

SAFETY DATA SHEETS

This SDS packet was issued with item:

078935342

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

078699087 078941542



Material Safety Data Sheet

Material Name: Gabapentin Oral Solution, 250 mg / 5 mL

*** Section 1 - Chemical Product and Company Identification ***

Manufacturer Information

Amneal Pharmaceuticals
85 Adams Ave.
Hauppauge, NY 11788

Phone: 631.952.0214
Fax: 631.656.1009

*** Section 2 - Hazards Identification ***

Emergency Overview

May cause eye, skin and respiratory tract irritation.

Potential Health Effects: Eyes

May cause eye irritation.

Potential Health Effects: Skin

May cause skin irritation.

Potential Health Effects: Ingestion

Not considered a likely route of exposure under normal industrial use. May cause adverse effects as described in product insert when ingested.

Potential Health Effects: Inhalation

May cause respiratory tract irritation.

HMIS Ratings: Health: 1 Fire: 0 HMIS Reactivity 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

*** Section 3 - Composition / Information on Ingredients ***

CAS #	Component
7732-18-5	Water
60142-96-3	Gabapentin
9004-32-4	Sodium carboxymethyl cellulose
Trade Secret	Natural & Artificial Strawberry Anise Flavor
24634-61-5	Potassium sorbate
Trade Secret	Natural & Artificial Peppermint Flavor
55589-62-3	1,2,3-Oxathiazin-4(3H)-one, 6-methyl-, 2,2-dioxide, potassium salt
Trade Secret	Magnasweet 110

*** Section 4 - First Aid Measures ***

First Aid: Eyes

Flush eye(s) immediately with plenty of water. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

First Aid: Skin

Rinse immediately with plenty of water for at least 15 minutes.

First Aid: Ingestion

Acute overdose should be followed by immediate gastric lavage or emesis followed by supportive and symptomatic therapy. Contact a physician.

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First Aid: Inhalation

Remove the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms appear.

*** Section 5 - Fire Fighting Measures ***

General Fire Hazards

See Section 9 for Flammability Properties.
None anticipated.

Hazardous Combustion Products

Not Determined

Extinguishing Media

Use appropriate extinguishing media for surrounding fire.

Fire Fighting Equipment/Instructions

Firefighters should wear full protective gear.

NFPA Ratings: Health: 1 Fire: 0 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

*** Section 6 - Accidental Release Measures ***

Containment Procedures

Stop the flow of material, if this is without risk.

Clean-Up Procedures

Wipe up spills and rinse area with water. Dispose of these materials in accordance with federal, state, and local regulations.

Evacuation Procedures

Isolate area. Keep unnecessary personnel away.

Special Procedures

Wear appropriate personal protective equipment.

*** Section 7 - Handling and Storage ***

Handling Procedures

No special handling procedures needed.

Storage Procedures

Store at controlled temperatures. Keep tightly closed and out of reach of children.

*** Section 8 - Exposure Controls / Personal Protection ***

A: Component Exposure Limits

ACGIH, OSHA, and NIOSH have not developed exposure limits for any of this product's components.

Engineering Controls

Ensure adequate ventilation, especially in confined areas.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Safety glasses with side-shields

Personal Protective Equipment: Skin

Use impervious gloves.

Personal Protective Equipment: Respiratory

Breathing apparatus only if aerosol or dust is formed.

Personal Protective Equipment: General

Eye wash fountain is recommended.

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*** Section 9 - Physical & Chemical Properties ***

Appearance:	Clear, colorless	Odor:	Peppermint Strawberry
Physical State:	Liquid	pH:	ND
Vapor Pressure:	ND	Vapor Density:	ND
Boiling Point:	ND	Melting Point:	NA
Solubility (H2O):	Miscible with water	Specific Gravity:	ND
Evaporation Rate:	ND	VOC:	ND
Octanol/H2O Coeff.:	ND	Flash Point:	ND
Flash Point Method:	ND	Upper Flammability Limit (UFL):	ND
Lower Flammability Limit (LFL):	ND	Burning Rate:	ND
Auto Ignition:	ND		

*** Section 10 - Chemical Stability & Reactivity Information ***

Chemical Stability

This is a stable material.

Chemical Stability: Conditions to Avoid

Not Determined

Incompatibility

Not Determined

Hazardous Decomposition

None

Possibility of Hazardous Reactions

Will not occur.

*** Section 11 - Toxicological Information ***

Acute Dose Effects

A: General Product Information

No information available for the product.

B: Component Analysis - LD50/LC50

Water (7732-18-5)

Oral LD50 Rat >90 mL/kg

Sodium carboxymethyl cellulose (9004-32-4)

Inhalation LC50 Rat >5800 mg/m³ 4 h; Oral LD50 Rat 27000 mg/kg; Dermal LD50 Rabbit >2 g/kg

Potassium sorbate (24634-61-5)

Oral LD50 Rat 3200 mg/kg

Carcinogenicity

A: General Product Information

No information available for the product.

B: Component Carcinogenicity

None of this product's components are listed by ACGIH, IARC, OSHA, NIOSH, or NTP.

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*** Section 12 - Ecological Information ***

Ecotoxicity

A: General Product Information

No information available for the product.

B: Component Analysis - Ecotoxicity - Aquatic Toxicity

Potassium sorbate (24634-61-5)

Test & Species

96 Hr LC50 Brachydanio rerio

1250 mg/L [static]

48 Hr EC50 Daphnia magna

750 mg/L

Conditions

*** Section 13 - Disposal Considerations ***

US EPA Waste Number & Descriptions

Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

Disposal Instructions

All wastes must be handled in accordance with local, state and federal regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

*** Section 14 - Transportation Information ***

US DOT Information

Shipping Name: Not Regulated

*** Section 15 - Regulatory Information ***

US Federal Regulations

Component Analysis

None of this products components are listed under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), or CERCLA (40 CFR 302.4).

State Regulations

Component Analysis - State

None of this product's components are listed on the state lists from CA, MA, MN, NJ, PA, or RI.

Component Analysis - WHMIS IDL

No components are listed in the WHMIS IDL.

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Additional Regulatory Information

Component Analysis - Inventory

Component	CAS #	TSCA	CAN	EEC
Water	7732-18-5	Yes	DSL	EINECS
Gabapentin	60142-96-3	No	No	EINECS
Sodium carboxymethyl cellulose	9004-32-4	Yes	DSL	No
Potassium sorbate	24634-61-5	Yes	DSL	EINECS
1,2,3-Oxathiazin-4(3H)-one, 6-methyl-, 2,2-dioxide, potassium salt	55589-62-3	No	DSL	EINECS

*** Section 16 - Other Information ***

Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial, and local laws.

Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration., NJTSR = New Jersey Trade Secret Registry.

End of Sheet