SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Amiodarone Hydrochloride Injection (Hospira Inc.)
Trade Name: Amiodarone Hydrochloride Injection
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product for the treatment of cardiac arrhythmias

Details of the Supplier of the Safety Data Sheet
Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
Reproductive Toxicity: Category 2
Carcinogenicity: Category 2
Specific target organ systemic toxicity (repeated exposure): Category 2

Label Elements
Signal Word: Warning
Hazard Statements:
H351 - Suspected of causing cancer
H361 - Suspected of damaging fertility or the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure: lungs

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards

Note: No data available

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENZYL ALCOHOL</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Acute Tox. 4 (H302)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4 (H332)</td>
<td></td>
</tr>
<tr>
<td>Amiodarone hydrochloride</td>
<td>19774-82-4</td>
<td>243-293-2</td>
<td>Carc 2 (H351)2 (H361fd)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE 2 (H373)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>500-019-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
- Hazardous Combustion: May include oxides of carbon.
- Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
- Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
- Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
- Storage Conditions: Store as directed by product packaging.
- Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

BENZYL ALCOHOL
- Pfizer OEL TWA-8 Hr: 10 ppm
- Bulgaria OEL - TWA: 5.0 mg/m³
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Amiodarone hydrochloride
Pfizer Occupational Exposure Band (OEB):
OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: No data available.
Color: Pale yellow
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: Soluble
pH: 3-4
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value) No data available

Amiodarone hydrochloride

BENZYL ALCOHOL
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density:</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity:</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability:</td>
<td></td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity:</td>
<td>No data available</td>
</tr>
<tr>
<td>Chemical Stability:</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td></td>
</tr>
<tr>
<td>Oxidizing Properties:</td>
<td>None</td>
</tr>
<tr>
<td>Conditions to Avoid:</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials:</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products:</td>
<td>Thermal decomposition products may include carbon monoxide and carbon dioxide</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

<table>
<thead>
<tr>
<th>General Information:</th>
<th>The information included in this section describes the potential hazards of the individual ingredients.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Term:</td>
<td>Suspected of causing cancer. Repeat-dose studies in animals have shown a potential to cause adverse effects on fertility, the developing fetus.</td>
</tr>
<tr>
<td>Known Clinical Effects:</td>
<td>Adverse effects most commonly reported in clinical use include lung toxicity (pulmonary toxicity), hypersensitivity reactions, lung inflammation (pneumonitis), liver effects, irregular heartbeat (cardiac arrhythmia). Adverse effects associated with therapeutic use include effects on the thyroid: cancer.</td>
</tr>
</tbody>
</table>

Acute Toxicity: (Species, Route, End Point, Dose)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone hydrochloride</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 3000 mg/kg</td>
</tr>
<tr>
<td>BENZYL ALCOHOL</td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>1230 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>1360 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Dermal</td>
<td>LD 50</td>
<td>2 gm/kg</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

Polysorbate 80
Rat  Intravenous  LD 50  1790 mg/kg
Mouse  Oral  LD 50  25 g/kg

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Amiodarone hydrochloride
Embryo / Fetal Development  Rat  Oral  25 mg/kg/day  NOAEL  Developmental toxicity
Embryo / Fetal Development  Rabbit  Oral  25 mg/kg/day  NOAEL  Fetal mortality
Reproductive & Fertility  Rat  Oral  90 mg/kg/day  LOAEL  Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Amiodarone hydrochloride
In Vitro Bacterial Mutagenicity (Ames)  Salmonella  Negative
Micronucleus  Not specified  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Amiodarone hydrochloride
2 Year(s)  Rat  No route specified  5 mg/kg/day  LOAEL  Thyroid, Tumors

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

BENZYL ALCOHOL
Fathead Minnow  NPDES  LC-50  96 Hours  460 - 770 mg/L
Bluegill  NPDES  LC-50  96 Hours  10 mg/L
Daphnia Magna (Water Flea)  Surrogate  ErC50  48 Hours  23 - 400 mg/L

Persistence and Degradability:  No data available

Bio-accumulative Potential:  No data available

Mobility in Soil:  No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

BENZYL ALCOHOL

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-859-9

Polysorbate 80

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 500-019-9

Water for Injection

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 231-791-2

Amiodarone hydrochloride
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Material Name: Amiodarone Hydrochloride Injection (Hospira Inc.)
Revision date: 25-Jul-2016

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Regulation/Reporting</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>developmental toxicity 8/26/1997</td>
</tr>
<tr>
<td>Australia (AICS)</td>
<td>female reproductive toxicity 8/26/97</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Present</td>
</tr>
<tr>
<td></td>
<td>243-293-2</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Reproductive toxicity-Cat.2; H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.
Revision date: 25-Jul-2016
Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet