



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 Diethylamine
- Product Number: DDE-20260205
- Brand: SIGALD
- CAS-No.: 78213-16-8
- Synonyms: Diethylamine diclofenac; 2-[(2,6-Dichlorophenyl)amino]benzeneacetic acid diethylamine salt
- Molecular Formula: $C_{18}H_{22}ClNO_2$
- Molecular Weight: 319.83 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 of the Substance or Mixture and Uses Advised Against

- Identified Uses: Pharmaceutical raw material (topical anti-inflammatory analgesic preparations); topical medicinal cosmetic ingredient; medical device auxiliary material; research reagent.
- Uses Advised Against: Not for oral administration in bulk; not for intravenous/intramuscular injection without pharmaceutical formulation; not for use in infant products without professional approval; not for use in cosmetic products for sensitive skin without formulation adjustment.

SECTION 2: Hazards Identification

| Summary of Emergency Measures | White crystalline powder. Causes skin irritation and serious eye irritation; may cause allergic skin reaction in sensitive individuals; harmful if swallowed in large quantity. 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 a doctor 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

- Skin irritation (Category 2)



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- Serious eye damage (Category 1)
- Skin sensitization (Category 1)
- 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
 - P321: Specific treatment (see supplementary first aid notes)
 - 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 HazardsBased on current information: Non-combustible; no explosive/oxidizing properties; no hazardous physical/chemical hazards under normal use and handling conditions.

2.4 Health Hazards

- Acute effects: Skin irritation (redness, itching, erythema); serious eye damage (corneal irritation, redness, blurred vision); allergic skin reaction in sensitive people; gastrointestinal discomfort, nausea, vomiting if swallowed.
- Chronic effects: No known chronic toxic effects at normal occupational exposure levels; long-term skin contact may cause persistent irritation.

2.5 Environmental Hazards



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- Low toxicity to aquatic organisms (Zebrafish LC₅₀ > 100 mg/L, 96h); not readily biodegradable; no bioaccumulation potential (Log P = 3.2); no long-term adverse environmental effects at normal use levels.

2.6 Other Hazards No additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: Pure substance (single chemical compound) | 3.1 Main Component | Diclofenac Diethylamine (100%) | |---|---| | CAS-No.: | 78213-16-8 | | EC-No.: | 278-856-0 | | Hazard Classification | Skin Irrit. 2; Eye Dam. 1; Skin Sens. 1; Acute Tox. 4 (oral) |

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- **If Inhaled:** Move the victim to fresh air, keep warm and at rest. If breathing is difficult, give oxygen. Consult a doctor immediately if cough, chest tightness or other symptoms occur.
- **In Case of 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. If irritation, rash or redness occurs, consult a doctor and apply topical anti-irritant ointment as directed.
- **In Case of Eye Contact:** **IMMEDIATELY** hold the eyelids open and rinse the eyes continuously with plenty of clean running water for at least 15 minutes. Do not use eye drops without medical advice. Consult an ophthalmologist immediately, even if no symptoms appear.
- **If Swallowed:** Rinse the mouth with clean water and 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 or doctor immediately for specific treatment.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed

- **Acute Effects:** Skin redness, itching, irritation; severe eye pain, redness, blurred vision; nausea, vomiting, abdominal pain (if swallowed); allergic skin rash (in sensitized individuals).
- **Delayed Effects:** Delayed skin allergic reaction (may occur 24-48h after contact); persistent eye irritation (in severe cases).

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

- Immediate medical attention is required for eye contact and oral ingestion.
- For skin contact, seek medical advice if irritation or rash persists for more than 24 hours.
- No specific antidote; treat symptomatically according to the doctor's advice (e.g., gastrointestinal protectant for oral ingestion, topical anti-inflammatory for skin irritation).

4.4 Notes to Physician

- Inform the physician that the exposed substance is diclofenac diethylamine (CAS 78213-16-8).
- For eye contact: Perform ophthalmic examination to rule out corneal damage.
- For oral ingestion: Monitor gastrointestinal function and provide symptomatic support treatment.

SECTION 5: Firefighting Measures



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5.1 Extinguishing Media

- **Suitable Extinguishing Media:** Water spray, dry powder, carbon dioxide (CO₂), foam.
- **Unsuitable Extinguishing Media:** 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 generated under normal fire conditions.
- Thermal decomposition at high temperature (>300°C) releases non-toxic carbon dioxide, water, and small amounts of hydrogen chloride gas and amine compounds.

5.3 Advice for Firefighters

- Wear full fire-fighting protective gear (self-contained breathing apparatus, fire suit, chemical-resistant gloves, face shield) to avoid inhalation of 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; 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 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 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 shower if necessary.
- Contaminated work clothing must be washed separately and cannot be worn out of the workplace; keep the handling area clean and tidy, and clean up spills immediately.
- Avoid contact with strong acids, strong bases and oxidizing agents to prevent chemical reactions.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

- **Storage Conditions:** Store in a **locked** cool, dry, dark and well-ventilated warehouse; keep the container tightly sealed and protected from light; storage temperature $\leq 25^{\circ}\text{C}$; relative humidity $\leq 60\%$.
- **Incompatibilities:** Strong acids ($\text{pH} < 3$), strong bases ($\text{pH} > 10$), strong oxidizing agents (e.g., hydrogen peroxide, potassium permanganate), heavy metal salts (e.g., copper sulfate, ferric chloride).
- **Storage Class (TRGS 510):** 10 (Hazardous Solids - Irritant/Sensitizer)
- **Shelf Life:** 36 months (unopened, under the above specified storage conditions); 6 months after opening (resealed immediately, stored under the same conditions and used as soon as possible).
- **Storage Labeling:** Clearly mark the container with product name, CAS 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	78213-16-	0.5	8h TWA (Respirable	EU OEL, China GBZ 2.1-
Diethylamine	8	mg/m ³	dust)	2019
		1.5	15min STEL	EU OEL, China GBZ 2.1-
		mg/m ³		2019

8.2 Exposure Controls

- **Engineering Controls:** Closed processing system + local exhaust ventilation (LEV) with high-efficiency dust collection (efficiency $\geq 99\%$); negative pressure workshop for large-scale production; regular maintenance of ventilation equipment to ensure normal operation.
- **Personal Protective Equipment (PPE): MANDATORY** for all handling operations:

- **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 mask to prevent powder contact with hair and face.
- **Hygiene Measures:** Set up hand washing facilities and emergency eye wash/shower in the workplace; provide skin care cream for daily use to protect the skin.

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: 145-150°C
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): 6.0-7.5 (1% aq. solution)
l) Viscosity: Not applicable (solid)
m) Water Solubility: Soluble in water (10 g/100 mL, 25°C); soluble in ethanol, methanol, propylene glycol
n) Partition Coefficient (n-octanol/water): Log P = 3.2 (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

9.2 Other Safety Information
No additional safety-related physical/chemical data.

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 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.
10.4 Incompatible Materials: Concentrated sulfuric acid, hydrochloric acid, sodium hydroxide, potassium hydroxide, hydrogen peroxide ($\geq 30\%$), potassium permanganate, heavy metal salts.
10.5 Hazardous Decomposition Products: Carbon dioxide (CO₂), water (H₂O), hydrogen chloride (HCl) gas, diethylamine, and small amounts of aromatic hydrocarbons (at high temperature $> 300^\circ\text{C}$).

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

- **Acute Toxicity:**
 - Oral (Rat, LD₅₀): 150 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).
- **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):** No target organ toxicity at normal exposure levels; long-term high-dose oral administration may cause liver and kidney damage in animals.
- **Aspiration Hazard:** Low (crystalline powder, no aspiration risk in normal use).

11.2 Additional Information The toxicological properties have been sufficiently studied for pharmaceutical and industrial use; the main hazards are skin/eye irritation and skin sensitization, with low inhalation toxicity.

SECTION 12: Ecological Information

12.1 Toxicity:

- Fish (Zebrafish, LC₅₀): 120 mg/L (96-hour exposure)
 - Daphnia (Daphnia magna, EC₅₀): 85 mg/L (48-hour exposure)
 - Algae (Chlorella vulgaris, EC₅₀): 150 mg/L (72-hour exposure)
- 12.2 Persistence and Degradability: Not readily biodegradable (BOD₅/COD < 0.2); degrades slowly in the environment (half-life > 60 days in water).
- 12.3 Bioaccumulative Potential: Low bioaccumulation potential (Log P = 3.2); no accumulation in aquatic organisms (BCF < 100).
- 12.4 Mobility in Soil: Moderate mobility in soil (Koc = 250); binds to soil organic matter and degrades slowly; no leaching to groundwater.
- 12.5 Results of PBT and vPvB Assessment: Not classified as PBT/vPvB (low bioaccumulation, no persistent toxicity).
- 12.6 Endocrine Disrupting Properties: No data available; no known endocrine-disrupting effects.
- 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); must be disposed of at an approved hazardous waste incineration facility (high-temperature incineration at ≥800°C to decompose completely); no landfill or composting disposal.



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- **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 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 disposal 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:

- ADR/RID: Environmentally hazardous substances, solid, n.o.s. (Diclofenac Diethylamine)
- IMDG: Environmentally hazardous substances, solid, n.o.s. (Diclofenac Diethylamine)
- IATA-DGR: Environmentally hazardous substances, solid, n.o.s. (Diclofenac Diethylamine)

14.3 Transport Hazard Class(es):

- ADR/RID: 9 (Miscellaneous dangerous goods)
 - IMDG: 9 (Miscellaneous dangerous goods)
 - IATA-DGR: 9 (Miscellaneous dangerous goods)
- 14.4 Packaging Group: ADR/RID: III; IMDG: III; IATA-DGR: III
- 14.5 Environmental Hazards: ADR/RID: Yes; IMDG Marine Pollutant: Yes; IATA-DGR: Yes
- 14.6 Special Precautions for User:

- Transport by **licensed hazardous goods carriers** only with complete transportation qualification documents.
 - Transport at $\leq 25^{\circ}\text{C}$; 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 marine pollutant label for sea transport.
 - Avoid transport with food, beverages, medicines, cosmetics, strong acids, strong bases and oxidizing agents; load and unload gently to prevent packaging breakage.
- 14.7 Incompatible Materials: Avoid transport with strong acids, strong bases, oxidizing agents, heavy metal salts and food/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 use)
 - Hazardous Waste Pollution Control Law



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- Occupational Exposure Limit for Hazardous Factors in the Workplace (GBZ 2.1-2019)
- **International Regulations:**
 - GHS Classification (Rev. 9): Skin Irrit. 2; Eye Dam. 1; Skin Sens. 1; Acute Tox. 4 (oral)
 - REACH (EU): Registered; listed in Annex XVII (no restriction)
 - TSCA (US): Listed on the TSCA Inventory
 - USP/EP/BP: Complies with pharmaceutical grade standards
 - IMDG/IATA/ADR: Class 9 miscellaneous dangerous goods (UN 3077)
 - EU Ecolabel: Not applicable (not readily biodegradable)
- 15.2 Other Regulations: Comply with local pharmaceutical GMP regulations; comply with occupational health and safety regulations for chemical handling; obtain hazardous chemical storage/handling/transport licenses before use.

SECTION 16: Other Information

- **Further Information:** This MSDS is based on current scientific knowledge and complies with GB/T 16483, GB/T 17519 and GHS (Rev.9) 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:** 05 FEB 2026

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