

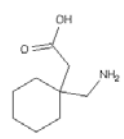
## SAFETY DATA SHEETS


**This SDS packet was issued with item:**

078653545

N/A

## Material Safety Data Sheet

Section 1. Product Identification and Uses			
<b>Common/Trade name</b>	<b>Gabapentin</b>	<b>DSL#</b>	Not on the DSL list.
<b>Synonyms</b>	1-(Aminomethyl)cyclohexaneacetic acid	<b>CAS#</b>	60142-96-3
<b>Chemical name</b>	Cyclohexaneacetic acid, 1-(aminomethyl)-	<b>Molecular weight</b>	171.24g/mole
<b>Chemical family</b>	Cyclohexane-acetic acid derivative	<b>Chemical formula</b>	C <sub>9</sub> H <sub>17</sub> NO <sub>2</sub>
<b>Supplier</b>	Jiangxi Synergy Pharmaceutical CO., LTD Jiangxi Fengxin Industrial Park 330700 Fengxin, Jiangxi Tel. 86-795-4605608	<b>Chemical structure</b>	
<b>Material uses</b>	Pharmaceutical active ingredient. Therapeutic category: Anticonvulsant.	<b>Manufacturer</b>	Same as supplier.
<b>Emergency phone</b>	(416)-749-9300 ext. 5555 For general information call ext. 8483 (8 AM-4 PM)	<b>DIN</b>	Not applicable

Section 2. Hazards Identification	
<b>Potential Acute Health Effects</b>	Possible eye, skin, gastrointestinal and/or respiratory tract irritation.
<b>Potential Chronic Health Effects</b>	Possible hypersensitization.
<b>WHMIS</b>	WHMIS CLASS D-2B: Material causing other toxic effects (TOXIC).
	
<b>Remark</b>	Covered by Food & Drug Act and therefore not regulated under WHMIS
<b>Apotex Hazard Classification (For Apotex internal practices only)</b>	This material has been assigned hazard class: <b>1</b>

Section 3. First Aid Measures	
<b>Eye contact</b>	IMMEDIATELY flush eyes with running water for at least 15 minutes, keeping eyelids open. Take care not to rinse contaminated water into the non-affected eye. Always seek medical attention for accidents involving the eyes.
<b>Skin contact</b>	Flush the contact area with lukewarm running water for at least 15 minutes. Seek medical attention if symptoms persist.
<b>Hazardous skin contact</b>	Flush the contact area with lukewarm running water for at least 15 minutes. Seek medical attention if symptoms persists. If contamination is extensive, remove clothing under running water. Discard or decontaminate clothing before reuse. Unless contact has been slight or if irritation persists see medical attention.
<b>Slight inhalation</b>	Allow the victim to rest in a well ventilated area. Seek immediate medical attention if irritation persists.
<b>Hazardous inhalation</b>	Take proper precautions to ensure your own safety before attempting rescue. Remove source of contamination or move victim to fresh air. If breathing has stopped, trained personnel should begin artificial respiration (use protective mask with one-way valve), or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.
<b>Slight ingestion</b>	Flush out mouth with water. Seek medical attention if symptoms persist.

**Continued on Next Page**

**Hazardous ingestion** Never give anything by mouth if victim is rapidly losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing has stopped, trained personnel should begin artificial respiration (use protective mask with one -way valve), or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.

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 4. Hazardous Ingredients

Name	CAS #	% (w/w)
Gabapentin	60142-96-3	100

#### Toxicity values of the hazardous ingredients

Refer to Sec. 11.

**TLV** Not established

#### Section 5. Fire Fighting Measures

<b>The product is:</b>	May be combustible.
<b>Autoignition temperature</b>	Not available.
<b>Fire degradation products</b>	Decomposition products may include the following materials: carbon oxides (CO, CO <sub>2</sub> ), nitrogen oxides (NO, NO <sub>2</sub> etc.).
<b>Flash points</b>	Not applicable
<b>Flammable limits</b>	Not available.
<b>Fire extinguishing procedures</b>	Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Flammability</b>	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. When heated to decomposition material emits toxic fumes under fire conditions.
	<b>Remark</b> No additional remark.
<b>Risks of explosion</b>	Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Fine airborne dust can be ignited by static discharge.
	<b>Remark</b> No additional remark.

#### Section 6. Accidental Release Measures

**Spill and leak** Vacuum or sweep up spillage. Avoid dust. Place spillage into an appropriate labeled waste disposal container. Wash contaminated clothing before reuse. Ventilate area and wash spill site. Follow appropriate Safe Work Practices.

#### Protective Clothing Pictograms in case of large spill and/or high exposure levels

**Protective clothing in case of large spill** Full suit with hood, or disposable/washable coveralls. Full facepiece Air Purifying Respirator with combination particulate/organic vapour cartridge. Rubber gloves (impervious).



## Section 7. Handling and Storage

<b>Precautions</b>	Use with adequate dust control. In case of insufficient ventilation, wear suitable respiratory equipment. Avoid contact with eyes and skin. Avoid breathing dust.
<b>Storage</b>	Store in suitable labelled containers. Keep containers tightly closed when not in use and when empty. Protect from damage. Store in a cool (below 30°C), dry, well-ventilated area, out of direct sunlight.

## Section 8. Exposure Controls/Personal Protection

<b>Engineering Controls</b>	Exposure to this material can be controlled in many ways. The measures appropriate for a particular worksite depend on how this material is used and on the extent of exposure. This general information can be used to help develop specific control measures. Ensure that control systems are properly designed and maintained. Comply with occupational, environmental, fire, and other applicable regulations. Engineering methods to control hazardous conditions are preferred. Methods include mechanical (local exhaust) ventilation, process or personnel enclosure and control of process conditions. Administrative controls and personal protective equipment may also be required. Supply sufficient replacement air to make up for air removed by exhaust system.
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<b>Personal Protection</b>	Splash goggles. Covering uniform. Half facepiece Air Purifying Respirator with particulate cartridge P100 (HEPA) (less than 1 kg). Full facepiece Air Purifying Respirator with particulate cartridge P100 (HEPA) (greater than 1 kg). Rubber gloves (impervious). Chemical fume hood.
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### Protective Clothing (Pictograms)



#### PERSONAL PROTECTIVE EQUIPMENT:

If engineering controls and work practices are not effective in controlling exposure to this material, then wear suitable personal protective equipment, including approved respiratory protection. Have appropriate equipment available for use in emergencies such as spills or fire. If respiratory protection is required, institute a complete respiratory protection program, including selection, fit testing, training, maintenance and inspection. Refer to the CSA Standard Z94, "Selection, Care, and Use of Respirators".

#### RESPIRATORY PROTECTION GUIDELINES:

Where Local Exhaust Ventilation (LEV) at dust generating process points exists, respiratory protection may not be required.

When working with quantities less than 1 kg and in the absence of Local Exhaust Ventilation (LEV) with dusty processes, a half facepiece Air Purifying Respirator with combination particulate/organic vapour cartridge or Filterind facepiece and goggles is recommended.

When working with quantities greater than 1 kg and in the absence of Local Exhaust Ventilation (LEV) with dusty processes, a Full facepiece Air Purifying Respirator with combination particulate/organic vapour cartridge is recommended.

The specific respirator selected must be based on contamination levels found in the work place, the specific operation and must not exceed the working limits of the respirator.

When performing cleaning activities refer to appropriate cleaning solution MSDS.

EYE/FACE PROTECTION: Splash goggles/safety glasses.

PROTECTIVE CLOTHING/SKIN PROTECTION: Glove selection must take into account any solvents and other hazards present. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Full environmental suit with hood, and/or other resistant protective clothing when working in dusty areas. Have a safety shower/eye-wash fountain readily available in the immediate work area.

EXPOSURE CONTROLS/PERSONAL PROTECTION COMMENTS: In the event clothing becomes contaminated, remove promptly. Launder before use. Inform laundry personnel of contaminant's hazards. Do not eat, drink or smoke in work areas. Wash hands thoroughly after handling this material. Maintain good housekeeping.

Physical state and appearance	Crystalline powder.	Odor	Odorless
pH	6.5 - 8.0 (2% solution)	Taste	Not available.
Odor threshold	Not applicable	Color	White to off-white
Volatility	Not available.		
Melting point/ Freezing point	162-167°C		
Boiling point	Not available.		
Specific gravity	Not available.		
Vapor density	Not available.		
Vapor pressure	Not available.		
Partition Coefficient:	n-octanol/water: -1.10		
Ionicity (surface active agent)	Not available.		
Critical temperature	Not available.		
Instability temperature	Not available.		
Conditions of instability	Not available.		
Dispersion properties	See solubility		
Evaporation rate	Not available.		
Solubility	Freely soluble in water. Freely soluble in alkaline solutions and in acidic solutions. High lipid solubility		

<b>Stability</b>	Normally stable.
<b>Hazardous decomp. products</b>	When heated to decomposition material emits fumes with odour.
<b>Degradability</b>	Not available.
<b>Corrosivity</b>	Not available.
	<b>Remark</b> No additional remark.
<b>Reactivity/Incompatibility</b>	Material undergo reaction during heating. Protect from heat and open flame.
	<b>Remark</b> No additional remark.

Routes of entry	Eye contact. Ingestion. Inhalation. Skin contact.
Toxicity data	LD50: >5000 mg/kg (oral-rat) LD50: >5000 mg/kg (oral-mouse) Irritancy data: rabbit/eye: non-irritating

**Long-term effects**

Possible hypersensitization.

Carcinogenicity: Not listed by IARC, NTP, ACGIH, or OSHA.

Gabapentin was not carcinogenic in mice fed up to 2000 mg/kg/day for two years. Gabapentin caused. Reproductive and Developmental Effects: Pregnancy Category C: 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.

No adverse effect on fertility or reproduction were observed in rats at doses up to 2000 mg/kg (approximately 5 times the maximum recommended human dose on an mg/m<sup>2</sup> basis).

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.

**Remark**

Medical conditions aggravated by exposure: Hypersensitivity to material, active alcoholism, and impaired kidney function.

**Short-term effects and Signs & Symptoms of overexposure**

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

The usual adult oral dose of Gabapentin is 300 mg three time a day initially. The dose may be gradually increased, but should not exceed a maximum of 3600 mg per day in divided doses.

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 abdominal pain, diarrhea, double vision, slurred speech, sluggishness, and drowsiness.

**Remark**

The above adverse effects are based on clinical studies.

**Section 12. Ecological Information****Ecological Information**

Not available.

**Section 13. Disposal Considerations****Waste Disposal**

For internal Apotex waste disposal: Collect in sealed containers and place in appropriate labeled pharmaceutical solid waste class 261N.

For external waste disposal: Follow all appropriate safe work procedures and federal, provincial and local regulations for disposal. Use only licensed disposal and waste hauling companies.

**Section 14. Transport Information TDG, IATA, IMDG**

Not controlled under TDG (Canada).

**UN**

Not applicable (PIN and PG).

**Special Provisions for Transport**

No additional remark.

**Section 15. Other Regulatory Information and Pictograms**

**\*\*NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) HAZARD INDEX\*\***

NFPA-HEALTH-blue :1-Slightly hazardous to health.

NFPA-FLAMMABILITY-red :1-Materials that must be preheated before ignition can occur.

NFPA-REACTIVITY-yellow :0-Normally stable.

National Fire  
Protection  
Association (U.S.A.)

Health



Fire Hazard  
Reactivity  
Specific Hazard

#### Hazardous Material Information System (U.S.A.)

Health Hazard	1
Fire Hazard	1
Reactivity	0
Personal Protection	X

\* - Chronic hazard indicator  
X - See Section 8

#### HCS (Hazardous Communication System) (OHSA, U.S.A.)

Not controlled under the HCS (United States).

#### DOT (Department of Transportation) (U.S.A) (Pictograms)

Not a DOT controlled material (United States).

#### EU Classification and Labelling

R36/37/38- Irritating to eyes, respiratory system and skin. R47- May cause birth defect. R40-Limited evidence of a carcinogenic effect. S36- Wear suitable protective clothing.



#### ADR (European Agreement of Dangerous goods by Road) (Pictograms)

Not controlled under ADR (Europe).

#### Other Regulations

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

## Section 16. Other Information

#### References

The Merck Index,  
HSDB & RTECS Database  
PDR Electronic Library

#### MSDS:

U.S. Pharmacopeia

#### Validation date: (year.month)

January 7, 2009

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