methapharm

SAFETY DATA SHEET

Verapamil Hydrochloride Injection

Section 1: Identification

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Product Identifier:	Verapamil Hydrochloride Injection
Container Information	Vial
Synonyms/ Common Name:	benzeneacetonitrile, α-[3-[{2-(3,4-dimethoxyphenyl)ethyl} methylamino] propyl]-3,4-dimethoxy-α-(1-methylethyl) hydrochloride
Recommended use:	Pharmaceutical product used a calcium antagonist or slow-channel inhibitor
Product Type:	Regulated Prescription Drug

Section 2: Hazard(s) Identification

Emergency Overview

Verapamil Hydrochloride Injection is a solution containing verapamil hydrochloride, a calcium-channel blocking agent used in the treatment of hypertension, cardiac arrhythmias, and some cases of angina pectoris. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potent drug. Based on clinical use, possible target organs include the cardiovascular system.

US OSHA Specific – Classification

Physical Hazard: Not Classified

Label Elements

Signal Word: N/A

Pictogram: N/A

Hazard Statements: N/A

Precautionary Statements:

Prevention Do not breathe vapor or spray.

Response	Get medical attention if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.
Note:	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: Composition/information on ingredients

Ingredient	Approximate % by weight	CAS No.	RTECS Number
Verapamil Hydrochloride	≤0.25	152-11-4	YV8320000

Active Ingredient Name Verapamil Hydrochloride
Chemical Formula $C_{27}H_{38}N_2O_4 \cdot HCl$

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride. Hydrochloric acid is used to adjust the pH.

Section 4: 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.

Ingestion: Remove from source of exposure. If 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.

Section 5: Fire-fighting measures

Flammability None anticipated for this aqueous product.

Fire / Explosion Hazards: None anticipated for this aqueous product

Extinguishing Media:	As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.
Fire Fighting Procedures:	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

Section 6: Accidental release measures

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

Section 7: Handling and Storage

General Handling	No special handling required for hazard control under conditions of normal product use.
Storage Conditions	No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
Special Precautions	No special precautions required for hazard control.

Section 8: Exposure controls/personal protection

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Verapamil Hydrochloride	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

Respiratory Protection	Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Skin Protection	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Eye Protection	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Engineering Controls	Engineering controls are normally not needed during the normal use of this product.

Section 9: Physical/Chemical Properties

Appearance/Physical State	Clear aqueous solution
Odor	NA
Odor Threshold	NA
pH	4.9 (4.0 to 6.5)
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	NA
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

Section 10: Stability and reactivity

Reactivity:	Not determined.
Chemical Stability:	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to avoid:	Not determined
Incompatible materials:	Not determined
Hazardous Decomposition Products:	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.
Hazardous Polymerization	Not anticipated to occur with this product.

Section 11: Toxicological information

Acute Toxicity - Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Verapamil Hydrochloride	100	LD50	Oral	108, 150 163 140 >400	mg/kg mg/kg mg/kg mg/kg	Rat Mouse Guinea Pig Dog
Verapamil Hydrochloride	100	LD50	Intravenous	16 5.8	mg/kg mg/kg	Rat Mouse

LD 50: Dosage that produces 50% mortality.

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. In clinical use, adverse effects on the heart include bradycardia, AV block, worsening heart failure, and transient asystole. Other adverse effects include nausea, constipation, hypotension, dizziness, flushing, headaches, fatigue, tinnitus, dyspnea, and peripheral edema. There have been reports of skin reactions and some cases of abnormal liver function and hepatotoxicity. Gingival hyperplasia has occurred. Hyperprolactinemia has been reported in some patients receiving verapamil. Gynaecomastia has been reported rarely.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	None anticipated from normal handling of this product.
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may

	produce irritation with redness and tearing.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product.
Reproductive Effects	None anticipated from normal handling of this product. Studies in female rats at daily dietary doses up to 5.5 times (55 mg/kg/day) the maximum recommended human dose did not show impaired fertility. Effects on male fertility have not been determined. Reproduction studies have been performed in rabbits and rats at oral verapamil doses up to 1.5 (15 mg/kg/day) and 6 (60 mg/kg/day) times the human oral daily dose, respectively, and have revealed no evidence of teratogenicity. In the rat, this dose was embryocidal and retarded fetal growth and development, probably because of adverse maternal effects reflected in reduced weight gains of the dams. This oral dose has also been shown to cause hypotension in rats.
Mutagenicity	Verapamil was not mutagenic in the Ames test in 5 test strains at 3 mg per plate with or without metabolic activation.
Carcinogenicity	Studies in rats using verapamil dosages of 6 times the recommended maximum human dosage for 18 months did not reveal evidence of carcinogenicity. There was no evidence of a carcinogenic potential of verapamil administered in the diet of rats for 2 years at dosages of 10, 35, and 120 mg/kg per day or approximately 1x, 3.5x, and 12x, respectively, the maximum recommended human daily dose (480 mg per day or 9.6 mg/kg/day).
Carcinogen Lists	**IARC**: Not listed **NTP**: Not Listed **OSHA**: Not Listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	In chronic animal toxicology studies, verapamil caused lenticular and/or suture line changes at 30 mg/kg/day or greater, and frank cataracts at 62.5 mg/kg/day or greater in the beagle dog but not in the rat. Development of cataracts due to verapamil has not been reported in man. Based on clinical use, possible target organs include the cardiovascular system.

Section 12: Ecological information

Aquatic Toxicity:	Not determined for product.
Persistence and Biodegradability:	Not determined for product.
Bio-accumulative:	Not determined for product.

Mobility in Soil:	Not determined for product.

Section 13: Disposal considerations

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

Section 14: Transport information

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

Section 15: Regulatory information

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP Classification*	*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention	Do not breathe vapor or spray Wash hands thoroughly after handling
Response	Get medical attention if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.
EU Classification*	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

Section 16: Other information

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure

STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

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Disclaimer: Methapharm, Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document, there is no known information at this time.

End of Safety Data Sheet