SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Pyridoxine 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:	May 05, 2025
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Class:	Reproductive toxicity. Effects on or via lactation.
Hazard Statements:	May cause harm to breast-fed children.
Precautionary Statements:	Obtain special instructions before use. Do not breathe 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. IF exposed or concerned: Get medical advice/attention.
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: paresthesia, somnolence, and low serum folic acid levels. Pyridoxine given to animals in amounts of 3 to 4 gm/kg of body weight, produced convulsions and death. In man, a dose of 25 mg/kg of body weight is well tolerated. Occupational exposure has not been fully investigated.
Aggravation of Pre-Existing Conditions:	Individuals with a history of sensitivity to pyridoxine or to any of the ingredients in Pyridoxine Hydrochloride Injection, USP.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Pyridoxine Hydrochloride	58-56-0	100 mg/mL	
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

Personal 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:	208°C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	2.0 - 3.8
Molecular Formula:	Mixture
Molecular Weight:	205.5
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:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity:	Eye, skin, and respiratory irritation may occur.
Acute Effects:	Eye, skin, and respiratory irritation may occur.
Chronic Effects:	Hypersensitivity reactions ranging from mild to severe may occur.
Pyridoxine Hydrochloride :	
RTECS Number:	UV1350000
Ingestion:	Oral - Mouse LD50: 5500 mg/kg [Behavioral - Convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration - Dyspnea] Oral - Rat LD50: 4 gm/kg [Behavioral - Convulsions or effect on seizure threshold; Behavioral - Excitement]

Other Toxicological Information:	Intravenous. - Mouse LD50: 660 mg/kg [Behavioral - convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration - dyspnea] Intravenous. - Rabbit LD50: 464 mg/kg [Peripheral Nerve and Sensation - spastic paralysis with or without sensory change; Behavioral - convulsions or effect on seizure threshold] Intravenous. - Rat LD50: 530 mg/kg [Behavioral - convulsions or effect on seizure threshold; Behavioral - excitement] Subcutaneous - Mouse LD50: 2450 mg/kg [Behavioral - convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration - dyspnea] Subcutaneous - Rat LD50: 3 gm/kg [Behavioral - convulsions or effect on seizure threshold; Behavioral - excitement] Intraperitoneal. - Rat TDLo: 8400 mg/kg/7D (intermittent) [Peripheral Nerve and Sensation - structural change in nerve or sheath; Behavioral - ataxia; Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Rat TDLo: 1250 mg/kg/1W (intermittent) [Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Rat TDLo: 5000 mg/kg/2W (intermittent) [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count); Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - dehydrogenases] Intraperitoneal. - Rat TDLo: 5000 mg/kg/4W (intermittent) [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count); Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Rat TDLo: 10000 mg/kg/4W (intermittent) [Liver - other changes; Reproductive - Paternal Effects - testes, epididymis, sperm duct; Related to Chronic Data - changes in testicular weight] Intraperitoneal. - Rat TDLo: 7500 mg/kg/6W (intermittent) [Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Rat TDLo: 15000 mg/kg/6W (intermittent) [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count); Reproductive - Paternal Effects - testes, epididymis, sperm duct; Related to Chronic Data - changes in testicular weight] Intraperitoneal. - Rat TDLo: 360 mg/kg/3D (intermittent) [Peripheral Nerve and Sensation - sensory change involving trigeminal nerve; Behavioral - ataxia] Intraperitoneal. - Rat TDLo: 3 gm/kg/3D (intermittent) [Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Rat TDLo: 9 gm/kg/9D (intermittent) [Behavioral - changes in motor activity (specific assay); Behavioral - muscle weakness] Intraperitoneal. - Rat TDLo: 14 gm/kg/14D (intermittent) [Peripheral Nerve and Sensation - sensory change involving peripheral nerve] Intraperitoneal. - Rat TDLo: 4800 mg/kg/4D (intermittent) [Peripheral Nerve and Sensation - sensory change involving trigeminal nerve; Peripheral Nerve and Sensation - sensory change involving peripheral nerve] Intraperitoneal. - Rat TDLo: 15 gm/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct] Intraperitoneal. - Rat TDLo: 7500 mg/kg [Reproductive - Paternal Effects - prostate, seminal vesicle, Cowper's gland, accessory glands] Intraperitoneal. - Rat TDLo: 15 gm/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)] Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Fertility - male fertility index (e.g.numbermales impregnating females pernumbermales exposed to fertile nonpregnant females)] Intraperitoneal. - Rat TDLo: 15 gm/kg [Reproductive - Fertility - male fertility index (e.g.numbermales impregnating females per number males exposed to fertile nonpregnant females)]

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

Pyridoxine Hydrochloride :

TSCA Inventory Status:	Listed
EINECS Number:	200-386-2

Canada DSL:	Listed

Chlorobutanol :

TSCA Inventory Status:	Listed
EINECS Number:	200-317-6
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:	January 08, 2009
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SDS Revision Notes:	Overall SDS review - no changes to formulation.
SDS Format:	

Disclaimer:

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