SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	:	Verapamil Hydrochloride Injection (Caplin Steriles Limited)
Chemical Family	:	Opioid analgesic

Manufacturer or supplier's details

Details of the Supplier of the Safety Data Sheet	:	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.
Emergency Telephone Number	:	+91-4467901901/02/03

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use	:	Pharmaceutical product

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS Pictograms



Signal word	Danger
GHS -Classification	Reproductive Toxicity: Category 2
Hazard statements	H361 - Suspected of damaging fertility or the unborn child
Precautionary Statements	P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P280 - Wear protective gloves/protective clothing/eye protection/face protection P308 + P313 - IF exposed or concerned: Get medical attention/advice P405 - Store locked up P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
Note:	This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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 INGREDIENT

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	<1
Verapamil Hydrochloride	152-11-4	205-800-5	Acute Tox. 3, H301 Repr. 2, H361dAcute 2,H401Chronic 2,H411	</= 0.25
Hydrochloric acid	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire / Explosion Hazards: Fine particles (such as mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

SODIUM CHLORIDE

Latvia OEL-TWA	5 mg/m^3
Lithuania OEL-TWA	5 mg/m^3

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3
Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3 8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	2 ppm 3.0 mg/m^3
Latvia OEL - TWA	5 ppm 8 mg/m^3
Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 ppm 8 mg/m^3

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3
Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Sodium chloride **Pfizer Occupational Exposure Band (OEB):**	OEB 1 (control exposure to the range of 1000ug/m^3 to 3000ug/m^3)
Verapamil Hydrochloride **Pfizer Occupational Exposure Band (OEB):**	OEB 3 (control exposure to the range of 10ug/m^3 to 100ug/m^3)

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State:	Solution.
Color	Clear, Colorless.
Odor:	No data available.
Odor Threshold:	No data available
Molecular Formula:	Mixture
Molecular Weight:	Mixture
Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	4.9 (4.0- 6.5)
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	
Sodium chloride	No data available
Water for injection	No data available
Verapamil Hydrochloride	Measured Log P 3.79
Hydrochloric Acid	No data available
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

Flammability:

Auto ignition 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:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dusts, mists and vapors) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition products:	No data available

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on liver (based on components)
Known Clinical Effects:	May cause low blood pressure and dizziness. Occasional, transient changes reported in liver function tests, but no liver damage seen.

Acute Toxicity: (Species, Route, End Point, Dose)

Sodium chloride

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Verapamil Hydrochloride

Rat	Oral	LD 50	108 mg/kg
Mouse	Oral	LD 50	163 mg/kg
Rat	Intravenous	LD 50	16 mg/kg
Mouse	Intravenous	LD 50	5975 mg/kg
Rat	Subcutaneous	LD 50	107 mg/kg

Hydrochloric Acid

Rat	Oral	LD 50	238-277 mg/kg

Ingestion Acute Toxicity May be harmful if swallowed

SECTION 11: TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

Verapamil Hydrochloride

Skin Irritation	Rabbit	Mild

Irritation / Sensitization Comments: May cause eye irritation.

Skin Irritation / Sensitization May cause mild skin irritation.

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Verapamil Hydrochloride

Reproductive & Fertility	Rat	Oral	55 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Rat	Oral	60 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Oral	60 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral	15 mg/kg/day	NOAEL	Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Verapamil Hydrochloride

Bacterial Mutagenicity (Ames)	Salmonella , E. coli	Negative

Hydrochloric Acid

Bacterial Mutagenicity (Ames)	Salmonella	Negative
In Vivo Micronucleus	Rat	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Verapamil Hydrochloride

18 Month(s)	Rat	58 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Rat	58 mg/kg/day	NOAEL	Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

HYDROCHLORIC ACID

IARC: Group 3 (Not Classifiable)

SECTION 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Verapamil Hydrochloride

Oncorhynchus mykiss (Rainbow Trout)	LC50	96 Hours	2.72 mg/L
Daphnia magna (Water Flea)	LC50	48 Hours	7.04 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Verapamil Hydrochloride

Pimephales promelas (Fathead Minnow)	OECD	28 Day(s)	NOEC	0.3 mg/L	Growth
Pimephales promelas (Fathead Minnow)	OECD	28 Day(s)	NOEC	0.6 mg/L	Survival

Persistence and Degradability: No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Verapamil Hydrochloride

Measured	Log P	3.79

Mobility in Soil: No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14: TRANSPORT INFORMATION

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Sodium chloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3
Water for injection	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Verapamil Hydrochloride	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	205-800-5
Hydrochloric Acid	
CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substance and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II

SECTION 16: OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411-Toxic to aquatic life with long lasting effects
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Prepared by: Caplin Steriles Limited

Data Sources: Publicly available toxicity information. Caplin proprietary drug development information

SDS creation date	:	Dec 07, 2024
SDS Revision date	:	NA
Version #	:	00

Disclaimer: To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

---End of Safety Data Sheet---