



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)

Product Name: Tapentadol Hydrochloride CAS-No.: 143562-04-5 **Product Number: TAP-20260228** **Brand: SIGALD** **Revision Date: 28 FEB 2026**

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

1.1 Product Identifiers

- Product Name: Tapentadol Hydrochloride
- Synonyms: (1R,2R)-3-(3-Dimethylamino-1-ethyl-2-methylpropyl)phenol hydrochloride; Nucynta
- CAS-No.: 143562-04-5
- MDL Number: MFCD09743645

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 for the production of centrally acting analgesic drugs.
- Uses Advised Against: Not for direct human consumption, cosmetic, food or industrial non-pharmaceutical use; keep away from children and unauthorized personnel.

SECTION 2: Hazards Identification

Summary of Emergency Measures	White crystalline powder. Harmful if swallowed. Causes serious eye irritation. May cause respiratory depression if inhaled in large amounts. After inhalation: Move to fresh air, give oxygen if needed. In case of skin contact: Rinse skin with water. After eye contact: Rinse with plenty of water for 5-10 minutes; consult a doctor if irritation persists. After swallowing: Rinse mouth with water; do not induce vomiting; consult a doctor immediately. Non-combustible. No risk of explosion.
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2.1 GHS Classification

- Acute oral toxicity (Category 4) - H302
- Serious eye irritation (Category 2) - H319
- Specific target organ toxicity (single exposure) - Respiratory depression (Category 3) - H335

2.2 GHS Label Elements

- Hazard Pictogram: (Exclamation mark)
- Signal Word: WARNING
- Hazard Statements:



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- H302: Harmful if swallowed
- H319: Causes serious eye irritation
- H335: May cause respiratory irritation/depression
- Precautionary Statements:
 - P261: Avoid breathing dust/fume/gas/mist/vapours/spray
 - P264: Wash skin thoroughly after handling
 - P270: Do not eat, drink or smoke when using this product
 - P280: Wear eye/face protection, protective gloves
 - P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 - P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 - P337+P313: If eye irritation persists: Get medical advice/attention
 - P340: Remove to fresh air and rest in a position comfortable for breathing

2.3 Physical and Chemical HazardsBased on current information: No flammable, explosive, corrosive or oxidizing properties identified.

2.4 Health HazardsBased on current information: Harmful if swallowed; causes serious eye irritation; may cause mild respiratory depression/irritation if inhaled in large amounts; no skin irritation or sensitization identified; long-term occupational exposure has no known chronic health hazards.

2.5 Environmental HazardsBased on current information: Low aquatic toxicity; fully biodegradable; no adverse effects on aquatic organisms and the environment at normal use levels.

2.6 Other HazardsNo additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: Pure Chiral Chemical
- Active Ingredient: Tapentadol Hydrochloride (100%, w/w)
- CAS-No.: 143562-04-5
- EC-No.: 600-555-2
- No hazardous impurities present (all impurities meet pharmaceutical grade standards)

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move victim to fresh air immediately. Rest in a position comfortable for breathing. Administer oxygen if breathing is difficult. Consult a doctor immediately if cough, dizziness or shortness of breath occurs.
- In Case of Skin Contact: Rinse skin with plenty of running water for 5-10 minutes. Remove contaminated clothing; wash clothing before reuse. No special treatment needed for mild contact.



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- In Case of Eye Contact: Rinse eyes thoroughly with plenty of running water for 15-20 minutes. Remove contact lenses if present. Consult a doctor immediately if irritation, redness, tearing or blurred vision persists.

- If Swallowed: Do not induce vomiting. Rinse mouth with water. Call a poison center or doctor immediately. Do not give anything by mouth to an unconscious person.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed

- Acute Effects: Nausea, vomiting, abdominal pain, dizziness, drowsiness, eye redness/irritation, mild respiratory depression.

- Delayed Effects: No known delayed toxic effects based on current data.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

No specific medical treatment required; treat symptomatically (e.g., oxygen supply for respiratory depression) if needed.

4.4 Notes to Physician

Inform the physician of the product composition and symptoms if medical consultation is required.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO₂), dry powder.
- Unsuitable Extinguishing Media: No limitations of extinguishing agents.

5.2 Special Hazards Arising from the Substance or Mixture

Non-combustible; no hazardous combustion gases generated under normal fire conditions. Thermal decomposition at high temperature may produce small amounts of nitrogen oxides, hydrogen chloride and carbon oxides.

5.3 Advice for Firefighters

Wear standard fire-fighting gear and self-contained breathing apparatus (SCBA) to avoid inhalation of thermal decomposition products. Keep containers cool with water spray during fire.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Wear N95 dust mask, chemical splash goggles and nitrile rubber gloves. Ensure good ventilation in the spill area. Evacuate non-essential personnel if large spills occur.

6.2 Environmental Precautions

Prevent spilled material from entering drains, sewers, rivers or other water bodies. Contain the spill to avoid environmental contamination.

6.3 Methods and Materials for Containment and Cleaning Up

- Small Spill: Sweep up with inert absorbent materials (e.g., sand, diatomaceous earth) and place in a sealed plastic container for proper disposal.
- Large Spill: Contain with dikes; transfer to sealed HDPE drums using a vacuum pump. Do not wash the spill into drains or sewers.

6.4 Reference to Other Sections

For disposal, see Section 13.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling Operate in a well-ventilated fume hood/area; avoid generating dust (use low-dust handling procedures). Wear personal protective equipment (PPE) as specified in Section 8. Do not eat, drink or smoke in the handling area. Wash hands thoroughly with soap and water after handling.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

- Storage Conditions: Store in a cool, dry, well-ventilated warehouse at 15-25°C. Keep container tightly closed and protected from light and moisture.
- Incompatibilities: Strong acids, strong bases, oxidizing agents, heavy metal salts, alkaline carbonates.
- Storage Class (TRGS 510): 10 (Pharmaceutical Raw Materials, Non-Hazardous Solids)
- Shelf Life: 36 months (unopened, under specified storage conditions).
- Packaging: Sealed HDPE drums with food-grade plastic inner lining (meets pharmaceutical packaging standards).

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

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Component	CAS-No.	Value	Control Parameters	Basis
Tapentadol Hydrochloride	143562-04-5	No occupational exposure limits	-	No relevant national/international exposure standards

8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation to capture dust at the source; general ventilation to maintain air quality.
- Personal Protective Equipment (PPE):
 - Eye/Face Protection: Chemical splash goggles
 - Skin Protection: Nitrile rubber gloves (thickness ≥ 0.11 mm), lab coat
 - Respiratory Protection: N95 dust mask for dust-generating operations; SCBA for emergency situations
 - Hand Protection: Disposable nitrile gloves (replace if damaged)

SECTION 9: Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties
 a) Physical State: Solid (crystalline powder)
 b) Color: White to off-white
 c) Odor: Odorless
 d) Melting Point/Freezing Point: 178-182°C
 e) Initial Boiling Point and Boiling Range: Decomposes before boiling
 f) Flammability (Liquid/Gas): Non-flammable
 g) Upper/Lower Flammability or Explosive Limits: Not applicable
 h) Flash Point: Not applicable
 i) Autoignition Temperature: Not applicable
 j) Decomposition Temperature: $>220^{\circ}\text{C}$
 k) pH Value (25°C): 4.0-6.0 (1% in water)
 l) Viscosity (25°C): Not applicable (solid)
 m) Water Solubility: Freely soluble in water; soluble in methanol/ethanol
 n) Partition



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Coefficient (n-octanol/water): Log Pow = 1.25o) Vapor Pressure (25°C): <0.0001 hPap) Density (25°C): 1.19 g/cm³ (bulk density)q) Relative Vapor Density: Not applicabler) Particle Characteristics: 95% passing 120 meshes) Explosive Properties: Not explosivet) Oxidizing Properties: None

9.2 Other Safety InformationNo additional safety-related physical/chemical data.

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions (15-25°C, sealed, protected from light).10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal use and processing conditions.10.3 Conditions to Avoid: High temperature (>30°C), direct sunlight, moisture, contact with strong acids/alkalis/oxidizing agents.10.4 Incompatible Materials: Concentrated hydrochloric acid, sulfuric acid, sodium hydroxide, potassium permanganate, hydrogen peroxide, sodium carbonate.10.5 Hazardous Decomposition Products: Nitrogen oxides (NO_x), hydrogen chloride (HCl), carbon monoxide (CO), carbon dioxide (CO₂) (only at high temperature thermal decomposition).

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

- Acute Toxicity:
 - Oral (Rat, LD₅₀): 1100 mg/kg
 - Dermal (Rabbit, LD₅₀): >2000 mg/kg
 - Inhalation (Rat, LC₅₀): >8 mg/m³ (4-hour exposure)
- Skin Corrosion/Irritation: No irritation (Rabbit, 4-hour exposure)
- Serious Eye Damage/Eye Irritation: Severe irritation (Category 2, Rabbit, 24-hour exposure)
- Respiratory or Skin Sensitization: No sensitizing effects (Maximization Test)
- Germ Cell Mutagenicity: Negative (Ames test, chromosome aberration test)
- Carcinogenicity: IARC Class 3 (not classifiable as to its carcinogenicity to humans)
- Reproductive Toxicity: No adverse reproductive effects at occupational exposure levels
- Specific Target Organ Toxicity (Single/Repeated Exposure): May cause mild respiratory depression (Category 3)
- Aspiration Hazard: Low (solid powder, low dustiness)

11.2 Additional InformationThe toxicological properties have been sufficiently studied for safe industrial and pharmaceutical use.

SECTION 12: Ecological Information

12.1 Toxicity:

- Fish (Zebrafish, LC₅₀): >500 mg/L (96-hour exposure)
- Daphnia (EC₅₀): >200 mg/L (48-hour exposure)
- Algae (EC₅₀): >200 mg/L (72-hour exposure)
- 12.2 Persistence and Degradability: Fully biodegradable (BOD₅/COD = 0.88)
- 12.3 Bioaccumulative Potential: Low (Log Pow = 1.25; no bioaccumulation in aquatic organisms)
- 12.4 Mobility in Soil: Low mobility; binds to soil organic



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matter12.5 Results of PBT and vPvB Assessment: Not classified as PBT/vPvB12.6 Endocrine Disrupting Properties: No data available12.7 Other Adverse Effects: No known adverse ecological impacts at normal use levels

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Dispose of as pharmaceutical waste through licensed waste treatment facilities. Incinerate at a temperature >1200°C with flue gas treatment system if unused; recycle if possible.
- Packaging Waste: Rinse packaging with water for residual material recovery, then dispose of as non-hazardous waste or recycle directly.
- Comply with local, national, and international waste disposal regulations.

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: -; IMDG: -; IATA-DGR: -14.2 UN Proper Shipping Name: ADR/RID: Not dangerous goods; IMDG: Not dangerous goods; IATA-DGR: Not dangerous goods14.3 Transport Hazard Class(es): ADR/RID: -; IMDG: -; IATA-DGR: -14.4 Packaging Group: ADR/RID: -; IMDG: -; IATA-DGR: -14.5 Environmental Hazards: ADR/RID: No; IMDG Marine Pollutant: No; IATA-DGR: No14.6 Special Precautions for User: Transport at 15-25°C; avoid direct sunlight, moisture, collision and rough handling during transport.14.7 Incompatible Materials: Avoid transport with strong acids, strong bases, or oxidizing agents.

Further Information: Not classified as dangerous under transport regulations.

SECTION 15: Regulatory Information

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

- National Regulations (China): Complies with Pharmaceutical Raw Material Quality Standard, Non-hazardous Chemical Classification
- International Regulations:
 - GHS Classification (Rev. 9): H302, H319, H335
 - REACH (EU): Registered, not in SVHC Candidate List
 - TSCA (US): Listed on the TSCA Inventory
 - USP 45 / Ph. Eur. 10.0: Compliant

15.2 Other Regulations: Comply with local pharmaceutical raw material import/export and transport regulations; provide COA and MSDS for customs clearance.

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 standards. It is intended for safe handling, storage, transport, and disposal. The supplier is not liable for damage caused by improper use or non-compliance with safety precautions.
- Revision Date: 28 FEB 2026