

## SAFETY DATA SHEET

Gabapentin Oral Solution 250 mg/5mL

### 1. IDENTIFICATION

**Product identifier:** Gabapentin Oral Solution 250 mg/5mL  
**Product Codes:** 0121-1067-16, 0121-4067-40, 0121-2134-40

**Supplier Name and Address:** PAI Pharma  
 1700 Perimeter Road  
 Greenville, SC 29605  
**Telephone number:** (864) 277-7282  
**Emergency phone number:** CHEMTREC 800-424-9300

**Recommended use:** Human drug – fever and pain reliever  
**Restrictions on use:** Use only as directed.

### 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Not hazardous	Reproductive Toxicity Category 2

**Label Elements:**  
**Warning!**



**Hazard statement(s)**

Suspected of damaging the unborn child.

**Precautionary statement(s)**

Obtain special instructions before use.  
 Do not handle until all safety precautions have been read and understood.  
 Wear protective clothing and gloves.  
 IF exposed or concerned: Get medical attention.  
 Store locked up.  
 Dispose in accordance with local and national regulations.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Gabapentin	60142-96-3	5%
Carboxymethylcellulose sodium	9004-32-4	Proprietary
Acesulfame Potassium	55589-62-3	<0.5%
Methylparaben Sodium	5026-62-0	<0.1%
Propylparaben Sodium	35285-69-9	<0.1%
Ethylparaben	120-47-8	<0.1%
Hydrochloric Acid	7647-01-1	pH Adj

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Sodium Hydroxide	130-73-2	pH Adj
Water	7732-18-58	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

#### 4. FIRST-AID MEASURES

**Inhalation:** Remove person to fresh air. If irritation occurs, get medical attention.

**Skin contact:** First aid is generally not required. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

**Ingestion:** In the case of unintentional ingestion or overdose, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if any adverse effects occur or for overdose.

**Most important symptoms/effects, acute and delayed:** May cause mild eye irritation. Swallowing may cause gastrointestinal effects (nausea, vomiting, constipation), dizziness, headache, tremor, sleepiness, fatigue and abnormal thinking. Suspected to cause adverse reproductive effects.

**Indication of immediate medical attention and special treatment, if necessary:** Medical attention is recommended for large unintended ingestion.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

**Specific hazards arising from the chemical:** This product is not a fire hazard but may burn under fire conditions after the water has evaporated.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8. Caution – spilled liquid may present a slip hazard.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

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### 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Exposure guidelines:

Gabapentin	None Established
Carboxymethylcellulose sodium	None Established
Acesulfame Potassium	None Established
Methylparaben Sodium	None Established
Propylparaben Sodium	None Established
Ethylparaben	None Established
Hydrochloric Acid	2 ppm Ceiling ACGIH TLV 5 ppm Ceiling OSHA PEL
Sodium Hydroxide	2 mg/m <sup>3</sup> Ceiling ACGIH TLV 2 mg/m <sup>3</sup> TWA OSHA PEL

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

#### Individual protection measures:

**Respiratory protection:** None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** None required for normal use. Impervious gloves recommended for manufacturing operations.

**Eye protection:** None required for normal use. Chemical safety goggles recommended for manufacturing operations.

**Other:** None known.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b> Liquid	<b>Color:</b> Colorless to slightly yellow
<b>Odor:</b> Odorless	<b>pH:</b> 6.0-7.0
<b>Melting point/freezing point:</b> Not determined	<b>Boiling Point:</b> Not determined
<b>Flash point:</b> Not applicable	<b>Particle Characteristics:</b> Not applicable
<b>Flammability:</b> Not flammable	<b>VOC:</b> Not determined
<b>Flammable limits: LEL:</b> Not determined	<b>UEL:</b> Not determined
<b>Vapor pressure:</b> Not determined	<b>Relative Vapor density:</b> Not determined
<b>Density:</b> 0.964 -1.066 g/cm <sup>3</sup>	<b>Solubility(ies):</b> Soluble

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<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not available
<b>Decomposition temperature:</b> Not available	<b>Kinematic Viscosity:</b> Not determined

### 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use.

**Chemical stability:** Stable.

**Possibility of hazardous reactions:** None known.

**Conditions to avoid:** None known.

**Incompatible materials:** Avoid oxidizing agents.

**Hazardous decomposition products:** Thermal decomposition may yield carbon oxides.

### 11. TOXICOLOGICAL INFORMATION

**Acute effects of exposure:**

**Inhalation:** Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract.

**Ingestion:** Swallowing gastrointestinal effects (nausea, vomiting, constipation), dizziness, headache, tremor, sleepiness, fatigue and abnormal thinking.

**Skin contact:** May cause mild irritation.

**Eye contact:** May cause mild irritation with redness and tearing.

**Chronic Effects:** None currently known.

**Sensitization:** Components are not known to be sensitizers.

**Germ Cell Mutagenicity:** None of the components have been shown to cause germ cell mutagenicity.

Gabapentin was not mutagenic in in-vitro bacterial reverse mutation assay, HGPRT forward mutation assay in Chinese hamster lung cells) and *in vivo* (chromosomal aberration and micronucleus test in Chinese hamster bone marrow, mouse micronucleus, unscheduled DNA synthesis in rat hepatocytes) assays.

**Reproductive Toxicity:** Gabapentin resulted in embryofetal toxicity in mice, rats and rabbits including skeletal abnormalities and mortality.

**Carcinogenicity:** None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. Gabapentin was administered orally to mice and rats in 2-year carcinogenicity studies. No evidence of drug-related carcinogenicity was observed in mice treated at doses up to 2,000 mg/kg/day. In rats, increases in the incidence of pancreatic acinar cell adenoma and carcinoma were found in male rats receiving 2,000 mg/kg. The mechanism of gabapentin-induced pancreatic carcinogenesis in rats indicate that gabapentin stimulates DNA synthesis in rat pancreatic acinar cells *in vitro* and, thus, may be acting as a tumor promoter by enhancing mitogenic activity. It is not known if this mechanism is relevant to humans.

**Acute Toxicity Values:** Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Gabapentin: Oral rat LD50 >8000 mg/kg

### 12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

**Ecotoxicity values:** No data available.

**Persistence and degradability:** No data available.

**Bioaccumulative potential:** No data available.

**Mobility in soil:** No data is available.

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**Other adverse effects:** None known.

### 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

### 14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

**Transport in bulk according to IMO instruments:** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

### 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Refer to Section 2 for the OSHA Hazard Classification.

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

**California Proposition 65:** This product is not known to contain regulated chemicals.

**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

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**16. OTHER INFORMATION****Issue Date:** 06/01/2025**Revision Number:** 01**Revision Date:** New SDS**SDS Revision History:** New SDS

**Disclaimer:** The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.