SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Hydralazine 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. Category 2.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of damaging fertility or the unborn child.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
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.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
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.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Store locked up.
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.

Signs/Symptoms:
Adverse reactions from therapeutic doses include: headache, anorexia, nausea, vomiting, diarrhea, palpitations, tachycardia, and angina pectoris. No deaths due to acute poisoning have been reported. Highest known dose survived: adults, 10 gm orally. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:
Individuals with hypersensitivity to hydralazine, coronary artery disease, and mitral valvular rheumatic heart disease.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Hydralazine Hydrochloride	86-54-4	20 mg/mL	
Propylparaben	94-13-3	0.35 mg/mL	
Methylparaben	99-76-3	0.65 mg/mL	

Propylene Glycol	57-55-6	103.6 mg/mL
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 15 to 30°C (59 to 86°F).
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:	275°C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	3.4 - 4.4
Molecular Formula:	Mixture
Molecular Weight:	196.64
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

Hydralazine Hydrochloride :

Acute Toxicity:	LD50: IV Rat 34 mg/kg LD50: IP Mouse 83 mg/kg LD50: SC Mouse 73 mg/kg LD50: IV Mouse 71 mg/kg

Hydralazine Hydrochloride :

IARC:	IARC: Group 3: Unclassifiable as to carcinogenicity to humans.

Hydralazine Hydrochloride :

RTECS Number:	TH8925000
Ingestion:	Oral - Rat LD50: 90 mg/kg [Cardiac - Pulse rate increase, without fall in BP Vascular - BP lowering not characterized in autonomic section] Oral - Mouse LD50: 122 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: 34 mg/kg [Cardiac - change in rate Behavioral - somnolence (general depressed activity) Gastrointestinal - nausea or vomiting] Intravenous. - Mouse LD50: 52 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 3 mg/kg [Vascular - BP lowering not characterized in autonomic section] Subcutaneous - Mouse LD50: 150 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse TDLo: 40 mg/kg [Immunological Including Allergic - increase in humoral immune response] Intraperitoneal. - Rat LD50: 25 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 80 mg/kg [Details of toxic effects not reported other than lethal dose value]

Propylparaben :

RTECS Number:	DH2800000
Ingestion:	Oral - Mouse LD50: 6332 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Subcutaneous - Mouse LD50: 1650 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse TDLo: 51 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine

weight]
Subcutaneous - Rat TDLo: 99 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight]
Subcutaneous - Mouse TDLo: 195 mg/kg/3D (intermittent) [Reproductive - Maternal Effects - uterus, cervix, vagina Related to Chronic Data - changes in uterine weight]
Intraperitoneal. - Mouse LD50: 200 mg/kg [Details of toxic effects not reported other than lethal dose value]

Methylparaben :

RTECS Number: DH2450000

Skin: Administration onto the skin - Rabbit Standard Draize test.: 0.1 mL/24H
Administration onto the skin - Rabbit Standard Draize test.: 0.5 mL/21D (Intermittent)
Administration onto the skin - Rat TDLo: 374.92 gm/kg/13W (Intermittent) [Nutritional and Gross Metabolic - Weight loss or decreased weight gain Blood - Other changes]

Ingestion: Oral - Mouse LD50: >8 gm/kg [Peripheral Nerve and Sensation - Flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - Ataxia]
Oral - Mouse LD50: >8000 mg/kg [Behavioral - Ataxia]
Oral - Rat LD50: 2100 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse TDLo: 100 mg/kg [Vascular - shock Lungs, Thorax, or Respiration - respiratory depression]
Intravenous. - Mouse TDLo: 2.5 mg/kg [Lungs, Thorax, or Respiration - tumors]
Subcutaneous - Mouse TDLo: 165 mg/kg [Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]
Subcutaneous - Mouse LD50: 1.2 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rat LD50: >500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse TDLo: 49.5 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight]
Subcutaneous - Mouse TDLo: 165 mg/kg/3D (intermittent) [Reproductive - Maternal Effects - uterus, cervix, vagina Related to Chronic Data - changes in uterine weight]
Intraperitoneal. - Mouse LD50: 960 mg/kg [Peripheral Nerve and Sensation - flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - somnolence (general depressed activity) Behavioral - ataxia]
Intraperitoneal. - Mouse LD50: 125 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD50: 960 mg/kg [Details of toxic effects not reported other than lethal dose value]

Propylene Glycol :

RTECS Number: TY2000000

Eye: Eye - Rabbit Standard Draize test.: 500 mg/24H [mild]

Skin: Administration onto the skin - Rabbit LD50: 20800 mg/kg [Details of toxic effects not reported other than lethal dose value]
Administration onto the skin - Rabbit LD50: 20800 mg/kg [Behavioral - Ataxia Behavioral - Tetany Lungs, Thorax, or Respiration - Respiratory depression]
Administration onto the skin - Mouse TDLo: 1284800 mg/kg/2Y (Intermittent) [Skin and Appendages - Tumors]

Ingestion: Oral - Rat LD50: 20 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 22 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 20300 mg/kg [Behavioral - Ataxia Behavioral - Tetany Lungs, Thorax, or Respiration - Respiratory depression]

Other Toxicological Information: Intravenous. - Rat LD50: 6423 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse LD50: 6630 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rabbit LD50: 6500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse LD50: 8000 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression]
Intravenous. - Rat LD50: 6800 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression]
Intravenous. - Rabbit LDLo: 4200 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression]
Subcutaneous - Rat LD50: 22500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: 17370 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - muscle contraction or spasticity Lungs, Thorax, or Respiration - cyanosis]
Subcutaneous - Guinea pig LDLo: 15500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: 17400 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression]
Subcutaneous - Rat LD50: 28000 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression]
Subcutaneous - Guinea pig LDLo: 15500 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression]
Subcutaneous - Mouse DNA inhibition: 8000 mg/kg
Subcutaneous - Mouse Cytogenetic analysis: 8000 mg/kg
Intraperitoneal. - Rat LD50: 6660 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 9718 mg/kg [Lungs, Thorax, or Respiration - chronic pulmonary edema Kidney/Ureter/Bladder - changes in both tubules and glomeruli Blood - changes in spleen]
Intraperitoneal. - Mouse LD50: 11400 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression]
Intraperitoneal. - Rat TDLo: 19500 mg/kg [Behavioral - ataxia Behavioral - tetany Lungs, Thorax, or Respiration - respiratory depression]
Intraperitoneal. - Mouse TDLo: 100 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Intraperitoneal. - Mouse TDLo: 100 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

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

EINECS Number:	201-680-3
Propylparaben :	
TSCA Inventory Status:	Listed
EINECS Number:	202-307-7
Canada DSL:	Listed
Methylparaben :	
TSCA Inventory Status:	Listed
EINECS Number:	202-785-7
Canada DSL:	Listed
Propylene Glycol :	
TSCA Inventory Status:	Listed
EINECS Number:	200-338-0
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.1362(1454)
Water for Injection :	
TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 01, 2015
SDS Format:	
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