

SAFETY DATA SHEET

 Date: 06/29/2015

Generic Name: Gabapentin Capsules, USP 100, 300 and 400 mg.

Brand Equivalent: Neurontin® (Gabapentin) Capsules, 100/300 and 400 mg

SECTION 1: IDENTIFICATION	
Product Name	Gabapentin Capsules, USP
Active substance	Gabapentin
Synonyms	N/A
Formula	C ₉ H ₁₇ NO ₂
Intended Use	For the management of postherpetic neuralgia in adults. Adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients over 12 years of age with epilepsy
Chemical Name	2-[1-(aminomethyl)cyclohexyl]acetic acid
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Additional Hazard Information: Short Term:	Dust may cause irritation (based on components). The active ingredient is not acutely toxic.
Known Clinical Effects:	Adverse effects associated with therapeutic use include dizziness, tiredness, swelling, and nausea.
Statement of Hazard	Non-hazardous in accordance with international standards for workplace safety.
EU Classification EU Indication of danger	Not classified
Australian Hazard Classification (NOHSC):	Non-Hazardous Substance. Non-Dangerous Goods.

3. Composition/Information on ingredients		
Components	CAS-No	Concentration (%w/w)
Gabapentin, USP	60142-96-3	80.0
Pregelatinized Starch, NF (Starch 1500)	9005-25-8	*
Talc, USP (140)	14807-96-6	*
Hard gelatin capsules	Mixture	*

* Proprietary, 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	
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.

5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Use carbon dioxide, dry chemical, or water spray. Use fire-extinguishing media appropriate for surrounding materials.
Hazardous Combustion Products:	Not known
Fire Fighting Procedures	During all fire fighting activities, wear appropriate protective equipment, including selfcontained breathing apparatus.
Fire / Explosion Hazards:	Not applicable

6. ACCIDENTAL RELEASE MEASURES	
Health and Safety Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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.
Measures for Environmental Protections	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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	
General Handling	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing
Storage Conditions	Store at Controlled Room Temperature: 20° to 25° C (68°to77° F). Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light.

8. Exposure controls/Personal protection	
Environmental Exposure Controls	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations- preferred, Maintain eyewash facilities in the work area.
Eyes	Wear safety glasses or goggles if eye contact is possible
Skin	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection	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.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
<i>Appearance</i> Physical State Color	solid white/white shell-100 mg yellow/yellow shell-300 mg orange/orange shell-400 mg
Form	capsules
<i>Odour</i> Odour Odor Threshold	Not available Not available
pH	Not available
<i>Other information</i>	
Bulk density	Not available
Evaporation rate	Not available
Molecular formula	C ₉ H ₁₇ NO ₂
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	Freely soluble in water, 0.1N HCl, 0.1N in Sodium Hydroxide
Specific Gravity/ Relative Density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available
<i>Thermal/Stability properties</i>	
Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	Not available

Vapor Properties	Not available
Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. Stability and Reactivity	
Chemical Stability	Stable under normal conditions
Conditions to Avoid	Avoid exposure to heat, sources of ignition, and electrostatic discharge.
Incompatible Materials	As a precautionary measure, keep away from strong oxidizers

11. Toxicological Information	
Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact
Eye Irritation	Gabapentin, Severely irritating to eyes
Respiratory Irritation	Gabapentin, Respiratory Irritant
Acute Toxicity Study	Due to lack of data the classification is not possible
Repeated Dose Toxicity	Due to lack of data the classification is not possible
Genetic Toxicity	Due to lack of data the classification is not possible
Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA
Reproductive Toxicity	Due to lack of data the classification is not possible
Developmental Toxicity	Due to lack of data the classification is not possible
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	
Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available
Mobility in soil	Not available
Other adverse effects	Not available

13. Disposal considerations	
Advice On Disposal And Packaging	Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.
Other information	Disposal by incineration is recommended.

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

15. Regulatory Information	
EU Indication of danger	Not classified
International Regulatory Information:	EINECS # 262-076-3
U.S regulations	No applicable information found.

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	06/29/2016
Revision	01
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