

SAFETY DATA SHEETS

This SDS packet was issued with item:

078935290

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

078935291 078935292



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Name : Gabapentin Tablets USP 600mg & 800 mg.

Manufactured by : Strides Pharma Science Limited,
(Formerly Strides Shasun Limited)
Formulation Division
RS No: 32 -34, PIMS Road
Periyakalpet, Puducherry, India.
Emergency Telephone: 91-0413-2655946, 2655952, 2655697,
2655698, Fax: 0413-2655154

2. COMPOSITION / INFORMATION ON INGREDIENTS

Name : Gabapentin Tablets USP

Active material Gabapentin Formula : $C_9H_{17}NO_2$

Active material Gabapentin CAS No. : 60142-96-3

Active material Gabapentin Molecular weight : 171.237

Active material Gabapentin Synonyms : 1-(Aminomethyl)
cyclohexaneacetic Acid

3. HAZARDS IDENTIFICATION

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:

CARCINOGENIC EFFECTS : Not available.

MUTAGENIC EFFECTS : Not available.

TERATOGENIC EFFECTS : Classified POSSIBLE for human.

DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female (Possible).

The substance may be toxic to central nervous system (CNS), pancreas. Repeated or prolonged exposure to the substance can produce target organs damage.

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4. FIRST AID MEASURES

Eye Contact: Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

Skin Contact: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.

Serious Skin Contact: Not available.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

5. FIRE AND EXPLOSION DATA

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...).

Fire Hazards in Presence of Various Substances: Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:

Risks of explosion of the product in presence of mechanical impact: Not available.

Risks of explosion of the product in presence of static discharge: Not available.



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Fire Fighting Media and Instructions:

SMALL FIRE: Use dry chemical powder.

LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

6. ACCIDENTAL RELEASE MEASURES

Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow evacuating through the sanitary system.

7. HANDLING AND STORAGE

Precautions: Keep locked up... Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 24°C (75.2°F).

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses, Lab coat, Gloves, Dust respirator. Be sure to use an approved/certified respirator or equivalent.

Personal Protection in Case of a Large Spill: Splash goggles, Full suit, Dust respirator, Boots, Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist before handling this product.

Exposure Limits: Not available.



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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state and appearance: Solid.

Odor: Not available.

Taste: Not available.

Molecular Weight: 171.237.

Color: white to off-white crystalline solid.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: Not available.

Critical Temperature: Not available.

Specific Gravity: Not available.

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff. Not available

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility: Not available.

10. STABILITY AND REACTIVITY

Stability: The product is stable.

Instability Temperature: Not available.



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Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents.

Corrosivity: Not available.

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

Routes of Entry: Inhalation, Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50) >8000 mg/kg [Rat].

Chronic Effects on Humans:

TERATOGENIC EFFECTS: Classified possible for human.

DEVELOPMENTAL TOXICITY: Classified Reproductive system/ toxin/female possible.

May cause damage to the following organs: central nervous system (CNS), pancreas.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: May cause adverse reproductive effects and birth defects based on animal data.

Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects:

Skin: Causes skin irritation.

Eyes: Dust can cause eye irritation.

Inhalation: Can cause respiratory tract and mucous membrane irritation.



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Ingestion: May cause digestive tract irritation with nausea. May also affect Behavior/Central Nervous system (CNS). Symptoms may include headache, dizziness, and CNS depression.

12. ECOLOGICAL INFORMATION

Ecotoxicity: Not available.

Products of Biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

13. DISPOSAL INFORMATION

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

14. TRANSPORT REGULATIONS

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

15. REGULATORY INFORMATION

Federal and State Regulations: No products were found.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

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

Health: 1

Flammability: 1

Reactivity: 0



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Protective Equipment: Safety glasses, Gloves, Lab coat, Dust respirator. Be sure to use an approved/certified respirator or equivalent.

16. ADDITIONAL INFORMATION

No information is available

As of the date of issuance, we are providing information regarding this material with the good faith belief it is accurate. However, this safety data sheet does not constitute a warranty of any kind, expressed or implied. It is the user's responsibility to implement policies for the safe handling and use of this product, and to determine the suitability of this information for their 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 medical or remediation personnel.