Safety Data Sheet (MSDS)

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

Revision Date: 20 FEB 2026

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

1.1 Product Identifiers

- Product Name: Opicapone
- Product Number: OPC-20260220
- Brand: SIGALD
- CAS-No.: 130929-57-6
- Synonyms: 3,4-Dihydro-2H-1,2,4-benzothiadiazin-5-carboxamide 1,1-dioxide; Ongentys

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 COMT inhibitor drugs; adjuvant treatment of Parkinson's disease.
- Uses Advised Against: Direct human consumption; unauthorized pharmaceutical formulation; non-pharmaceutical use; veterinary use without official approval.

SECTION 2: Hazards Identification

|Summary of Emergency Measures|Yellow to orange crystalline powder. Harmful if swallowed; causes serious eye irritation; may cause mild gastrointestinal discomfort if ingested. Inhalation: Move to fresh air, rest. Skin contact: Rinse with water for 10 mins. Eye contact: Rinse for 10-15 mins, seek medical help. Swallowing: Rinse mouth, do not induce vomiting, call poison center immediately. Non-combustible; no explosion risk.| |---|

2.1 GHS Classification

- Acute toxicity, oral (Category 4); Eye irritation (Category 2); Skin irritation (Category 2)2.2 GHS Label Elements
- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H315: Causes skin irritation
  - H319: Causes serious eye irritation
- Precautionary Statements:

- P261: Avoid breathing dust
- P264: Wash hands thoroughly after handling
- P270: Do not eat, drink or smoke when using
- P280: Wear protective gloves/eye/face protection
- P301+P312: If swallowed: Call a POISON CENTER/doctor if unwell
- P302+P352: If on skin: Wash with plenty of water
- P305+P351+P338: If in eyes: Rinse cautiously with water, remove contact lenses, continue rinsing

2.3 Physical and Chemical HazardsBased on current information: Non-combustible; no explosive/oxidizing properties; no hazardous decomposition under normal use conditions.2.4 Health HazardsBased on current information: Acute oral toxicity; skin irritation; serious eye irritation; mild gastrointestinal upset from ingestion; no chronic health hazards at occupational exposure levels.2.5 Environmental HazardsBased on current information: Harmful to aquatic organisms; moderate biodegradability; no significant bioaccumulation potential.2.6 Other HazardsNo additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: Pure chemical compound | 3.1 Main Components | Opicapone | | --- | --- | | Formula | $C_{14}H_{15}N_3O_4$ | | Molecular Weight | 289.29 g/mol | | CAS-No.: | 130929-57-6 | | EC-No.: | 600-654-5 |

Hazardous Ingredients

Component	Classification	Concentration (w/w)
Opicapone	Acute oral toxicity Cat4; Skin irritation Cat2; Eye irritation Cat2	100%

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move victim to fresh air and place in a comfortable position. Consult a doctor if cough or chest tightness persists.
- In Case of Skin Contact: Remove contaminated clothing and rinse skin with running water for 10 minutes. Wash clothing before reuse; apply mild moisturizer if irritation occurs.
- In Case of Eye Contact: Rinse eyes thoroughly with plenty of running water for 10-15 minutes (hold eyelids open). Remove contact lenses if present. **Seek immediate medical attention** if irritation lasts more than 24 hours.
- If Swallowed: Rinse mouth with water. Do not induce vomiting. Call a poison center or doctor immediately and provide the product label.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed

- Acute Effects: Gastrointestinal upset (nausea/diarrhea) from ingestion; skin redness/itching; severe eye redness/tearing; mild respiratory irritation from dust inhalation.
- Delayed Effects: No known delayed toxic effects based on current data.

4.3 Indication of Any Immediate Medical Attention and Special Treatment NeededSymptomatic treatment required; no specific antidote (supportive care only); treat skin/eye irritation with topical medications if needed.

4.4 Notes to PhysicianInform the physician of opicapone exposure; monitor gastrointestinal status if large amounts are ingested.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO_2), dry powder.
- Unsuitable Extinguishing Media: No limitations of extinguishing agents.

5.2 Special Hazards Arising from the Substance or MixtureNon-combustible; no hazardous combustion gases or fumes generated under fire conditions; thermal decomposition at high temperature releases non-toxic organic compounds.

5.3 Advice for FirefightersWear standard fire-fighting gear and a dust mask; avoid inhalation of dust from fire-related disturbance; keep containers cool with water spray if exposed to fire.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency ProceduresWear full PPE (nitrile gloves, chemical safety goggles, N95 dust mask, lab coat); ensure good ventilation; evacuate non-essential personnel from the spill area.

6.2 Environmental PrecautionsPrevent spillage from entering drains, rivers or groundwater; collect spilled material to avoid aquatic contamination.

6.3 Methods and Materials for Containment and Cleaning Up

- Small Spill: Sweep up with a clean brush and transfer to a sealed HDPE container for professional disposal.
- Large Spill: Contain with plastic dikes; transfer to sealed drums with a clean shovel; clean the area with a small amount of water and collect wash water for disposal.

6.4 Reference to Other SectionsFor disposal, see Section 13.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

- Operate in a well-ventilated, dust-free GMP workshop; use closed handling/transfer systems to avoid dust generation and inhalation.
- Avoid contact with strong acids, strong bases, high-temperature environments (>60℃) and direct sunlight to prevent structural degradation and discoloration.
- Hygiene Measures: Wash hands and face thoroughly after handling; no eating/drinking/smoking in the work area.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

- Storage Conditions: Store in a cool, dry, dark warehouse (≤25℃); keep container tightly sealed; avoid direct sunlight and high humidity (>60%).

- Incompatibilities: Strong acids (HCl/H_2SO_4), strong bases (NaOH/KOH), oxidizing agents, heavy metal salts.
- Storage Class (TRGS 510): 6.1 (Toxic Solids)
- Shelf Life: 24 months (unopened, under specified storage conditions).

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

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Component	CAS-No.	Value	Control Parameters	Basis
Opicapone	130929-57-6	0.2 mg/m³	TWA (respirable dust)	EU/China proposed occupational exposure limit

8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency dust collection; dust-free Class 10000 workbench (pharmaceutical grade).
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical safety goggles + face shield (mandatory for all handling).
  - Skin Protection: Nitrile rubber gloves (≥0.11 mm) + chemical-resistant lab coat + disposable arm covers + shoe covers.
  - Respiratory Protection: N95 dust mask (normal handling); powered air-purifying respirator (PAPR) for high-dust environments.
- Control of Environmental Exposure: Prevent dust emission and aquatic contamination; comply with local environmental protection regulations.

SECTION 9: Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Propertiesa) Physical State: Powderb) Color: Yellow to orangec) Odor: Practically odorlessd) Melting Point/Freezing Point: 188-192℃e) Initial Boiling Point and Boiling Range: Decomposes before boiling (>200℃)f) Flammability (Liquid/Gas): Non-combustibleg) Upper/Lower Flammability or Explosive Limits: Not applicableh) Flash Point: Not applicablei) Autoignition Temperature: >400℃j) Decomposition Temperature: ≥200℃k) pH Value (25℃): 5.5-7.5 (0.5% aqueous suspension)l) Viscosity (25℃): Not applicable (powder)m) Water Solubility: Sparingly soluble (0.8 g/100 mL, 25℃)n) Partition Coefficient (n-octanol/water): Log P = 1.9o) Vapor Pressure (25℃): <0.0001 hPap) Density (25℃): 1.42 g/cm³q) Relative Vapor Density: Not applicabler) Particle Characteristics: 90% passing 100 mesh (pharmaceutical grade)s) Explosive Properties: Nonet) 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 (≤25℃, dry, dark, sealed); no hygroscopy or chemical degradation.10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal use and handling conditions.10.3 Conditions to Avoid: High

temperature (>60℃), direct sunlight, high humidity (>60%), strong acids/bases, oxidizing agents, heavy metal salts.10.4 Incompatible Materials: Concentrated hydrochloric acid, sulfuric acid, sodium hydroxide, hydrogen peroxide (30%+), ferric chloride.10.5 Hazardous Decomposition Products: No hazardous decomposition products; thermal decomposition at high temperature releases non-toxic organic and inorganic compounds.

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

- Acute Toxicity:
  - Oral (Rat, LD_{50}): 1100 mg/kg
  - Dermal (Rabbit, LD_{50}): >2000 mg/kg
  - Inhalation (Rat, LC_{50}): >5 mg/m³ (4-hour exposure)
- Skin Corrosion/Irritation: Category 2 (mild redness/itching, reversible in 48h; Rabbit, 24-hour exposure).
- Serious Eye Damage/Eye Irritation: Category 2 (severe redness and tearing, reversible in 72h; Rabbit, 24-hour exposure).
- Respiratory or Skin Sensitization: No sensitizing effects.
- Germ Cell Mutagenicity: Negative (Ames test, chromosome aberration test).
- Carcinogenicity: IARC Class 3 (not classifiable as carcinogenic to humans).
- Reproductive Toxicity: No reproductive harm at normal occupational exposure; high doses cause mild fetal developmental changes (animal studies).
- Specific Target Organ Toxicity: No specific target organ toxicity at occupational exposure levels.

SECTION 12: Ecological Information

12.1 Toxicity:

- Fish (Zebrafish, LC_{50}): 32 mg/L (96-hour exposure)
- Daphnia (EC_{50}): 22 mg/L (48-hour exposure)
- Algae (EC_{50}): 35 mg/L (72-hour exposure)12.2 Persistence and Degradability: Moderate biodegradability (BOD_5/COD = 0.35-0.45) in aquatic environments; degrades within 50 days.12.3 Bioaccumulative Potential: Low (Log P = 1.9); no significant accumulation in aquatic organisms.12.4 Mobility in Soil: Low (binds to soil organic matter; no leaching to groundwater under normal conditions).12.5 Results of PBT and vPvB Assessment: Not classified as PBT/vPvB.12.6 Other Adverse Effects: Temporary inhibition of aquatic organism feeding behavior at high concentrations; no long-term ecological harm.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Classified as hazardous pharmaceutical waste; incinerate at licensed hazardous waste incineration facilities (≥1200℃) with gas treatment.

- Packaging Waste: Rinse packaging with a small amount of dimethyl sulfoxide; collect rinsate for hazardous waste treatment; dispose of packaging as hazardous waste.13.2 Disposal Regulations: Comply with China HW02 (Medical Waste) and Basel Convention; do not dispose with municipal solid waste or aquatic environments.

SECTION 14: Transport Information

14.1 UN Number: UN 281114.2 UN Proper Shipping Name: Toxic solids, organic, n.o.s. (Opicapone)14.3 Transport Hazard Class(es): 6.1 (Toxic Substances)14.4 Packaging Group: III14.5 Environmental Hazards: IMDG Marine Pollutant: No14.6 Special Precautions for User: Transport at ≤25℃; use sealed HDPE/fiber drums; mark with GHS hazard labels + UN 2811; avoid direct sunlight and high humidity; do not transport with strong acids/bases/oxidizing agents.14.7 Incompatible Materials: Avoid transport with strong acids, strong bases, oxidizing agents and heavy metal salts.

Further Information: Classified as dangerous goods under international transport regulations.

SECTION 15: Regulatory Information

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

- National Regulations (China):
  - NMPA Pharmaceutical Raw Material; Pharmacopoeia (2020)
  - Hazardous Chemical Safety Management Regulation (2015)
- International Regulations:
  - GHS Classification (Rev. 9): Acute oral toxicity Cat4; Skin irritation Cat2; Eye irritation Cat2
  - REACH (EU): Registered; Ph. Eur. 10.0 compliant; ECHA non-SVHC
  - TSCA (US): Listed; USP 45 compliant; FDA-regulated pharmaceutical raw material

15.2 Other Regulations: Comply with local pharmaceutical manufacturing, GMP and hazardous waste disposal regulations; indoor use must meet occupational safety standards.

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: 20 FEB 2026