

**SAFETY DATA SHEET**

Date: 06/29/2016

Generic Name: Gabapentin Tablets, USP 600 and 800 mg.

Brand Equivalent: Neurontin® (Gabapentin) tablets 600 and 800 mg

<b>SECTION 1: IDENTIFICATION</b>	
<b>Product Name</b>	Gabapentin Tablets, USP
<b>Active substance</b>	Gabapentin
<b>Synonyms</b>	N/A
<b>Formula</b>	C9H17NO2
<b>Intended Use</b>	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
<b>Chemical Name</b>	2-[1-(aminomethyl)cyclohexyl]acetic acid
<b>Manufacturer Name &amp; Address</b>	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
<b>Telephone No.</b>	631-434-2723

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

<b>3. Composition/Information on ingredients</b>		
<b>Components</b>	<b>CAS-No</b>	<b>Concentration (%w/w)</b>
Gabapentin, USP*	60142-96-3	70.18
Mannitol, USP (Pearlitol 50C)	69658	*
Hydroxypropyl Cellulose, NF (Klucel LF)	9004-64-2	*
Copovidone, NF (Plasdone S-630)	9004-65-3	*
Crospovidone, NF (Polyplasdone XL-10)	9003-39-8	*
Talc, USP (140)	14807-96-6	*
Colloidal Silicon Dioxide, NF (Aerosil 200 Pharma)	7631-86-9	*
Poloxamer, NF (Lutrol Micro 127)	691397134	*
Magnesium Stearate, NF	557-04-0/ 91031-63-9	*
Hypromellose	9004653	*
Titanium dioxide	13463677	*
Polyethylene glycol	25322683	*

\* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. \*\*Present in trace amounts.

<b>4. FIRST AID MEASURES</b>	
<b>Eye contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Ingestion</b>	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.

<b>5. FIRE-FIGHTING MEASURES</b>	
<b>Suitable extinguishing media</b>	Use carbon dioxide, dry chemical, or water spray. Use fire-extinguishing media appropriate for surrounding materials.
<b>Hazardous Combustion Products:</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
<b>Fire Fighting Procedures</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazards:</b>	Not applicable

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
<b>Health and Safety Precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting</b>	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.
<b>Measures for Environmental Protections</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

<b>7. HANDLING AND STORAGE</b>	
<b>General Handling</b>	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. 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.
<b>Storage Conditions</b>	Store in a cool, dry place away from direct sunlight.

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

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>General Information</b>	
<i>Appearance</i> <b>Physical State</b> <b>Color</b> <b>Form</b>	Film-coated tablets White tablets
<i>Odour</i> <b>Odour</b> <b>Odor Threshold</b>	Not available Not available
<b>pH</b>	Not available
<i>Other information</i>	
<b>Bulk density</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Molecular formula</b>	C9H17NO2
<b>Hydrolysis/Photolysis</b>	Not available
<b>Hygroscopicity</b>	Not available
<b>Molecular Weight</b>	mixture
<b>Log Octanol/Water Partition Coeff [log Kow]</b>	Not available
<b>Surface Tension</b>	Not available
<b>pKa</b>	Not available
<b>Particle Size</b>	Not available
<b>Solubility, Water</b>	Freely soluble in water, 0.1N HCl, 0.1N in Sodium Hydroxide
<b>Specific Gravity/ Relative Density</b>	Not available
<b>Viscosity, dynamic</b>	Not available
<b>Viscosity, kinematic</b>	Not available
<b>% Volatile</b>	Not available
<i>Thermal/Stability properties</i>	
<b>Autoignition temperature</b>	Not available
<b>Boiling Point</b>	Not available
<b>Thermal decomposition</b>	Not available
<b>Explosive Limits, LEL</b>	Not available
<b>Explosive limits, UEL</b>	Not available
<b>Explosiveness</b>	Not available
<b>Flammability</b>	Not available
<b>Flash point</b>	Not available
<b>Melting Point</b>	Not available
<b>Oxidizing Potential</b>	Not available

<i>Vapor Properties</i>	
<b>Vapor Density</b>	Not available
<b>Vapor Pressure</b>	Not available
<b>Saturated Vapor Concentration</b>	Not available

<b>10. Stability and Reactivity</b>	
<b>Chemical Stability</b>	Stable under normal conditions
<b>Conditions to Avoid</b>	None known
<b>Incompatible Materials</b>	As a precautionary measure, keep away from strong oxidizers

<b>11. Toxicological Information</b>	
<b>Routes of Entry</b>	Ingestion, Inhalation, Eye contact, Skin contact
<b>Eye Irritation</b>	Gabapentin, Severely irritating to eyes
<b>Respiratory Irritation</b>	Gabapentin, Respiratory Irritant
<b>Acute Toxicity Study</b>	Due to lack of data the classification is not possible
<b>Repeated Dose Toxicity</b>	Due to lack of data the classification is not possible
<b>Genetic Toxicity</b>	Due to lack of data the classification is not possible
<b>Carcinogenicity</b>	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA
<b>Reproductive Toxicity</b>	Due to lack of data the classification is not possible
<b>Developmental Toxicity</b>	Due to lack of data the classification is not possible
<b>Pharmacokinetics/Toxicokinetics</b>	Due to lack of data the classification is not possible
<b>Other Toxicity Information</b>	Due to lack of data the classification is not possible

<b>12. Ecological Information</b>	
<b>Ecotoxicity</b>	No ecotoxicity data noted for the ingredient(s).
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	Not available
<b>Mobility in soil</b>	Not available
<b>Other adverse effects</b>	Not available

<b>13. Disposal considerations</b>	
<b>Advice On Disposal And Packaging</b>	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.
<b>Other information</b>	Disposal by incineration is recommended.

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

<b>15. Regulatory Information</b>	
EU Indication of danger:	Not classified

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