

SAFETY DATA SHEET

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1. Product Information**Product Name: Pregabalin Extended Release Tablets 82.5 mg, 165 mg and 330 mg****2. Composition/Information on Ingredients**

C.A.S. No : 148553-50-8
Molecular Formula : $C_8H_{17}NO_2$
Molecular Weight : 159.23
Chemical Name : (S)-3-(Aminomethyl)-5-methylhexanoic acid.

3. Hazards Identification**Classification of the Substance or Mixture****GHS - Classification****Reproductive Toxicity: Category 2****Label Elements****Signal Word:** Warning**Hazard Statements:** H361d - Suspected of damaging the unborn child**Precautionary Statements:**

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations

4. First Aid Measures**Description of First Aid Measures****Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.**Most Important Symptoms and Effects, Both Acute and Delayed****Symptoms and Effects of Exposure:**

For information on potential signs and symptoms of exposure, See Section 3 – Hazards Identification and/or Section 12 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

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Indication of the Immediate Medical Attention and Special Treatment Needed**Notes to Physician:** None**5. Emergency Overview****Major Health Hazards:** No major health hazards are known.**6. Fire Fighting Measures****Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.**Special Hazards Arising from the Substance or Mixture****Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.**Fire / Explosion Hazards:** Not applicable**Advice for Fire-Fighters:** During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.**7. Accidental Release Measures****Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up**Measures for Cleaning /Collecting:**

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

8. Handling and Storage**Precautions for Safe Handling:**

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Use appropriate ventilation. Avoid generating airborne dust. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions

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of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at 20-25°C (68-77°F). Excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

Specific end use(s): Pharmaceutical drug product

9. Exposure Controls/Personal Protection

Control Parameters: Refer to available public information for specific member state Occupational Exposure Limits.

Pregabalin OEL TWA-8 Hr: 500µg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international)

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10. Physical and Chemical Properties**Appearance:**

82.5 mg: Brown colored, almond shaped, biconvex, film coated tablets debossed with "MP12" on one side and plain on other side

165 mg: Pink colored, almond shaped, biconvex, film coated tablets debossed with "MP 11" on one side and plain on other side

330 mg : Cream yellow colored, almond shaped, biconvex, film coated tablets debossed with "MP10" on one side and plain on other side

11. Stability and Reactivity

Reactivity: No data available

Stability: Stable under normal conditions of use.

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: None known

12. Toxicological Information**Information on Toxicological Effects****General Information:**

The information included in this section describes the potential hazards of the individual ingredients.

Long Term: Animal studies indicate that this material may cause adverse effects on the fetus

Known Clinical Effects: Adverse effects most commonly reported in clinical use include dizziness, blurred vision, weight gain, sleepiness (somnolence), dry mouth, inability to concentrate, swelling. Hypersensitivity reactions may also occur in susceptible individuals. Other less common effects include suicidal behavior.

Acute Toxicity: (Species, Route, End Point, Dose)**Pregabalin:**

Rat IV LD50 > 300 mg/kg

Mouse Oral LD50 > 5000mg/kg

Rat Oral LD50 > 5000mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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Irritation / Sensitization: (Study Type, Species, Severity)

Pregabalin

Skin Sensitization - LLNA Rat Negative

Skin Sensitization - Beuhler Guinea Pig Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Pregabalin

13 Week(s) Rat Oral 50 mg/kg/day NOAEL Central nervous system, Male reproductive system

4 Week(s) Rat Oral 500 mg/kg/day LOAEL Central Nervous System, Male reproductive system

4 Week(s) Monkey Oral 100 mg/kg/day NOAEL Central Nervous System

52 Week(s) Rat Oral 50 mg/kg/day LOAEL Blood forming organs

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Pregabalin

Peri-/Postnatal Development Rat Oral 100 mg/kg/day NOAEL Developmental toxicity, Fertility

Fertility & Early Embryonic Development - Males Rat Oral 250 mg/kg/day NOAEL No effects at maximum dose

Fertility & Embryonic Development-Females Rat Oral 1250 mg/kg/day NOAEL Negative

Embryo / Fetal Development Rat Oral 500 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Rabbit Oral 500 mg/kg/day NOAEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Pregabalin

Bacterial Mutagenicity (Ames) Bacteria Negative

In Vivo Unscheduled DNA Synthesis Rat Negative

In Vivo Micronucleus Mouse Negative

In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Pregabalin

104 Week(s) Mouse Oral 1000 mg/kg/day NOAEL Not carcinogenic

13. Ecological Information

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Pregabalin

Daphnia magna (Water Flea) EC50 48 Hours > 1000 mg/L

Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 1000 mg/L

Green algae OECD EbC50 72 Hours > 300 mg/L

Green Algae OECD ErC50 72 Hours > 300 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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Bacterial Inhibition: (Inoculum, Method, End Point, Result)**Pregabalin***Aspergillus niger* (Fungus) OECD MIC > 1000 mg/L*Trichoderma viride* (Fungus) OECD MIC > 1000 mg/L*Clostridium perfringens* (Bacterium) OECD MIC > 997 mg/L*Bacillus subtilis* (Bacterium) OECD MIC > 1000 mg/L*Nostoc sp.* (Freshwater Cyanobacteria) OECD MIC > 1000 mg/L**14. Disposal Considerations**

Dispose of in accordance with prevailing country, federal, state and local regulations.

15. Transport Information**The following refers to all modes of transportation unless specified below.**

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

16. Regulatory Information**California Proposition 65:** Not Listed**Inventory - United States TSCA - Sect. 8(b):** Present**Australia (AICS):** Present**EU EINECS/ELINCS List** Not Listed**Additional Information:** U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule V**17. Other Information**

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.