


SAFETY DATA SHEET

Date: 10/11/2018

Generic Name: Pregabalin Capsules

Brand Equivalent: Lyrica ®

SECTION 1: IDENTIFICATION	
Product Name	Pregabalin Capsules , 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg & 300mg
Active substance	Pregabalin USP
Synonyms	N/A
Formula	C ₈ H ₁₇ NO ₂
Intended Use	Anti Epileptic and Fibromyalgia
Chemical Name	(3S)-3-(Aminomethyl)-5-methylhexanoic acid
How Supplied	<p>25mg -White to Off white powder filled in size "4" hard gelatin capsules with white opaque colored cap and white opaque colored body imprinted with "SG" on cap and "350" on body with black Ink.</p> <p>50mg - White to Off white powder filled in size "3" hard gelatin capsules with white opaque colored cap and white opaque colored body imprinted with "SG" on cap and "351" on body with black ink.</p> <p>75mg - White to Off white powder filled in size "4" hard gelatin capsules with orange opaque colored cap and white opaque colored body imprinted with "SG" on cap and "352" on the body with black ink.</p> <p>100mg- White to Off white powder filled in size "3" hard gelatin capsules with orange opaque colored cap and orange opaque colored body imprinted with "6SG" on cap and "353" on body with black ink.</p> <p>150mg - White to Off white powder filled in size "2" hard gelatin capsules with white opaque colored cap and white opaque colored body imprinted with "SG" on cap and "354" on the body with black ink.</p> <p>200mg - White to Off white powder filled in size "1" hard gelatin capsules with light orange colored cap and light orange colored body imprinted with "SG" on cap and "355" on the body with black ink.</p> <p>225mg - White to Off white powder filled in size "1" hard gelatin capsules with light orange colored cap and white opaque colored body imprinted "SG" on cap and "356" on body with black ink.</p> <p>300mg -White to Off white powder filled in size "0" hard gelatin capsules with orange opaque colored cap and white opaque colored body imprinted with "SG" on cap and "357" on body with black ink.</p>
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
UN Globally Harmonized System (GHS)	
Classification	Reproductive Toxicity: Category 2
OSHA hazard(s)	Not classified.
Symbol	
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.
Other Hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8). Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. Composition/Information on ingredients		
Components	CAS-No	Concentration (%w/w)
Pregabalin, USP	148553-50-8	25% for 25 mg and 50 mg & 75% for other strengths
Pregelatinized Starch, NF (Starch 1500)	9057-07-2	*
Talc, USP (140)	14807-96-6	*
Hard Gelatin Capsules	Mixture	*

* Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES	
General advice	Immediate medical attention is required. If symptoms persist, call a physician.
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
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
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
Self-protection of the first aid	Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.
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 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure:	None known
Indication of the Immediate Medical Attention and Special Treatment Needed Notes to Physician	None

5. FIRE-FIGHTING MEASURES	
Fire / Explosion Hazards:	Not available
Suitable 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.
Protection of Firefighters	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Other information:	Decontaminate protective clothing and equipment before reuse.

6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions, Protective Equipment and Emergency Procedures	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). 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. Clean up operations should only be undertaken by trained personnel

7. 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 (see Section 8). 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 of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Conditions for Safe	Store as directed by product packaging.

Storage, Including any Incompatibilities Storage Conditions	
Specific use(s)	Pharmaceutical drug product

8. Exposure controls/Personal protection	
Control Parameters Exposure Controls	Refer to available public information for specific member state Occupational Exposure Limits
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.
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 equivalent.)
Eye protection	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.)
Hand protection	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.)
Skin and body Protection	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.)
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
<i>Appearance</i> Physical State Color Form	Capsules Refer to the section 1 -How it is supplied
Odor	Not available
Odor Threshold	Not available
Molecular Formula:	Mixture
Molecular Weight:	Mixture
Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available
Partition Coefficient: (Method, pH, Endpoint, Value) Lactose NF, monohydrate	No data available
Talc (non-asbestiform)	No data available
Corn Starch	No data available
Pregabalin Predicted 7.4 Log D - 1.35 Hard gelatin capsules	No data available
Decomposition Temperature (°C):	No data available
Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available
Flammability:	No data available
Auto Ignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available
Polymerization:	Will not occur

10. Stability and Reactivity	
Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
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:	No data available

11. 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), inability to concentrate, swelling, dry mouth. Hypersensitivity reactions may also occur in susceptible individuals. Other less common effects include suicidal behavior.
Acute Toxicity: (Species, Route, End Point, Dose)	
Talc (non-asbestiform)	Rat Oral LD50 > 1600 mg/kg
Pregabalin	Rat IV LD50 > 300 mg/kg Mouse 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.
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. <i>In Vivo</i> Unscheduled DNA Synthesis Rat Negative. <i>In Vivo</i> Micronucleus Mouse Negative <i>In Vitro</i> 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. 104 Week(s) Rat Oral 450 mg/kg/day NOAEL Not carcinogenic. 104 Week(s) Mouse Oral 200 mg/kg/day NOAEL Malignant tumors.
Carcinogen Status:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Talc (non-asbestiform) IARC:	Group 3 (Not Classifiable)
Pharmacokinetics/Toxicokinetics	Due to lack of data the classification is not possible
Other Toxicity Information	Due to lack of data the classification is not possible


12. Ecological Information	
Environmental Overview:	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
Toxicity:	
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)	<i>Daphnia magna</i> (Water Flea) EC50 48 Hours > 1000 mg/L <i>Oncorhynchus mykiss</i> (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.
Bacterial Inhibition: (Inoculum, Method, End Point, Result)	Pregabalin <i>Aspergillus niger</i> (Fungus) OECD MIC > 1000 mg/L <i>Trichoderma viride</i> (Fungus) OECD MIC > 1000 mg/L <i>Clostridium perfringens</i> (Bacterium) OECD MIC > 997 mg/L <i>Bacillus subtilis</i> (Bacterium) OECD MIC >1000 mg/L <i>Nostoc sp.</i> (Freshwater Cyanobacteria) OECD MIC > 1000 mg/L
Persistence and Degradability:	No data available
Bio-accumulative Potential: Partition Coefficient: (Method, pH, Endpoint, Value)	Pregabalin <i>Bacillus subtilis</i> (Bacterium) OECD MIC >1000 mg/L Predicted 7.4 Log D -1.35
Mobility in Soil:	No data available

13. Disposal considerations	
Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. Transport Information	
The following refers to all modes of transportation unless specified below.	Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. Regulatory Information	
Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture	Canada - WHMIS: Classifications WHMIS hazard class: Class D, Division 2, Subdivision A

	
Hard gelatin capsules	CERCLA/SARA 313 Emission reporting Not Listed Page 8 of 8 California Proposition 65 Not Listed EU EINECS/ELINCS List Not Listed
Additional Information:	U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule V

16. Other information	
Text of CLP/GHS Classification abbreviations mentioned in Section 3	H361d - Suspected of damaging the unborn child
Recommended Restrictions for Use:	Not available
Prepared on	10/16/18
Revision	00
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