

SAFETY DATA SHEET

Product Name: Amiodarone Hydrochloride Injection


1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
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. HAZARD(S) IDENTIFICATION

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, a potential occupational reproductive hazard, and a potential photosensitizer. Based on clinical use, possible target organs include the lungs, skin, liver, central nervous system, cardiovascular system, and thyroid.
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U.S. OSHA GHS Classification

Physical Hazards	Hazard Class Not Classified	Hazard Category Not Classified
Health Hazards	Hazard Class Toxic to Reproduction STOT – RE Sensitization – Skin	Hazard Category 2 2 1
Label Element(s)		
Pictogram		
Signal Word	Warning	
Hazard Statement(s)	Suspected of damaging fertility or the unborn child May cause damage to organs through prolonged or repeated exposure May cause an allergic skin reaction	
Precautionary Statement(s)		
Prevention	Obtain special instructions before use Do not handle until all safety precautions have been read and understood Wear protective gloves/protective clothing/eye protection/face protection Do not breathe vapor or spray Wash hands thoroughly after handling Contaminated work clothing must not be allowed out of the workplace	
Response	Get medical attention if you feel unwell. 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. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.	

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Amiodarone Hydrochloride
Chemical Formula $C_{25}H_{29}I_2NO_3 \bullet HCl$

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

Non-hazardous ingredients include Water for Injection.

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 such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting 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 control 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.

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	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Amiodarone Hydrochloride	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established
Benzyl Alcohol	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: 10 ppm	8 hr TWA: Not Established
Polysorbate 80	8 hr TWA: Not established	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 AIHA WEEL: Workplace Environmental Exposure Level
 EEL: Employee Exposure Limit.
 TWA: 8-hour Time Weighted Average.
 STEL: 15-minute Short Term Exposure Limit.

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

Appearance/Physical State	Amiodarone HCl injection is a sterile clear, pale-yellow micellar solution
Odor	NA
Odor Threshold	NA
pH	3-4 (for a 5% aqueous solution)
Melting point/Freezing point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	NA
Partition coefficient: n-octanol/water	NA
Auto-ignition temperature	NA
Decomposition temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	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.
Hazardous Polymerization	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:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
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

LD 50: Dosage that produces 50% mortality.

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 anticipated from normal handling of this product. In clinical use, adverse effects may include 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.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	None anticipated from normal handling of this product. Prolonged clinical use of this product has results in photosensitization manifest primarily as an exaggerated sunburn-like response to sunlight.
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product.

11. TOXICOLOGICAL INFORMATION: continued

Reproductive Effects	<p>None anticipated from normal handling of this product. 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.</p> <p>In a reproductive study in which amiodarone was given intravenously 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.</p>		
Mutagenicity	Mutagenicity studies conducted with amiodarone HCl (Ames, micronucleus, and lysogenic induction tests) were negative.		
Carcinogenicity	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).		
Carcinogen Lists	IARC: Not listed	NTP: Not listed	OSHA: Not listed
Specific Target Organ Toxicity – Single Exposure	NA		
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs include the skin, liver, central nervous system, cardiovascular system, respiratory system, and thyroid.		

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	<p>Not determined for product.</p> <p>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</p>
Persistence/Biodegradability	<p>Not determined for product.</p> <p>Benzyl alcohol was degraded over 90% in a 28-day biodegradation assay in sewage sludge.</p>
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

Notes:

1. LC50: Concentration in water that produces 50% mortality in fish.
2. EC50: Concentration in water that produces 50% inhibition of growth in algae.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP 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	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe vapor or spray
Wash hands thoroughly after handling
Contaminated work clothing must not be allowed out of the workplace

Response

Get medical attention if you feel unwell.

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.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

15. REGULATORY INFORMATION: continued

<u>EU Classification*</u>	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes 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
LD ₅₀	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
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Disclaimer:

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