



## 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 60045  
USA

**Emergency Telephone** CHEMTREC: 800 424-9300  
**Hospira, Inc.** 224 212-2055

**Product Name** Amiodarone Hydrochloride Injection, USP

**Synonyms** None

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Ingredient Name** Amiodarone Hydrochloride  
**Chemical Formula**  $C_{25}H_{30}ClI_2NO_3$

| Component                | Approximate Percent by Weight | CAS Number | RTECS Number |
|--------------------------|-------------------------------|------------|--------------|
| Amiodarone Hydrochloride | 5                             | 19744-82-4 | N/A          |
| Benzyl Alcohol           | 2                             | 100-51-6   | DN3150000    |
| Polysorbate 80           | 10                            | 9005-65-6  | WG2932500    |
| Water                    | 83                            | 7732-18-5  | ZC0110000    |

### 3. HAZARD INFORMATION

**Emergency Overview** In clinical use, this material is used to treat arrhythmias. Target organs include the lungs, cardiovascular system, liver, nervous system, and skin.

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

**Signs and Symptoms** No signs or symptoms from occupational exposure are known. Clinical data suggests the following: slow heart rate, tremor, peripheral neuropathy, pneumonitis, altered blood pressure, headaches, vomiting, abdominal pain, eye irritation, skin irritation.

**Medical Conditions Aggravated by Exposure** Hypersensitivity to the material and/or similar materials. Pre-existing liver, nervous system, cardiovascular system, respiratory system, or thyroid ailments.

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**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:** Flash Point: Not Determined

**Fire & Explosion Hazard:** None

**Extinguishing Media:** Use extinguishing media appropriate for the underlying 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** Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

**7. HANDLING AND STORAGE**

**Handling Storage** Protect from light by retaining in carton until contents have been used.  
No special storage required for hazard control. For product protection store at controlled room temperature of 15-30°C (59-86°F).

**Special Precautions** Protect from freezing, light and extreme heat.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Exposure Guidelines**

| Component                | Exposure limits           |                           |  |
|--------------------------|---------------------------|---------------------------|--|
|                          | OSHA-PEL                  | ACGIH-TLV                 | Hospira EEL  |
| Amiodarone Hydrochloride | 8 hr TWA: Not Established | 8 hr TWA: Not Established | 8 hr TWA: 70 mcg/m3<br>STEL: Not Established       |
| Benzyl Alcohol           | 8 hr TWA: Not Established | 8 hr TWA: Not Established | 8 hr TWA: Not Established<br>STEL: Not Established |
| Polysorbate 80           | 8 hr TWA: Not Established | 8 hr TWA: Not Established | 8 hr TWA: Not Established<br>STEL: 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.  
EEL: Employee Exposure Limit.  
TWA: 8 hour Time Weighted Average.  
STEL: 15-minute Short Term Exposure Limit.

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**Respiratory Protection** Respiratory protection is not needed during normal product use.

**Skin Protection** If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.

**Eye Protection** Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.

**Engineering Controls** Engineering controls are not needed during normal product use conditions.

**9. PHYSICAL/CHEMICAL PROPERTIES**

**Appearance/Physical State** Clear liquid

**Odor** Not determined

**Boiling Point** Not determined

**Freezing Point** Not determined

**Vapor Pressure** Not determined

**Vapor Density (Air=1)** Not Applicable

**Evaporation Rate** Not Applicable

**Bulk Density** Not Determined

**Specific Gravity** Not determined

**Solubility** Not determined

**pH** Not determined

**10. STABILITY AND REACTIVITY**

**Chemical Stability** Stable under standard use and storage conditions.

**Incompatibilities** None

**Hazardous Decomposition Products** Toxic fumes of nitrogen and carbon oxides

**Hazardous Polymerization** None

**11. TOXICOLOGICAL INFORMATION:**

**Acute Toxicity:**

| Ingredient(s)            | Percent | Test Type | Value         | Units | Species          |
|--------------------------|---------|-----------|---------------|-------|------------------|
| Amiodarone Hydrochloride | 100     | LD50      | 3000-5000     | mg/kg | Rats, Mice, Dogs |
| Benzyl Alcohol           | 100     | LD50      | 1040-3100     | mg/kg | Animals          |
| Polysorbate 80           | 100     | LD50      | 25,000-36,750 | mg/kg | Mice, Rats       |

**Acute Toxicity – Dermal:**

| Ingredient(s)  | Percent | Test Type | Value | Units | Species |
|----------------|---------|-----------|-------|-------|---------|
| Benzyl Alcohol | 100     | LD50(sc)  | 2000  | mg/kg | Rabbits |

**Acute Toxicity – Inhalation:**

| Ingredient(s)  | Percent | Test Type | Value | Units | Species |
|----------------|---------|-----------|-------|-------|---------|
| Benzyl Alcohol | 100     | LC50      | 2000  | ppm   | Rats    |

LD50 (sc) is the value for skin contact

LD50 (iv) is the intravenous dosage that produces 50% mortality.

LC50 is the concentration in air that produces 50% mortality.

**Mutagenicity** Negative in the Ames test and the micronucleus test.

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**Target Organ Effects** In clinical use target organ effects include the lungs, cardiovascular system, liver, nervous system, and skin.

**12. ECOLOGICAL INFORMATION:**

**Aquatic Toxicity** Not determined.

**13. DISPOSAL CONSIDERATIONS:**

**Waste Disposal** 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**

**DOT** Not Regulated

Notes: DOT - US Department of Transportation Regulations

**15. REGULATORY INFORMATION**

**TSCA Status** Not Regulated  
**CERCLA Status** Not Regulated  
**SARA Status** Not Regulated  
**RCRA Status** Not Regulated  
**PROP 65 (Calif.)** Not Regulated

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

**16. OTHER INFORMATION:**

**MSDS Coordinator** Global Occupational Toxicology  
**Date Prepared** September 15, 2005  
**Date Revised:** October 21, 2008

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