



## MATERIAL SAFETY DATA SHEET

**Product Name: Amiodarone Hydrochloride Injection**

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

**Manufacturer Name And Address** Hospira Inc.  
275 North Field Drive  
Lake Forest, Illinois USA  
60045

**Emergency Telephone** CHEMTREC: North America: 800-424-9300;  
International 1-703-527-3887; Australia (02) 8014 4880

**Hospira, Inc., Non-Emergency** 224-212-2000

**Product Name** Amiodarone Hydrochloride Injection

**Synonyms** 2-Butyl-3-benzofuranyl[4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl]methanone hydrochloride.

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name** Amiodarone Hydrochloride

**Chemical Formula**  $C_{25}H_{29}I_2NO_3 \bullet HCl$

**Preparation** Non-hazardous ingredients include Water for Injection.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Benzyl Alcohol	2	100-51-6	DN3150000
Amiodarone Hydrochloride	5	19774-82-4	OB1361000
Polysorbate 80	10	9005-65-6	WG2932500

### 3. HAZARD INFORMATION

#### Carcinogen List

Substance	IARC	NTP	OSHA
Amiodarone Hydrochloride	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	Not Listed	Not Listed	Not Listed
Polysorbate 80	Not Listed	Not Listed	Not Listed

**Emergency Overview** Amiodarone Hydrochloride Injection is a solution containing amiodarone hydrochloride, an iodinated benzofuran-derivative antiarrhythmic agent. In clinical use, amiodarone is indicated for the treatment of life-threatening recurrent ventricular arrhythmias. In the workplace, this material should be considered potentially irritating to the eyes and respiratory system, a potential occupational reproductive hazard, and a potential photosensitizer. Based on clinical use, possible target organs include the skin, liver, central nervous system, cardiovascular system, respiratory system, and thyroid.

**Occupational Exposure Potential** Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

**Signs and Symptoms** None known from occupational exposures. In clinical use, adverse effects may include

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hypotension, asystole/cardiac arrest/electromechanical dissociation (EMD), cardiogenic shock, congestive heart failure, bradycardia, pulmonary toxicity, liver function test abnormalities, VT, and AV block, alopecia, photosensitivity, hyperthyroidism/hypothyroidism, constipation, altered liver enzyme levels, headache, dizziness, incoordination, and neurological disturbances.

**Medical Conditions Aggravated by Exposure** Pre-existing hypersensitivity to amiodarone hydrochloride; pre-existing cardiovascular, central nervous system, pulmonary, skin, thyroid, endocrine or liver ailments.

### 4. FIRST AID MEASURES

**Eye contact** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin contact** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

### 5. FIRE FIGHTING MEASURES

**Flammability** None anticipated for this product.

**Fire & Explosion Hazard** None anticipated for this product.

**Extinguishing media** As with any fire, use extinguishing media appropriate for primary cause of fire.

**Special Fire Fighting Procedures** No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

**Spill Cleanup and Disposal** Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

### 7. HANDLING AND STORAGE

**Handling** No special handling required under conditions of normal product use. Protect from light by retaining in carton until contents have been used.

**Storage** No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions** No special precautions required for hazard control.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Exposure Guidelines**

Component	Type	Exposure limits			
		mg/m <sup>3</sup>	ppm	µg/m <sup>3</sup>	Note
Benzyl Alcohol	AIHA WEEL	N/A	10	N/A	8-hr TWA
Polysorbate 80	Not Applicable	N/A	N/A	N/A	None Established
Amiodarone Hydrochloride	Hospira EEL	N/A	N/A	70	8hr TWA

**Respiratory protection**      Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**              If skin contact with the product is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**                Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**        Engineering controls are normally not needed during the normal use of this product.

**9. PHYSICAL/CHEMICAL PROPERTIES**

<b>Appearance/Physical State</b>	Liquid
<b>Color</b>	Clear, pale-yellow micellar solution
<b>Odor</b>	NA
<b>Odor Threshold:</b>	NA
<b>pH:</b>	3-4 (for a 5% aqueous solution)
<b>Melting point/Freezing point:</b>	NA
<b>Initial Boiling Point/Boiling Point Range:</b>	NA
<b>Evaporation Rate:</b>	NA
<b>Flammability (solid, gas):</b>	NA
<b>Upper/Lower Flammability or Explosive Limits:</b>	NA
<b>Vapor Pressure:</b>	NA
<b>Vapor Density:</b>	NA
<b>Specific Gravity:</b>	NA
<b>Solubility:</b>	NA
<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Auto-ignition temperature:</b>	NA
<b>Decomposition temperature:</b>	NA

**10. STABILITY AND REACTIVITY**

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined.
<b>Conditions to avoid</b>	Not determined.
<b>Incompatibilities</b>	Not determined.
<b>Hazardous decomposition products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), hydrogen chloride and hydrogen iodide.
<b>Hazardous Polymerization</b>	Not anticipated to occur with this product.

**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity**

Not determined for the product formulation. Information for the ingredients is as follows:

<b>Ingredient(s)</b>	<b>Percent</b>	<b>Test Type</b>	<b>Route of Administration</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
Amiodarone Hydrochloride	100%	LD50	Oral	>3000 >3000	mg/kg mg/kg	Rat Dog
Amiodarone Hydrochloride	100%	LD50	Intravenous	170 5000	mg/kg mg/kg	Rat Dog
Benzyl Alcohol	100%	LD50	Oral	1040 - 2500	mg/kg	Rat, Mouse, Rabbit, Guinea Pig
Benzyl Alcohol	100%	LD50	Intravenous Intravenous	53 324	mg/kg mg/kg	Rat Mouse
Benzyl Alcohol	100%	LD50	Dermal	2000	mg/kg	Rabbit
Benzyl Alcohol	100%	LC50	Inhalation	>500	mg/m3	Rat, Mouse
Polysorbate 80	100%	LD50	Oral	25,000 37,260	mg/kg mg/kg	Mouse Rat

<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/Corrosion</b>	None anticipated from normal handling of this product.
<b>Ocular Irritation/Corrosion</b>	None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation. Prolonged clinical use of this product has results in photosensitization manifest primarily as an exaggerated sunburn-like response to sunlight.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product.
<b>Reproductive Effects</b>	Amiodarone hydrochloride reduced fertility when given orally at a dosage level of 90 mg/kg/day to male and female rats beginning 9 weeks prior to mating. In a reproductive study in which amiodarone was given intravenously

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to rabbits at dosages of 5, 10, or 25 mg/kg per day, maternal deaths occurred in all groups, including controls. Embryotoxicity (as manifested by fewer full-term fetuses and increased resorptions with concomitantly lower litter weights) occurred at dosages of 10 mg/kg and above. No evidence of embryotoxicity was observed at 5 mg/kg and no teratogenicity was observed at any dosage. In a teratology study in which amiodarone was administered by continuous intravenous infusion to rats at dosages of 25, 50, or 100 mg/kg per day, maternal toxicity (as evidenced by reduced weight gain and food consumption) and embryotoxicity (as evidenced by increased resorptions, decreased live litter size, reduced body weights, and retarded sternum and metacarpal ossification) were observed in the 100 mg/kg group.

<b>Mutagenicity</b>	Mutagenicity studies conducted with amiodarone HCl (Ames, micronucleus, and lysogenic induction tests) were negative.
<b>Carcinogenicity</b>	Oral administration of amiodarone caused a statistically significant, dose-related increase in the incidence of thyroid tumors (follicular adenoma and/or carcinoma) in rats. The incidence of thyroid tumors in rats was greater than the incidence in controls at the lowest dose level tested (5 mg/kg/day).
<b>Target Organ Effects</b>	None known from occupational exposures. Based on clinical use, possible target organs include the skin, liver, central nervous system, cardiovascular system, respiratory system, and thyroid.

## 12. ECOLOGICAL INFORMATION

<b>Aquatic Toxicity</b>	Not determined for product. LC50(96 hr) = 460 mg/L in <i>Pimephales promelas</i> for benzyl alcohol LC50 = 640 mg/L in <i>Leuciscus idus</i> for benzyl alcohol EC50(24 hr) = 400 mg/L in <i>Daphnia magna</i> for benzyl alcohol EC50 = 95 mg/L in <i>Chlorella pyrenoidosa</i> for benzyl alcohol
<b>Persistence/Biodegradability</b>	Not determined for product. Benzyl alcohol was degraded over 90% in a 28-day biodegradation assay in sewage sludge.
<b>Bioaccumulation</b>	Not determined for product.
<b>Mobility in Soil</b>	Not determined for product.

## 13. DISPOSAL CONSIDERATIONS

<b>Waste Disposal</b>	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

## 14. TRANSPORTATION INFORMATION

<b>ADR/ADG/ DOT STATUS:</b>	Not regulated
<b>IMDG STATUS:</b>	Not regulated

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ICAO/IATA STATUS: Not regulated

Transport Comments: None

**15. REGULATORY INFORMATION****USA Regulations**

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Amiodarone Hydrochloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	Listed	Not Listed	Not Listed	Not Listed	Not Listed
Polysorbate 80	Listed	Not Listed	Not Listed	Not Listed	Not Listed

**RCRA Status** Not Listed  
**U.S. OSHA Classification** Target Organ Toxin  
Possible Irritant

**GHS Classification** \*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

**Hazard Class** Not Applicable**Hazard Category** Not Applicable**Signal Word** Not Applicable**Symbol** Not Applicable**Prevention** P260 - Do not breathe dust/fume/gas/mist/vapors/spray.**Hazard Statement** Not Applicable**Response:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell.**EU Classification\***

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Amiodarone Hydrochloride

**Classification(s):** Not Applicable**Symbol:** Not Applicable**Indication of Danger:** Not Applicable**Risk Phrases:** Not Applicable

**Safety Phrases:** S23 - Do not breathe vapor.  
S24/25 - Avoid contact with skin and eyes.

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S37/39 - Wear suitable gloves and eye/face protection.

### 16. OTHER INFORMATION:

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS

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