ≤25°C; use sealed, light-proof, shockproof chemical-resistant packaging (HDPE/metal drums with inner plastic lining).
- Mark packages with UN 3077, Class 9, **ENVIRONMENTALLY HAZARDOUS** and hazard pictograms; attach marine pollutant label for sea transport.
- Avoid transport with food/beverages/medicines/cosmetics/strong acids/alkalis; load/unload gently to prevent breakage.

### SECTION 15: Regulatory Information

#### 15.1 National/International Regulations

- **China:** Hazardous Chemical Safety Management Regulation; Pharmaceutical Administration Law; GBZ 2.1-2019 (Occupational Exposure Limit).



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- **International:** GHS Rev.9; REACH (EU, registered); TSCA (US, listed); USP/EP/BP (pharmaceutical grade compliant); IMDG/IATA/ADR (Class 9 UN 3077).15.2 Other: Comply with pharmaceutical GMP regulations; obtain hazardous chemical storage/handling/transport licenses before use.

### SECTION 16: Other Information

- **Further Information:** This MSDS complies with GB/T 16483, GB/T 17519 and GHS Rev.9. For use by trained professional personnel only. Supplier is not liable for damage caused by improper use/non-compliance with safety precautions.
- **Revision Date:** 05 FEB 2026

