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_{2}NO_{3} \cdot HCl

Preparation Non-hazardous ingredients include Water for Injection.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>2</td>
<td>100-51-6</td>
<td>DN3150000</td>
</tr>
<tr>
<td>Amiodarone Hydrochloride</td>
<td>5</td>
<td>19774-82-4</td>
<td>OB1361000</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>10</td>
<td>9005-65-6</td>
<td>WG2932500</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

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
Product Name: Amiodarone Hydrochloride Injection

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>AIHA WEEL</td>
<td>mg/m³ ppm µg/m³</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>Not Applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Amiodarone Hydrochloride</td>
<td>Hospira EEL</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Clear, pale-yellow micellar solution</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>3-4 (for a 5% aqueous solution)</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>NA</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
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 (CO\textsubscript{x}), nitrogen oxides (NO\textsubscript{x}), 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:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone Hydrochloride</td>
<td>100%</td>
<td>LD50</td>
<td>Oral</td>
<td>( &gt;3000 )</td>
<td>mg/kg</td>
<td>Rat, Dog</td>
</tr>
<tr>
<td>Amiodarone Hydrochloride</td>
<td>100%</td>
<td>LD50</td>
<td>Intravenous</td>
<td>170( \leq 5000 )</td>
<td>mg/kg</td>
<td>Rat, Dog</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100%</td>
<td>LD50</td>
<td>Oral</td>
<td>1040 - 2500</td>
<td>mg/kg</td>
<td>Rat, Mouse, Rabbit, Guinea Pig</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100%</td>
<td>LD50</td>
<td>Intravenous</td>
<td>53( \leq 324 )</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100%</td>
<td>LD50</td>
<td>Dermal</td>
<td>2000</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100%</td>
<td>LC50</td>
<td>Inhalation</td>
<td>( &gt;500 )</td>
<td>mg/m\textsuperscript{3}</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>100%</td>
<td>LD50</td>
<td>Oral</td>
<td>25,000( \leq 37,260 )</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
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.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
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.

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).

Target Organ Effects

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

Aquatic Toxicity

Not determined for product. LC50(96 hr) = 460 mg/L in Pimephales promelas for benzyl alcohol LC50 = 640 mg/L in Leuciscus idus for benzyl alcohol EC50(24 hr) = 400 mg/L in Daphnia magna for benzyl alcohol EC50 = 95 mg/L in Chlorella pyrenoidosa for benzyl alcohol

Persistence/Biodegradability

Not determined for product. Benzyl alcohol was degraded over 90% in a 28-day biodegradation assay in sewage sludge.

Bioaccumulation

Not determined for product.

Mobility in Soil

Not determined for product.

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

IMDG STATUS: Not regulated
**Product Name: Amiodarone Hydrochloride Injection**

**ICAO/IATA STATUS:** Not regulated

**Transport Comments:** None

### 15. REGULATORY INFORMATION

#### USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone Hydrochloride</td>
<td>Not Listed</td>
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<tr>
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</tr>
<tr>
<td>Polysorbate 80</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**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.
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
Date Prepared:  09/01/2011
Obsolete Date:  10/21/2008

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