



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, GB/T 17519; Adapts to GHS, IMDG, IATA Standards)

Product Name: Pregabalin CAS-No.: 148553-50-8 Product Number: PREG-20260220 Brand: SIGALD Revision Date: 20 FEB 2026

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

1.1 Product Identifiers

- Product Name: Pregabalin
- Synonyms: (S)-3-(Aminomethyl)-5-methylhexanoic acid; Lyrica
- CAS-No.: 148553-50-8
- MDL Number: MFCD00969625

1.2 Details of the supplier

- Company: NEWAY SINOPHC TECH. LIMITED
- Address: 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 Identified Uses & Uses Advised Against

- Identified Uses: Pharmaceutical raw material for the production of anticonvulsant, analgesic and anxiolytic drugs.
- Uses Advised Against: Not for direct human consumption, cosmetic, food or industrial non-pharmaceutical use.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Eye irritation (Category 2) - H319
- Specific target organ toxicity (single exposure) - Mild respiratory irritation (Category 3) - H335

2.2 GHS Label Elements

- Hazard Pictograms: (Exclamation mark)
- Signal Word: WARNING
- Hazard Statements:
 - H319: Causes serious eye irritation
 - H335: May cause respiratory irritation
- Precautionary Statements:
 - P261: Avoid breathing dust/fume/gas/mist/vapours/spray
 - P264: Wash skin thoroughly after handling
 - P280: Wear eye/face protection
 - P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing



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- 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 Hazards

- No flammable, explosive, corrosive, oxidizing or reactive properties identified.

2.4 Health Hazards

- Causes serious eye irritation; may cause mild respiratory irritation if inhaled in large amounts.
- Low oral toxicity; no skin irritation or sensitization identified.
- No known chronic health hazards with occupational exposure.

2.5 Environmental Hazards

- Environmentally friendly; no acute aquatic toxicity; fully biodegradable.

2.6 Other Hazards

- No additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance: Pure Chemical (chiral compound, S-isomer)
- Active Ingredient: Pregabalin (100%, w/w)
- CAS-No.: 148553-50-8
- No hazardous impurities present (all impurities meet USP/Ph. Eur. pharmaceutical standards).

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- If Inhaled: Move victim to fresh air. Rest in a comfortable breathing position. Get medical advice if cough or irritation persists.
- 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.
- In Case of Eye Contact: Rinse eyes thoroughly with plenty of running water for 15-20 minutes. Remove contact lenses if present. Get medical attention if irritation, redness or blurred vision persists.
- If Swallowed: Rinse mouth with water. No serious toxicity expected; call a doctor only if nausea, vomiting or other discomfort occurs. Do not induce vomiting.

4.2 Most Important Symptoms

- Acute: Eye redness/irritation, tearing, mild cough, throat irritation.
- Delayed: No known delayed symptoms.

4.3 Medical Attention

- Treat symptomatically; provide this MSDS to the doctor if medical consultation is required.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable: Water spray, dry powder, carbon dioxide (CO₂), foam.
- Unsuitable: No limitations identified.

5.2 Special Hazards

- Non-combustible; no hazardous combustion gases generated. Thermal decomposition at high temperature may produce small amounts of ammonia (NH₃) and carbon oxides (CO/CO₂).

5.3 Firefighter Advice

- Wear standard fire-fighting gear (helmet, fire coat, gloves). Use self-contained breathing apparatus (SCBA) only if thermal decomposition occurs (high temperature >300°C). Keep containers cool with water spray.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear dust mask, eye protection and nitrile gloves. Ensure good ventilation. Evacuate non-essential personnel from the spill area.

6.2 Environmental Precautions

- No special environmental precautions; the product is biodegradable. Prevent large spills from entering drains to avoid blockage (water-soluble).

6.3 Containment & Clean-Up

- Small Spill: Sweep up with a clean brush and place in a sealed plastic container for reuse or disposal. Wipe the spill area with water.
- Large Spill: Contain with dikes (if dissolved in water). Transfer to a sealed drum for recovery. Flush the residual with water (no environmental contamination).

SECTION 7: Handling and Storage

7.1 Safe Handling

- Handle in a well-ventilated area. Avoid generating dust (use low-dust handling procedures, e.g., wet sweeping).
- Wear eye/face protection and dust mask during handling; wash hands thoroughly after operation.
- Do not eat, drink or smoke in the handling area to avoid accidental ingestion.

7.2 Safe Storage

- Storage Conditions: Store in a cool, dry, well-ventilated warehouse at 15-25°C. Keep container tightly sealed and protected from light and moisture.
- Incompatibilities: Strong oxidizing agents, concentrated acids, heavy metal salts (e.g., AgNO₃, HgCl₂).
- Storage Class: 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

- Occupational Exposure Limit (OEL): No official OEL established; use engineering controls to minimize dust exposure.

8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation for dust-generating operations; general ventilation to maintain air quality.
- Personal Protective Equipment (PPE):
 - Eye/Face Protection: Safety glasses or chemical splash goggles
 - Skin Protection: Nitrile rubber gloves, lab coat
 - Respiratory Protection: N95 dust mask for dust operations; no respiratory protection needed for normal handling
 - Hand Protection: Disposable nitrile gloves (replace if damaged)

SECTION 9: Physical and Chemical Properties

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Property	Details
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	190-194°C
Boiling Point	Decomposes before boiling (>250°C)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	Not applicable
Decomposition Temperature	>250°C
pH Value (5% in water, 25°C)	5.0-7.0
Solubility	Freely soluble in water/methanol; soluble in ethanol; slightly soluble in acetone
Density (25°C)	1.05 g/cm ³ (bulk density)
Vapor Pressure (25°C)	<0.0001 hPa
Optical Rotation	[α] ₂₀ ^D = +14.5° to +16.5° (1% in water)
Particle Size	95% passing 120 mesh
Stability	Stable under recommended storage conditions

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

- Stable at 15-25°C, protected from light and moisture. No decomposition under normal handling, storage and formulation processing.

10.2 Hazardous Reactions

- No hazardous reactions occur under normal use conditions. Avoid long-term contact with strong oxidizing agents and concentrated acids.

10.3 Conditions to Avoid

- High temperature (>30°C), direct sunlight, excessive moisture, strong oxidizing agents/concentrated acids.

10.4 Incompatible Materials

- Hydrogen peroxide (H₂O₂), potassium permanganate (KMnO₄), concentrated sulfuric acid (H₂SO₄), nitric acid (HNO₃).

10.5 Hazardous Decomposition Products

- Ammonia (NH₃), carbon monoxide (CO), carbon dioxide (CO₂) (only at high temperature >300°C).

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute oral toxicity (Rat, LD₅₀): >5000 mg/kg (practically non-toxic)
- Dermal toxicity (Rabbit, LD₅₀): >2000 mg/kg (non-toxic)
- Inhalation toxicity (Rat, LC₅₀): >10 mg/m³ (4h) (no hazard)
- Eye irritation (Rabbit): Severe irritation (Category 2)
- Skin irritation (Rabbit): No irritation (no classification)
- Sensitization: No skin/respiratory sensitization (Maximization Test)
- Carcinogenicity: IARC Class 3 (not classifiable as to its carcinogenicity to humans)
- Mutagenicity: Negative (Ames test, in vitro chromosome aberration test)
- Reproductive toxicity: No adverse reproductive effects at occupational exposure levels.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, LC₅₀): >500 mg/L (96h)
- Daphnia (EC₅₀): >200 mg/L (48h)
- Algae (EC₅₀): >200 mg/L (72h)

12.2 Persistence and Degradability

- Biodegradability: Fully biodegradable (BOD₅ /COD = 0.85)
- Persistence: No persistence in the environment; degraded by microorganisms within 7 days.

12.3 Bioaccumulative Potential

- Log Pow = -1.5 (no bioaccumulation in aquatic organisms; highly water-soluble)

12.4 Other Adverse Effects

- No known adverse effects on the environment; the product is environmentally friendly and can be biodegraded completely.

SECTION 13: Disposal Considerations

13.1 Waste Treatment



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- Product Waste: Reuse if possible; if unfit for use, dispose of as non-hazardous pharmaceutical waste through licensed waste treatment facilities. Incinerate with flue gas treatment or biodegrade through biological treatment systems.
- Packaging Waste: Rinse packaging with water (for residual material recovery), then dispose of as non-hazardous waste or recycle directly.
- No special disposal requirements; comply with local municipal waste regulations.

SECTION 14: Transport Information

14.1 UN Number: IMDG/IATA/ADR: N/A (Non-hazardous goods) 14.2 UN Proper Shipping Name: Not dangerous goods (Pregabalin) 14.3 Transport Hazard Class: N/A 14.4 Packaging Group: N/A 14.5 Environmental Hazards: IMDG Marine Pollutant: No 14.6 Special Precautions

- Transport at 15-25°C; use ordinary closed transport vehicles.
- Avoid direct sunlight, rain, collision and rough handling; protect the packaging from damage and moisture.
- Comply with ordinary cargo transport regulations (no hazardous goods certification required).

SECTION 15: Regulatory Information

15.1 National & International Regulations

- China: Complies with the Pharmaceutical Raw Material Quality Standard, Non-hazardous Chemical Classification
- EU: REACH (registered), not in SVHC Candidate List; Ph. Eur. 10.0 compliant
- US: TSCA listed, USP 45 compliant; FDA DMF available
- GHS: Classified in accordance with GHS Rev. 9

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

- This MSDS is based on current scientific and regulatory knowledge, complying with GB/T 16483, GB/T 17519, GHS, IMDG, IATA and ADR standards.
- The supplier is not liable for damage caused by improper handling, storage, transport or use of the product.
- For additional technical information (e.g., formulation compatibility), contact the supplier's technical department.