SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Thiamine Hydrochloride Injection, USP**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 01, 2015
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word:	DANGER.
GHS Class:	Respiratory sensitisation. Category 1. Reproductive toxicity. Effects on or via lactation.
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 Absorption. Injection.
Potential Health Effects:	
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, 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 Pre-Existing 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	EC Num.
Thiamine Hydrochloride	67-03-8	100 mg/mL	
Monothioglycerol	96-27-5	0.5 %	
Chlorobutanol	57-15-8	0.5 %	
Water for Injection	7732-18-5	Quantity Sufficient	

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 (800) 551-7176.

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 water.
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 Byproducts:	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. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.
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 : STABILITY and REACTIVITY

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 environmental information found for this product.

Chlorobutanol :

Ecotoxicity: Fathead Minnow (Pimephales promelas) LC50 (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.

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

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