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Material Safety Data Sheet (MSDS)

Product Name: Pregabalin IP Grade
MSDS Generate Date: 20-05-2017
Revision Date: 30-12-2024

Supplier:

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1. Identification of the Substance/Preparation and Company

- **Product name:** Pregabalin — IP Grade
- **Synonyms:** (S)-3-(Aminomethyl)-5-methylhexanoic acid (note: pharmaceutical active); trade/API names as applicable.
- **Recommended use:** Active Pharmaceutical Ingredient (API) for medicinal formulation.
- **Restrictions on use:** Not for direct consumer use; intended for pharmaceutical manufacturing under controlled conditions.

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2. Hazard(s) identification

- **GHS classification:** Based on available data, Pregabalin is *not* classified as a physical or health hazard under GHS criteria for solids in typical commercial forms. However, inhalation of dust or high exposures may cause irritation or other effects. Treat as an industrial chemical for occupational safety.
- **Signal word:** None required for classification.
- **Hazard statements (practical guidance):**

    - May cause respiratory tract irritation if inhaled as dust.
    - May cause skin or eye irritation in sensitive individuals.
    - Not classified as a carcinogen, mutagen, or reproductive toxin based on available data (use precaution; follow applicable regulations).
- **Precautionary statements:** Avoid inhalation of dust. Use engineering controls and appropriate PPE. Wash after handling. In case of contact, follow first aid measures.

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3. Composition / Information on ingredients

- **Substance:** Pregabalin (chemical name as above) — **Purity:** IP grade (specification batch-dependent).
- **CAS No.:** [If known supply; otherwise leave blank or include on customer data sheet]
- **Impurities / additives:** May contain trace residual solvents, impurities or process-related substances as defined in batch certificate of analysis. Refer to COA for exact composition and limits.

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4. First-aid measures

- **Inhalation:** Remove to fresh air. If breathing is difficult, give oxygen. If symptoms persist, seek medical attention.
- **Skin contact:** Remove contaminated clothing. Wash affected area with soap and water. Seek medical attention if irritation develops.
- **Eye contact:** Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. If irritation persists, get medical attention.
- **Ingestion:** Rinse mouth. Do NOT induce vomiting unless directed by medical personnel. Seek medical advice if large amounts swallowed or if symptoms occur. Provide product container or label to medical personnel.
- **Notes to physician:** Treat symptomatically. There is no specific antidote. Provide supportive care.

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5. Fire-fighting measures

- **Suitable extinguishing media:** Water spray, foam, dry chemical, or CO_2 — select appropriate agent for surrounding fire.
- **Unsuitable media:** None specific; avoid direct strong water jet if it will spread material.

- **Special hazards arising from the substance:** Combustion may produce oxides of carbon, nitrogen and other unidentified toxic gases.

- **Advice for firefighters:** Use self-contained breathing apparatus (SCBA) and full protective gear. Cool containers with water spray to prevent rupture. Prevent firewater run-off from entering drains/groundwater.

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6. Accidental release measures

- **Personal precautions:** Avoid dust formation. Use appropriate PPE (gloves, safety glasses, dust respirator if airborne dust). Evacuate non-essential personnel.

- **Environmental precautions:** Prevent release to drains, sewers or waterways. Contain spill to prevent environmental dispersion.

- **Methods for containment and cleanup:** Sweep or vacuum up dry material using a HEPA-filtered industrial vacuum. Avoid creating dust clouds. Collect and place in suitable labeled containers for disposal. Wash area with water after mechanical removal. For large spills, follow local regulatory reporting requirements.

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7. Handling and storage

- **Handling:** Avoid breathing dust. Use good industrial hygiene. Do not eat, drink or smoke in handling areas. Use local exhaust ventilation or other engineering controls to minimize dust.

- **Storage:** Store in tightly closed original containers in a cool, dry, well-ventilated area away from incompatible substances. Protect from moisture. Keep away from direct sunlight and heat sources.

- **Incompatibilities:** Strong oxidizing agents, strong acids or bases — avoid contact.

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8. Exposure controls / Personal protection

- **Occupational exposure limits:** No widely adopted specific occupational exposure limit (OEL) for Pregabalin is universally established. Where local OELs exist follow them. In absence of OEL, control exposures to lowest practicable levels.

- **Engineering controls:** Use local exhaust ventilation, dust collection systems, and closed transfer systems where practicable.

- **Personal protective equipment (PPE):**

    - **Respiratory protection:** If airborne dust is present, use an approved particulate respirator (e.g., N95/FFP2 or better); for high concentrations use appropriate supplied air respirator.

    - **Hand protection:** Chemical-resistant gloves (nitrile or equivalent).
    - **Eye protection:** Safety goggles or face shield.
    - **Skin/body protection:** Lab coat or protective clothing to prevent skin contact.
- **Hygiene measures:** Wash hands thoroughly after handling. Remove contaminated clothing and launder before reuse.

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9. Physical and chemical properties

- **Appearance:** White to off-white crystalline powder (typical for API; batch dependent).
- **Odor:** Odorless or slight characteristic odor.
- **pH:** Not applicable for solid; see aqueous solution data in technical dossier.
- **Melting point / range:** Refer to product specification / pharmacopeia.
- **Boiling point:** Not applicable.
- **Flash point:** Not combustible in standard tests for solids; no flash point.
- **Solubility:** Soluble in water (solubility increases with temperature); miscible in some polar solvents — refer to technical data sheet.
- **Vapour pressure / density:** Not applicable for non-volatile solid.
- **Other data:** Bulk density and particle size distribution available in QC documentation.

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10. Stability and reactivity

- **Reactivity:** Stable under normal conditions of storage and handling.
- **Chemical stability:** Stable under recommended storage conditions.
- **Possibility of hazardous reactions:** None known under normal conditions. Avoid contact with strong oxidizers.
- **Conditions to avoid:** Excessive heat, moisture.
- **Incompatible materials:** Strong oxidizing agents, strong acids/bases (avoid contact).
- **Hazardous decomposition products:** Thermal decomposition may yield oxides of carbon and nitrogen and other potentially toxic compounds.

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11. Toxicological information

- **Acute toxicity:** Low acute toxicity expected for normal handling amounts. Toxicological profile should be consulted from product-specific toxicology reports.

- **Routes of exposure:** Inhalation of dust, skin or eye contact, ingestion.

- **Symptoms / effects:** May cause respiratory irritation if inhaled as dust. Skin/eye irritation possible. Systemic effects are possible with significant ingestion or improper exposure — refer to pharmacology/toxicology data for clinical effects.

- **Chronic toxicity / Carcinogenicity / Mutagenicity / Reproductive toxicity:** No classification as carcinogen/mutagen/reproductive toxin in commonly referenced lists based on available public data. See detailed toxicology dossiers and regulatory submissions for definitive data.

- **Notes:** Medical surveillance is recommended for workers with chronic exposure. Refer to safety and toxicology data from manufacturer.

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12. Ecological information

- **Ecotoxicity:** No specific environmental classification is generally applied; nevertheless, avoid release to the environment. Test data on aquatic toxicity should be consulted from specific studies (see manufacturer ecotoxicology report).

- **Persistence and degradability:** Biodegradation data should be obtained from specific studies; many pharmaceutical actives persist to varying degrees—consult ecotoxicology dossier.

- **Bioaccumulative potential:** Data not generally available; assume low potential unless studies indicate otherwise.

- **Mobility in soil:** May be mobile depending on solubility and soil conditions. Prevent release to waterways/soil.

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13. Disposal considerations

- **Waste treatment methods:** Dispose of in accordance with local, regional, national and international regulations. Preferably incinerate in approved facilities or send to licensed pharmaceutical waste handlers. Do not dispose of into drains or into the environment.

- **Contaminated packaging:** Empty containers may retain residues; dispose of according to regulations and ensure containers are properly labeled and cleaned prior to recycling or disposal.

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14. Transport information — DETAILED (as requested)

Summary statement: Based on available data and typical properties of Pregabalin (IP grade) in its commercial solid form, it is **generally not classified** as a dangerous good for transport

under the UN Model Regulations, ADR (road), IMDG (sea), and IATA DGR (air). However, final classification for transport must always be confirmed by the shipper based on the actual packaged form, quantity, local/regional regulations, and any country-specific controls for pharmaceutical materials. Below is a comprehensive transport guidance framework to assist compliance.

A. General classification

- **UN Number:** Not assigned / Not regulated for transport (when shipped as a non-hazardous pharmaceutical ingredient in normal solid form).
- **Proper Shipping Name (UN):** Not applicable / Not regulated. For practical labeling, shippers often use: *"Not regulated — Pharmaceutical substance / Pregabalin (API)"* or equivalent per carrier guidance.
- **Transport hazard class:** Not applicable (no hazard class).
- **Packing group:** Not applicable.
- **Environmental hazards:** Not classified as a marine pollutant in typical tests. However, avoid marine discharge; follow local environmental regulations.
- **Special precautions for user / carrier:** See below.

B. Mode-specific guidance

- **Road / Rail (ADR / RID):**
    - ADR/RID classification: Not classified as Dangerous Goods.
    - Marking/placarding: None required under ADR for non-regulated materials.
    - Documentation: Commercial invoice and shipping documents; include statement "Not regulated for transport (pregabalin, API)" if helpful for carrier. Follow applicable national transport regulations.
    - Packaging: Use robust, sealed inner liners and outer packaging to prevent leakage of powder and to limit dust release. Use transit packaging that meets general commodity transport practices.
- **Sea (IMDG):**
    - IMDG classification: Not classified as Dangerous Goods.
    - Marine pollutant: Not listed as a marine pollutant; however, shipping documentation should instruct crew to prevent cargo from entering waterways.
    - Packaging: Preferably in moisture-resistant drums or UN-approved non-dangerous goods packaging. Use absorbent material if potential for release exists.

- **Air (IATA / ICAO):**
    - IATA DGR / ICAO TI: Pregabalin in standard API solid form is typically *not restricted* by IATA.
    - *Note:* Carriers may have additional acceptance requirements for pharmaceutical products (e.g., paperwork, permits). Always confirm carrier acceptance before booking.
    - Packaging: Use strong outer packaging and inner liners to prevent contamination. For international air transport of pharmaceutical APIs, include documentation that supports non-hazardous status.

C. Small quantity & passenger carriage:

- For samples or small quantities shipped by courier, treat as non-hazardous domestic/international cargo. For passenger baggage or air cargo, follow airline/courier rules — declare if requested.

D. Handling and segregation:

- Segregate from incompatible materials (strong oxidizers).
- Avoid packaging that may be punctured or crushed.
- Keep away from sources of heat and moisture.

E. Emergency response in transport:

- In case of spillage during transport: wear PPE (dust respirator, gloves, goggles). Contain the spill, avoid creating dust, sweep/vacuum with HEPA filters and place in labeled containers. Prevent entry to waterways. Provide SDS to emergency responders. For significant incidents, notify appropriate transport emergency services and local authorities.

F. Regulatory / country variations:

- Some countries may apply additional controls to APIs (import/export permits, narcotics scheduling, or pharmaceutical handling rules). Always verify import/export and transport compliance per origin, transit and destination country regulations.

G. Recommended shipping description example (non-hazardous):

- *Shipper's declaration / Description:* "Pregabalin (API) — non-hazardous solid pharmaceutical active ingredient; not regulated for transport under UN/ADR/IMDG/IATA when shipped in packaged form as described."
- Include Net weight, batch number, and emergency contact (e.g., +91 97272 88479) on shipping paperwork.

H. Notes & cautions:

- This section is informational and does **not** replace the legal responsibility of the consignor/shipper to classify and declare the shipment according to the actual packaged material, quantity, and current regulations. For internationally transported consignments, confirm with freight forwarders and carriers. If the product is formulated with other excipients, or if shipped as a solution or in combination with hazardous solvents, transport classification may change.

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15. Regulatory information

- **Pharmaceutical regulation:** Pregabalin is a regulated pharmaceutical API; compliance with local pharmacopeial monographs (IP/BP/USP) and regulatory authorities (DGCI, CDSCO, EMA, FDA as applicable) is required for manufacture, distribution and use.

- **Chemical safety assessment:** A supplier chemical safety assessment may be available on request. Follow applicable occupational health and safety regulations and pharmaceutical regulatory requirements.

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16. Other information

- **Disclaimer:** The information contained in this MSDS is believed to be correct as of the revision date shown. It is offered in good faith but without warranty, express or implied. Users should make their own investigations to determine suitability for particular applications. This MSDS does not constitute a guarantee of product properties. Final responsibility for compliance with applicable laws and regulations rests with the user/shipper. For the most current and product-specific data (impurities, CAS, OELs, toxicology), consult batch COA, technical dossier, and regulatory submissions.
- **MSDS Generate Date:** 20-05-2017
- **Revision Date:** 30-12-2024
- **Website:** www.rawpharmabiz.com
- MSDS are based on the manufacturer’s provided information.