# SAFETY DATA SHEET

## SECTION 1 : IDENTIFICATION

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| Product Name: | **Propranolol Hydrochloride Injection, USP** |
| Manufacturer Name: | Fresenius Kabi USA, LLC |
| Address: | Three Corporate Drive<br>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.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
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.
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.
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:
Exposure to propranolol and other beta-adrenergic blockade drugs may mask signs and symptoms of acute hypoglycemia in labile insulin-dependent diabetics. These individuals may have difficulty adjusting their dosage of insulin. Beta-adrenergic blockade drugs may also mask clinical signs of hyperthyroidism and change thyroid-function tests.

Eye:
Contact with eyes may cause irritation.

Signs/Symptoms:
Adverse reactions from therapeutic doses include: Cardiovascular (bradycardia, congestive heart failure), central nervous system (lightheadedness, mental depression, insomnia), gastrointestinal (nausea, vomiting, epigastric distress), pharyngitis, bronchospasm, agranulocytosis, and alopecia. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:
Individuals with cardiogenic shock, sinus bradycardia with greater than first degree block, bronchial asthma, and congestive heart failure.

## SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS# | Ingredient Percent | EC Num. |
|---|---|---|---|
| Propranolol Hydrochloride | 318-98-9 | 1 mg/mL | |
| Water for Injection | 7732-18-5 | Quantity Sufficient | |

## SECTION 4 : FIRST AID MEASURES

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| 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.<br>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

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| 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.<br>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

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| 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

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| 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]. Avoid freezing and excessive heat. |
| 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

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| 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.

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| 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

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| Physical State: | Liquid solution. |
| Boiling Point: | Not established. |
| Melting Point: | 165°C |
| Solubility: | Soluble. in water. |
| Vapor Density: | Not established. |
| Vapor Pressure: | Not established. |
| Percent Volatile: | Not established. |
| pH: | 2.8 - 4.0 |
| Molecular Formula: | Mixture |
| Molecular Weight: | 295.80 |
| Flash Point: | Not established. |
| Flash Point Method: | Not established. |
| Auto Ignition Temperature: | Not established. |

## SECTION 10 : STABILITY and REACTIVITY

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| Chemical Stability: | Stable under normal temperatures and pressures. |
| Hazardous Polymerization: | Not reported. |
| Conditions to Avoid: | Avoid freezing and excessive heat. |

## SECTION 11 : TOXICOLOGICAL INFORMATION

**Propranolol Hydrochloride :**

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| Acute Toxicity: | LD50 IP Rat: 76 mg/kg<br>LD50 SC Rat: 115 mg/kg<br>LD50 IV Rat: 21 mg/kg<br>LD50 IP Mouse: 80 mg/kg<br>LD50 SC Mouse: 208 mg/kg<br>LD50 IV Mouse: 18 mg/kg<br>LD50 IV Rabbit: 12.5 mg/m3 |

**Propranolol Hydrochloride :**

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| RTECS Number: | UB7525000 |
| Ingestion: | Oral - Rat LD50: 466 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Oral - Mouse LD50: 320 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Oral - Mouse LD50: 231 mg/kg [Peripheral Nerve and Sensation - Recording from peripheral motor nerve Behavioral - Somnolence (general depressed activity) Behavioral - Convulsions or effect on seizure threshold]<br>Oral - Mouse LD50: 331 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Respiratory stimulation]<br>Oral - Rat LD50: 449 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Respiratory stimulation] |
| Other Toxicological Information: | Intravenous. - Rat LD50: 21 mg/kg [Sense Organs and Special Senses (Eye) - mydriasis (pupillary dilation) Behavioral - convulsions or effect on seizure threshold Nutritional and Gross Metabolic - body temperature decrease]<br>Intravenous. - Mouse LD50: 18 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Intravenous. - Rabbit LD50: 12500 ug/kg [Details of toxic effects not reported other than lethal dose value]<br>Intravenous. - Guinea pig LDLo: 28100 ug/kg [Details of toxic effects not reported other than lethal dose value]<br>Intravenous. - Rat LD50: 40 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Intravenous. - Guinea pig TDLo: 1 mg/kg [Lungs, Thorax, or Respiration - structural or functional change in trachea or bronchi]<br>Intravenous. - Human TDLo: 0.1 mg/kg [Cardiac - change in rate Cardiac - cardiac output]<br>Intravenous. - Rat TDLo: 0.3 ug/kg [Cardiac - change in rate Vascular - BP lowering not characterized in autonomic section]<br>Intravenous. - Rat TDLo: 0.1 ug/kg [Vascular - BP lowering not characterized in autonomic section]<br>Intravenous. - Rat TDLo: 1 mg/kg [Cardiac - change in rate Vascular - BP elevation not characterized in autonomic section Vascular - BP lowering not characterized in autonomic section]<br>Intravenous. - Rabbit TDLo: 10500 ug/kg [Reproductive - Fertility - mating performance (e.g. number sperm positive females per number females mated; number copulations per number estrus cycles) Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea) Reproductive - Fertility - other measures of fertility]<br>Subcutaneous - Rat LD50: 115 mg/kg [Sense Organs and Special Senses (Eye) - mydriasis (pupillary dilation) Behavioral - convulsions or effect on seizure threshold Nutritional and Gross Metabolic - body temperature decrease]<br>Subcutaneous - Mouse LD50: 208 mg/kg [Sense Organs and Special Senses (Eye) - mydriasis (pupillary dilation) Behavioral - convulsions or effect on seizure threshold Nutritional and Gross Metabolic - body temperature decrease] |

Subcutaneous - Rat TDLo: 5 mg/kg [Biochemical - Metabolism (Intermediary) - other proteins]
Subcutaneous - Rat TDLo: 6 mg/kg [Behavioral - alteration of classical conditioning Behavioral - changes in psychophysiological tests]
Intraperitoneal. - Rat LD50: 76 mg/kg [Behavioral - muscle weakness Behavioral - irritability Lungs, Thorax, or Respiration - dyspnea]
Intraperitoneal. - Mouse LD50: 80 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat TDLo: 0.5 mg/kg [Gastrointestinal - hypermotility, diarrhea]
Intraperitoneal. - Rat TDLo: 1 mg/kg [Cardiac - other changes]
Intraperitoneal. - Rat TDLo: 1 mg/kg [Cardiac - other changes Biochemical - Metabolism (Intermediary) - lipids including transport]
Intraperitoneal. - Mouse TDLo: 10 mg/kg [Nutritional and Gross Metabolic - body temperature decrease]
Intraperitoneal. - Rat TDLo: 3 mg/kg [Behavioral - changes in motor activity (specific assay)]
Intraperitoneal. - Mouse LD50: 138 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - respiratory stimulation]

## SECTION 12 : ECOLOGICAL INFORMATION

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| Ecotoxicity: | No ecotoxicity data was found for the product. |
| Environmental Stability: | No environmental information found for this product. |

## SECTION 13 : DISPOSAL CONSIDERATIONS

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

## SECTION 14 : TRANSPORT INFORMATION

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| DOT Shipping Name: | Not Regulated. |
| DOT UN Number: | Not Regulated. |

## SECTION 15 : REGULATORY INFORMATION

**Propranolol Hydrochloride :**

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| EINECS Number: | 206-268-7 |
| Canada DSL: | Listed |

**Water for Injection :**

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| TSCA Inventory Status: | Listed |
| Canada DSL: | Listed |

## SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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