

Product Name: Gallopamil Hydrochloride
Issued: Dec-09-2011



SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Gallopamil Hydrochloride
Chemical Name: 5-[2-(3,4-dimethoxyphenyl)ethyl-methylamino]-2-propan-2-yl-2-(3,4,5-trimethoxyphenyl)pentanenitrile Hydrochloride
Synonyms: Gallopamil; Gallopamil Hydrochloride; Methoxyverapamil Hydrochloride; Gallopamil HCl
Drug Code Number: 47769

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064
USA
E-mail Address: Abbott.SDS@abbott.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute oral toxicity	Category 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2
Specific target organ systemic toxicity (single exposure)	Category 3
Chronic aquatic toxicity	Chronic toxicity 3

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: T - Toxic
Xi - Irritant
Risk Phrases: R25 - Toxic if swallowed
R36/37/38 - Irritating to eyes, respiratory system and skin
R52 - Harmful to aquatic organisms
R53 - May cause long-term adverse effects in the aquatic environment

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Section 2. Hazards identification

2.2 Label elements



Signal Word: Danger

Hazard Statements: H301 - Toxic if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation
H412 - Harmful to aquatic life with long lasting effects

Precautionary Statements: P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTER or doctor/physician if you feel unwell
P273 - Avoid release to the environment

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Gallopamil hydrochloride 16662-46-7	100	240-704-7	T, R25 Xi, R36/37/38 R52, R53	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Acute Tox. 3 (H301) Aquatic Chronic 3 (H412)	No data available

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

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Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: Analogy suggests the following: nausea, slow heart rate, fast heart rate, decreased blood pressure, headaches, edema, flushing, tingling in the extremities. numbness, abnormal liver function, and allergic reactions.

Medical Conditions Aggravated by Exposure: Data suggest any pre-existing ailments in the following organs: cardiovascular system, liver. Hypersensitivity to the material and/or similar materials. liver, Pregnancy.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Monitor cardiovascular system function.

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

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6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Abbott EEL	Skin Notation
Gallopamil hydrochloride 16662-46-7	Not Applicable	None

8.2. Exposure controls

Engineering Controls: Use inside a hood, glovebox or process enclosure.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Product Name: Gallopamil Hydrochloride
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Appearance: White to off-white Powder
Odor: Odorless.
Odor Threshold: Not determined
pH: 5 - 6 as an aqueous solution.
Boiling Pt. @ 760 mm Hg (°C): Not determined.
Melting/Freezing Point (°C): 150 - 157
Flash Point (°C): Not determined.
Evaporation Rate at 20°C: Not determined.
Flammability (Solid): Not determined.
Lower Explosive Limit: Not determined.
Upper Explosive Limit: Not determined.
Vapor Pressure (mm Hg): Not determined.
Vapor Density (Air = 1): Not determined.
Specific Gravity: Not determined.
Solubility(ies): Soluble in: methanol, water, ethanol.
Partition coefficient: n-octanol/water Not determined.
Autoignition Temp. (°C): Not determined.
Decomposition temperature (°C): Not Determined
Viscosity (centipoise): Not determined.
Explosion Severity: Not determined.
Oxidizer Properties: Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Exposure to light

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NO_x), Hydrogen chloride

Section 11. Toxicological information

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Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Yes
Dermal: Yes
Inhalation: Yes

Acute Toxicity - Oral: Data for similar material given below.

Chemical Name	Acute Test	Value	Units	Species
Gallopamil hydrochloride 16662-46-7	LD50 =	108	mg/kg, for a similar material	Rats
		140		Guinea Pigs
		163		Mice
	LD50 >	400		Dogs

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Not determined.

Other Toxicology Data: Data for a similar material given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Gallopamil hydrochloride 16662-46-7	LD50 (sc) =	68-107	mg/kg, for a similar material	Mice Rats	

Corrosivity: Not determined.

Dermal Irritation: Similar Material: May be a skin irritant.

Eye Irritation: Similar Material : May be an eye irritant.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Similar Material : May cause respiratory tract irritation

Reproductive Effects: Similar Material : Animal testing did not show any effects on fetal development
Animal testing did not show any effects on fertility

Carcinogenicity: Similar Material : Not carcinogenic in animal study.

Mutagenicity: Similar Material : Negative in the Ames assay.

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Similar Material: LC50 1 <= 10mg/L for fish in 96 hours.

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12.2. Persistence and degradability

Similar Material : Not readily biodegradable.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Regulated

- 14.1. UN Number:** UN2811
14.2. Proper shipping name: Toxic solid, organic, n.o.s. (Gallopamil Hydrochloride)
14.3. Hazard class: 6.1
14.4. Packing group: III
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Gallopamil hydrochloride 16662-46-7	240-704-7	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Gallopamil hydrochloride 16662-46-7	-	-	-	-	-	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Gallopamil hydrochloride	100	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Gallopamil hydrochloride	100	No	Not Applicable	Not applicable

Immediate Health: Yes

Delayed Health: No

Fire: No

Sudden Pressure: No

Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:

Health: 2

Fire: 1

Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Product Name: Gallopamil Hydrochloride
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Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R25 - Toxic if swallowed, R36/37/38 - Irritating to eyes, respiratory system and skin, R52 - Harmful to aquatic organisms, R53 - May cause long-term adverse effects in the aquatic environment

Full text of H-Statements referred to under sections 2 and 3

H335 - May cause respiratory irritation, H315 - Causes skin irritation, H319 - Causes serious eye irritation, H301 - Toxic if swallowed, H412 - Harmful to aquatic life with long lasting effects

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Disclaimer:

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