



MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT & COMPANY IDENTIFICATION

1501 East Woodfield Road **Emergency Telephone** **(800) 551-7176**
Suite 300 East
Schaumburg, IL 60173
(847) 969-2700

Product Identifier: Amiodarone Hydrochloride Injection
Chemical Name: Amiodarone Hydrochloride
Category: Antiarrhythmic

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Amiodarone Hydrochloride	19774-82-4	50 mg/mL
Benzyl Alcohol	100-51-6	20.2 mg/mL
Polysorbate 80	9005-65-6	100 mg/mL
Water for Injection	7732-18-5	q.s.

SECTION 3 - HAZARDS IDENTIFICATION

Route of Entry: Inhalation, eye/skin contact, or ingestion

Chemical Listing as Carcinogen

NTP: No
IARC: No
OSHA: No

Note: The amiodarone hydrochloride molecule contains 37.3% iodine by weight.

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Seek medical attention.
Skin: Wash area with soap and water and seek medical attention as needed.
Inhalation: If difficulty breathing, remove from exposure and administer oxygen. Seek medical attention. When appropriate and trained in CPR, provide artificial respiration.
Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

SECTION 4 - EMERGENCY & FIRST AID MEASURES...continued

Contact Info: For Adverse Event Information, please call (800) 551-7176 or (847) 969-2700.

SECTION 5 - FIRE FIGHTING MEASURES

Fire and Explosion Data

Closed Cup Flash Point: NA

Open Cup Flash Point: NA

Fire Point: NA

Autoignition: NA

Lower Explosion Limit: NA

Upper Explosion Limit: NA

General Hazard: No unusual fire or explosion hazard is known to exist.

Fire Fighting Instructions: Evacuate personnel to a safe area. Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.

Fire Fighting Equipment: Wear self-containing breathing apparatus and protective clothing.

Hazardous Combustion Products: Thermal decomposition may yield toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, and hydrogen chloride vapors.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Clean-Up: Wear recommended personal protective equipment (See Section 8 - Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.

SECTION 7 - HANDLING AND STORAGE

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Storage Conditions: Store at controlled room temperature 20° - 25°C (68° - 77°F). Protect from light and excessive heat. Use carton to protect contents from light until used.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Use local exhaust ventilation if necessary.

Personal Protective Equipment

Eye Protection: Safety glasses or goggles recommended.

Hand Protection: Latex rubber gloves recommended.

Respiratory Protection: Under normal use, respirators are not required. If aerosols are generated, an air purifying respirator with HEPA Cartridges (P100) should be worn. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Skin Protection: Disposable garments if direct skin contact is anticipated.

Exposure Limits:

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Amiodarone Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Benzyl Alcohol	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Polysorbate 80	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

**Physical Form/
Appearance:** Clear to pale yellow solution

**Boiling Point/Boiling
Range:** ~100°C

**Melting Point/Melting
Range:** ~0°C

Freezing Point: NA

Vapor Pressure : NA

Relative Vapor Density: NA

Percent Volatiles: NA

pH: NA

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES...continued

Molecular Weight: 681.78
Solvent Solubility: Very slightly soluble in water
Note: NA

SECTION 10 - STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Storage near oxidizers and water reactive materials.
Hazardous Polymerization: Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Signs & Symptoms of Exposure & Overexposure: 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. 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.

Medical Conditions Aggravated by Accidental Exposure: Hypersensitivity to amiodarone or any of the components of the product. Contraindicated in patients with cardiogenic shock, marked bradycardia, and second 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.

Acute Toxicity:

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Amiodarone Hydrochloride	LD ₅₀	Oral	Rat	>3 gm/kg
	LD ₅₀	IV	Rat	170 mg/kg
	LD ₅₀	IP	Rat	610 mg/kg
	LD ₅₀	Oral	Mouse	>3 gm/kg
	LD ₅₀	Oral	Dog	>5 gm/kg
	LD ₅₀	IP	Dog	5 gm/kg
Polysorbate 80	LD ₅₀	IP	Rat	6804 mg/kg
	LD ₅₀	IV	Rat	1790 mg/kg
	LD ₅₀	Oral	Mouse	25 mg/kg

SECTION 11 - TOXICOLOGY INFORMATION...continued

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.

SECTION 12 - TRANSPORTATION INFORMATION

UN/NA Number: NA
U.S. DOT Hazard Class: NA
Proper Shipping Name: NA
Shipping Label: NA

SECTION 13 - DISPOSAL INFORMATION

Disposal Procedure : Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

SECTION 14 - OTHER

Key to Abbreviations: ACGIH - American Conference of Governmental Industrial Hygienists
HEPA - High Efficiency Particulate Air
IARC - International Agency for Research on Cancer
NA - Not Applicable
NE - Not Established
NG - Not Given
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OEL - Occupational Exposure Limit
OSHA - Occupational Safety and Health Administration
PEL - Permissible Exposure Limit
PPM - Parts Per Million
QS - Quantity Sufficient
RCRA - Resource Conservation and Recovery Act
STEL - Short Term Exposure Limit
TLV - Threshold Limit Value
USP - United States Pharmacopeia

SECTION 14 - OTHER...continued

Disclaimer:

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