SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	:	Thiamine Hydrochloride Injection (Caplin Steriles Ltd.)
Synonyms	:	Vitamin B_1
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

SECTION 2: HAZARDS IDENTIFICATION

Hazard Statements	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause harm to breast-fed children.
Precautionary Statements		Obtain special instructions before use Do not breathe dust/fume/gas/mist/vapours/spray Avoid breathing dust/fume/gas/mist/vapours/spray Avoid contact during pregnancy and while nursing Wash hands thoroughly after handling Do not eat, drink or smoke when using this product In case of inadequate ventilation wear respiratory protection IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing IF exposed or concerned: Get medical advice/attention If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations
Emergency Overview		This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert
Route of Exposure		Inhalation Ingestion Eye contact Skin
Eye		Contact with eyes may cause irritation
Skin		May cause skin irritation
Inhalation		May cause irritation of respiratory tract
Ingestion		May cause irritation
Signs/Symptoms		Adverse reactions from therapeutic doses include: hypersensitivity or life-threatening anaphylactic reactions, collapse and death have been reported, feeling of warmth,

	pruritus, urticaria, weakness, sweating, nausea, and restlessness, tightness of the throat, angioneurotic, edema, cyanosis, pulmonary edema, and hemorrhage into the gastrointestinal tract. Occupational exposure has not been fully investigated
Aggravation of preexisting conditions	Individuals with a history of sensitivity to thiamine or to any of the ingredients in this product

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent
Thiamine Hydrochloride	G67-03-8	100 mg/mL
Monothioglycerol	96-27-5	0.5 %
Chlorobutanol Hemihydrate	6001-64-5	0.5 %[#]
Sodium Hydroxide	1310-73-2	Quantity Sufficient for pH
Water for Injection	7732-18-5	Quantity Sufficient

Note: [#] 0.525% of Chlorobutanol Hemihydrate is equivalent to 0.5% of Chlorbutanol anhydrous.

SECTION 4 : FIRST AID MEASURES

Eye Contact	:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention
Skin Contact		Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation		If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion		If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid		For Adverse Event Information please call 91-4467901901/02/03

SECTION 5 :FIRE FIGHTING MEASURES

Flash Point	Not established
Flash Point Method	Not established
Auto Ignition Temperature	Not established
Lower Flammable/Explosive Limit	Not established
Upper Flammable/Explosive Limit	Not established
Fire Fighting Instructions	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off wate r.
Extinguishing Media	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
Protective Equipment	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion By products	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion

SECTION 6 :ACCIDENTAL RELEASE MEASURES

Personnel Precautions	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue

SECTION 7 : HANDLING and STORAGE

Handling	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions
Storage	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Protect from light.
Work Practices	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist

SECTION 8 : EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits
Eye/Face Protection	Chemical splash goggles. Wear a face shield also when splash hazard exist
Skin Protection Description	Protective laboratory coat, apron, or disposable garment recommended
Hand Protection Description	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended
Respiratory Protection	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances

Other Protective	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State	Liquid solution
Color	Clear colorless to pale yellow
Boiling Point	Not established
Melting Point	248°C
Solubility	Soluble. in water
Vapor Density	Not established
Vapor Pressure	Not established
Percent Volatile	Not established
pH	2.5 - 4.5
Molecular Formula	Mixture
Molecular Weight	337.27
Flash Point	Not established
Flash Point Method	Not established
Auto Ignition Temperature	Not established

SECTION 10 : HANDLING and STORAGE

Chemical Stability	Stable under normal temperatures and pressures
Hazardous Polymerization	Not reported
Conditions to Avoid	Exposure to light or heat may cause decomposition

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity	Eye, skin, and respiratory irritation may occur

Thiamine Hydrochloride

Acute Toxicity	Acute Toxicity: LD50 IP Mouse: 200 mg/kg
Acute Effects	Eye, skin, and respiratory irritation may occur
Chronic Effects	Hypersensitivity reactions ranging from mild to severe may occur

Thiamine Hydrochloride

RTECS Number	XI7350000
Ingestion	Oral - Rat LD50: 3710 mg/kg [Peripheral Nerve and Sensation - Spastic paralysis with or without sensory change Behavioral - Tremor Lungs, Thorax, or Respiration - Other changes] Oral - Mouse LD50: 8224 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information	Intravenous. - Rat LD50: 118 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 74 mg/kg [Details of toxic effects not reported other than lethal dose value]. Intravenous. - Rabbit LD50: 117 mg/kg [Behavioral - muscle contraction or spasticity Lungs, Thorax, or Respiration - cyanosis Lungs, Thorax, or Respiration - other changes] Intravenous. - Guinea pig LD50: 140 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50: 560 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 266 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Guinea pig LD50: 872 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse TDLo: 11200 mg/kg/28D (intermittent) [Peripheral Nerve and Sensation - spastic paralysis with or without sensory change Sense Organs and Special Senses (Eye) - effect, not otherwise specified Behavioral - convulsions or effect on seizure threshold] Intraperitoneal. - Rat LD50: 481 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 200 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat TDLo: 8540 mg/kg/28D (intermittent) [Related to Chronic Data - death]

Monothioglycerol

RTECS Number	TY8140000
Skin	Administration onto the skin - Rat TDLo : 12 gm/kg/4W-I [Endocrine - Changes in thyroid weight]
Other Toxicological Information	Intravenous. - Rabbit LD50 : 250 mg/kg [Sense Organs and Special Senses (Eye) – lacrimation Behavioral - convulsions or effect on seizure threshold Behavioral - ataxia]
	Intraperitoneal. - Rat LD50 : 390 mg/kg [Sense Organs and Special Senses (Eye) - lacrimation Behavioral - convulsions or effect on seizure threshold Behavioral - ataxia]
	Intraperitoneal. - Mouse LD50 : 340 mg/kg [Sense Organs and Special Senses (Eye) - lacrimation Behavioral - convulsions or effect on seizure threshold Behavioral - ataxia]

Chlorobutanol

RTECS Number	UC0175000
Eye	Rabbit, Mild irritation
Skin	Rabbit, Mild irritation
Ingestion	Oral - Rat LD50 : 510 mg/kg (RTEC)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity	No ecotoxicity data was found for the product.
Environmental Stability	No ecotoxicity data was found for the product.
Chlorobutanol	
Ecotoxicity	Fathead Minnow (Pimephales promelas) LC 50 (96hr) 135 mg/L (ECOTOX)
Biodegradation	Not readily biodegradable (19% after 28 days).
Bioaccumulation	Low potential to bioaccumulate (BCF : 1.5).

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal	Dispose of in accordance with Local, State, Federal and Provincial regulations

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name	Not Regulated
DOT UN Number	Not Regulated
IATA	Not Regulated
TDG	Not Regulated

SECTION 15: REGULATORY INFORMATION

Thiamine Hydrochloride	
TSCA Inventory Status	Listed
EINECS Number	200-641-8
Canada DSL	Listed
Monothioglycerol	
TSCA Inventory Status	Listed
EINECS Number	202-495-0
Canada DSL	Listed
Chlorobutanol	
TSCA Inventory Status	Listed
EINECS Number	200-317-6
Canada DSL	Listed
Water for Injection	
TSCA Inventory Status	Listed
Canada DSL	Listed

SECTION 16: ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1
HMIS Fire Hazard:	1
HMIS Reactivity:	1
HMIS Personal Protection:	X

SDS creation date: September 27, 2022
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Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Caplin steriles assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product

---End of Safety Data Sheet---