

SAFETY DATA SHEETS

This SDS packet was issued with item:

078918206

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078484637 078484645 078816504 078816512

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078918205 078918207

MATERIAL SAFETY DATA SHEET

Gabapentin Capsules, USP

Effective Date: 04-26-2010

Section 1 - Chemical Product and Company

Manufacturer:

InvaGen Pharmaceuticals Inc
7, Oser Avenue
Hauppauge, NY 11788

Emergency Phone:

1-631-231-3233

Common Name: Gabapentin Capsules, USP

Synonym(s): Neurontin

Chemical Name: 1-(Aminomethyl)cyclohexaneacetic Acid

Chemical Family: Cyclohexane-acetic acid derivative

Trade Name(s): Gabapentin Capsules, USP 100 mg, 300 mg and 400 mg.

Therapeutic Category: Used to relieve pain, especially neuropathic pain;
Anticonvulsant

Molecular formula and weight: C₉H₁₇NO₂, and Wt: 171.24

Section 2 - Composition / Information on Ingredients

<u>Ingredient</u>	<u>CAS #</u>	<u>Concentration %</u>
		100 mg, 300 mg & 400 mg
Gabapentin	60142-96-3	≈ 80 %
Excipients	NA	≈ 20 %

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines:

Chronic Exposure:

Possible hypersensitization.

Acute Exposure:

Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Target Organ Effects:

Not Found.

Sensitization: No applicable information found.

Section 3 - Hazards Identification

Not considered hazardous when handled under normal conditions.

Emergency Overview

Emergency Overview Effective Date: 26-April-10

InvaGen Laboratory Labeling Codes:

Health 1

Fire 1

Reactivity 0

Primary Physical and Health Hazards: Not hazardous if intact.

Caution Statement: Intact Gabapentin Capsules are not considered to be a health hazard

Routes of Entry: Oral

Effects of Overexposure: Capsules are intended for human consumption under guidance of a physician. Intact capsules are not considered hazardous under normal handling procedures.

Adverse Effects:

Adverse effects may include unsteadiness; uncontrolled eye movements; vision problems; dizziness; drowsiness; unusual tiredness or weakness; muscle pain; back pain; swelling of face or extremities; shaking or twitching; memory loss; abnormal thinking; mood or behavior disturbances; slurred speech; frequent urination; constipation; diarrhea; indigestion; nausea; vomiting; headache; decrease in sexual desire or ability; trouble sleeping; runny nose; dry mouth and throat; sore throat; viral infection; ringing in ears; bruising or rash; high blood pressure; and weight gain. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose effects include any of the effects listed below:

Overdose effects include abdominal pain, diarrhea, double vision, slurred speech, sluggishness, and drowsiness

Medical conditions Aggravated by Exposure:

Hypersensitivity to material, active alcoholism, diabetes, and impaired kidney function.

Carcinogenicity:

Gabapentin - Not listed by IARC, NTP and OSHA.

Other Carcinogenicity Data: Gabapentin was not carcinogenic in mice fed up to 2000 mg/kg/day for two years. Gabapentin caused malignant pancreatic tumors in male rats but not female rats fed 2000 mg/kg/day for two years.

Section 4 - First Aid Measures

In case of Inhalation: May cause irritation. Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

In case of contact with Skin: Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

In case of contact with Eyes: Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

In case of Ingestion: If swallowed, was out mouth with water. This material is rapidly and well absorbed from the gastrointestinal tract provided person is conscious. Seek medical advice

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment:

Treatment for gabapentin overdose should be systematic and supportive and may include the following:

1. Do not induce vomiting because of potential for CNS depression.
2. Administer activated charcoal as a slurry.
3. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine.
4. For seizures, administer a benzodiazepine intravenously. Consider phenobarbital if seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia.
5. Gabapentin may be removed by hemodialysis. [Poisindex 2008]

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found

UFL: No applicable information found

LFL: No applicable information found

Extinguishing Media: Water spray, dry chemical powder, carbon dioxide or foam or appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Hazardous Combustion Products: Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6 - Accidental Release Measures

The following are recommended for manufacturing or other situations where exposure to the tablet, powder may occur.

Spills: Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Collect and place it in a suitable, properly labelled container for recovery or disposal.

Environmental Precautions For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Section 7 - Handling and Storage

Handling: Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling. Avoid contact with eyes. Handle and store as per the label to ensure product integrity.

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.

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Capsules are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Respiratory Protection: Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Eye Protection: Safety goggles or glasses.

Gloves: Chemically compatible

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Additional Exposure Precautions: In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

Section 9 - Physical and Chemical Properties

Physical Properties:

Appearance:

100 mg Capsules: Hard Gelatin Capsules Size “3” with White Opaque Cap and White Opaque body imprinted with **100 mg** and **IG321** filled with white to Off-white powder.

300 mg Capsules: Hard Gelatin Capsules Size “1” with Yellow Opaque Cap and Yellow Opaque body imprinted with **300 mg** and **IG322** filled with white to Off-white powder.

400 mg Capsules: Hard Gelatin Capsules Size “0” Orange Opaque Cap and Orange Opaque body imprinted with **400 mg** and **IG323** filled with white to Off-white powder.

Physical State: Solid

Odor : No applicable information found.

Chemical Properties:

Boiling Point: No applicable information found

Melting range: 162⁰C -167⁰C

Specific Gravity: No applicable information found

pH: 6.5 – 8.0

Evaporation Rate: No applicable information found

Solubility: Freely soluble in water, 0.1N HCl, 0.1N in Sodium Hydroxide

Vapor Density: No applicable information found

Vapor Pressure: No applicable information found

Section 10 - Stability and Reactivity

Conditions to Avoid: Avoid exposure to heat, sources of ignition, and electrostatic discharge.

Stability: Stable at normal temperatures and pressures.

Incompatibility: Strong oxidizing agents

Hazardous Decomposition: When heated to decomposition material emits toxic fumes under fire conditions.

Hazardous Polymerization: No.

Section 11 - Toxicological Information

Oral Rat: LD₅₀: >5000 mg/kg

Oral Mouse: LD₅₀: >5000 mg/kg.

Irritancy data : Rabbit/Eye: non irritant

Corrosivity: No applicable information found

Reproduction and Developmental Effects:

In rats, doses up to 2000 mg/kg had no adverse effects on fertility; doses of 500 mg/kg/day increased the incidence of hydroureter and hydronephrosis in the offspring but doses up to 2000 mg/kg/day did not cause an increase in other malformations. In mice, oral doses of 1000 or 3000 mg/kg/day during pregnancy caused delayed bone ossification in the offspring but did not cause malformations. In rabbits, doses of 60 to 1500 mg/kg/day during pregnancy increased the incidence of postimplantation loss but did not increase the incidence of malformations in the offspring.

Mutagenicity :

Gabapentin did not demonstrate mutagenic or genotoxic potential in three in vitro and four in vivo assays. It was negative in the Ames test and the in vitro HGPRT forward mutation assay in Chinese hamster lung cells; it did not produce significant increases in chromosomal aberrations in the in vitro Chinese hamster lung cell assay; it was negative in the in vivo chromosomal aberration assay and in the in vivo micronucleus test in Chinese hamster bone marrow; it was negative in the in vivo mouse micronucleus assay; and it did not induce unscheduled DNA synthesis in hepatocytes from rats given gabapentin.

Section 12 - Ecological Information

No applicable information found

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible InvaGen and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations: No applicable information found

International Regulatory Information: EINECS # 262-076-3

Section 16 - Other Information

MSDS Sections Revised: New

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute or product literature which may accompany the finished product.