Wintac
LIMITED

SAFETY DATA SHEET
PRODUCT: Verapamil Hydrochloride Injection USP

Section 1: PRODUCT AND COMPANY INFORMATION

54/1, Boodhihal village, Nelamangala, Bangalore, India-562123. PRODUCT NAME: Verapamil Hydrochloride Injection USP

Section 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW	
Appearance	A clear colorless solution. Filled in clear ampoules/vials.
Classification of the substance or Mixture	
GHS - Classification	Not classified as hazardous
EU Classification:	EU indication of danger: Not classified
Label Elements: Not classified in accordance with international standards for workplace safety	

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical Name	**CAS Number**
Verapamil Hydrochloride	152-11-4
Sodium Chloride USP*	7647-14-5
Hydrochloric acid NF**	7647-01-0
Water for injection*	7732-18-5

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace
safety. * Proprietary
** to adjust pH
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret

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.
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.

Section 5: FIRE FIGHTING MEASURES

Flammability	None anticipated for this aqueous product.
Fire & Explosion Hazard	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.
Special 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

Handling	No special handling required for hazard control under conditions of normal product use.
Storage	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

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 AND CHEMICAL PROPERTIES

Appearance Clear colourless liquid
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available
Flammablity: Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

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
Incompatibilities	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: TOXICOLOGY INFORMATION

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.
Reproductive Effects: continued	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

Ecotoxicity

Aquatic: No data available.

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bio accumulative Potential: No data available.

Mobility in Soil: No data available.

Mobility in Environment: No data available.

Other Adverse Effects: No data available.

Section 13: DISPOSAL CONDITIONS

Waste Disposal:
All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

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Section 14: TRANSPORTATION INFORMATION

UN Number None allocated

DG Class None allocated

Subsidiary Risk None allocated

Packing Group None allocated

Hazchem Code None allocated

The following refers to all modes of transportation unless specified below.
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: REGULATORY INFORMATION

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

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.

Section 16: OTHER INFORMATION

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

Data Sources: Publicly available toxicity information.

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