SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Amiodarone Hydrochloride Injection**
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:
Possible adverse reactions include: nausea, hypotension, transient fever, asystole/cardiac arrest/ electromechanical dissociation (EMD), cardiogenic shock, congestive heart failure, bradycardia, liver function test abnormalities, VT and AV block.

Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:
Hypersensitivity to amiodarone or any of the components of the product. Contraindicated in patients with cardiogenic shock, marked bradycar dia, andsecond or third degree AV block unless a functioning pacemaker is available. In patients with life-threatening arrhythmias, the potential risk of hepatic injury should be weighed against the potential benefit of Amiodarone HCl injection therapy. The drug may cause worsening of existing arrhythmias or precipitate a new arrhythmia.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Amiodarone Hydrochloride	19774-82-4	50 mg/mL	

Polysorbate 80	9005-65-6	100 mg/mL
Benzyl Alcohol	100-51-6	20.2 mg/mL
Water for Injection	7732-18-5	Quantity Sufficient

Note: Amiodarone Hydrochloride contains 37.3% Iodine by weight.

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 and excessive heat. Retain vial in carton until time of use.

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:	Clear to pale yellow
Boiling Point:	~100°C
Melting Point:	~0°C
Solubility:	Very slightly soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not established.
Molecular Formula:	Mixture
Molecular Weight:	681.78
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.
Incompatible Materials:	Avoid storage near oxidizers and water reactive materials.

SECTION 11 : TOXICOLOGICAL INFORMATION

Amiodarone Hydrochloride :

Acute Toxicity:	LD50 IV Rat 170 mg/kg LD50 IP Rat 610 mg/kg LD50 IP Dog 5 gm/kg

Polysorbate 80 :

Acute Toxicity:	LD50 IP Rat 6804 mg/kg LD50 IV Rat 1790 mg/kg
Teratogenicity:	Other: Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS) PREGNANCY CATEGORY D: May cause neonatal hypo-or hyperthyroidism. Amiodarone Hydrochloride Injection should be used during pregnancy only if the potential benefit to the mother justifies the risk to the fetus.

Amiodarone Hydrochloride :

RTECS Number:	OB1361000
Ingestion:	Oral - Rat LD50: >3 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: >3 gm/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: 170 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 50 mg/kg [Cardiac - change in rate Vascular - BP lowering not characterized in autonomic section] Intraperitoneal. - Rat LD50: 610 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 450 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat TDLo: 3250 mg/kg/4W (intermittent) [Gastrointestinal - peritonitis Nutritional and Gross Metabolic - weight loss or decreased weight gain Related to Chronic Data - death]

Polysorbate 80 :

RTECS Number:	WG2932500
Eye:	Eye - Rabbit Standard Draize test.: 150 mg [mild]
Ingestion:	Oral - Rat LD50: 34500 uL/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 25 gm/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: 1790 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 1790 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat TDLo: 10 gm/kg/27W (intermittent) [Tumorigenic - equivocal tumorigenic agent by RTECS criteria Tumorigenic - tumors at site of application] Intraperitoneal. - Rat LD50: 6804 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 7600 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat TDLo: 80 uL/kg [Reproductive - Maternal Effects - uterus, cervix, vagina Reproductive - Maternal Effects - menstrual cycle changes or disorders Reproductive - Effects on Newborn - physical]

Benzyl Alcohol :

RTECS Number:	DN3150000
Skin:	Administration onto the skin - Rabbit LD50: 2000 mg/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Standard Draize test.: 100 mg/24H Administration onto the skin - Rat LD50: 100 pph/90M [Details of toxic effects not reported other than lethal dose value]
Inhalation:	Inhalation - Mouse LC50: >500 mg/m3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression] Inhalation - Rat LC50: >500 mg/m3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]
Ingestion:	Oral - Rat LD50: 1230 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Excitement Behavioral - Coma] Oral - Mouse LD50: 1360 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 1360 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression] Oral - Rat LD50: 1660 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression] Oral - Rat LD50: 1.5 mL/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: 53 mg/kg [Lungs, Thorax, or Respiration - dyspnea] Intravenous. - Mouse LD50: 324 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LDLo: 1700 mg/kg [Sense Organs and Special Senses (Eye) - miosis (pupillary constriction) Behavioral - coma Kidney/Ureter/Bladder - other changes] Intraperitoneal. - Rat LD50: 400 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 650 mg/kg [Behavioral - altered sleep time (including change in righting reflex) Behavioral - somnolence (general depressed activity) Lungs, Thorax, or Respiration - dyspnea] Intraperitoneal. - Rat LDLo: 650 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression] Intraperitoneal. - Rat TDLo: 514 mg/kg [Behavioral - ataxia]

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

Amiodarone Hydrochloride :

EINECS Number:	243-293-2
California PROP 65:	Listed: developmental.

Polysorbate 80 :

TSCA Inventory Status:	Listed
EINECS Number:	500-019-9
Canada DSL:	Listed

Benzyl Alcohol :

TSCA Inventory Status:	Listed

EINECS Number:	202-859-9
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.169(170)

Water for Injection :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

SDS Creation Date:	January 08, 2009
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SDS Format:	
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