1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Cordarone Intravenous
Common Name: Not available
Chemical Name: Not applicable
Synonyms: Amiodarone HCl
Product Use: Pharmaceutical product
Classification: Cardiovascular Drug
Supplier: Wyeth
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Emergency Telephone Number:
Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview
This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance: Biopharmaceutical liquid
Physical State: Liquid
Odor: Not available

Potential Physical Hazards: Not available

Potential Health Effects
- Eyes: Irritating to eyes.
- Skin: May cause skin irritation.
- Inhalation: May cause mucous membrane and upper respiratory tract irritation.
- Ingestion:
  The most common effects may include dizziness, lightheadedness or fainting, trouble in walking, numbness or tingling in fingers or toes, trembling of shaking of hands, unusual and uncontrolled movements of body, weakness of arms and legs, photosensitivity, cough, painful breathing, shortness of breath, and slight fever. fast heartbeat, blue-gray coloring of skin on face, neck, and arms, swelling of feet or lower legs, thyroid abnormalities, liver toxicity, and ocular toxicity may also occur.
  May cause harm to the unborn child. May cause cancer. May cause harm to breastfed babies.

Therapeutic Target Organ(s): Cardiovascular system.

Potential Environmental Effects: There is no known ecological information for this product.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone HCl</td>
<td>19774-82-4</td>
<td>50 mg/ml</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>20.2 mg/ml</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>.? mg/tablet</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

Eye Contact
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Skin Contact
Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

Inhalation
Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

Ingestion
If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties
Slightly flammable.

Extinguishing Media

<table>
<thead>
<tr>
<th>Suitable Extinguishing Media</th>
<th>Unsuitable Extinguishing Media</th>
</tr>
</thead>
</table>
| Use alcohol-resistant foam, dry chemical, or carbon dioxide. | Do NOT use water jet.

Fire Fighting
Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products
Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters
In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions
Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions
Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

Methods for Containment
Not available

Methods for Cleaning up
Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.
7. HANDLING AND STORAGE

Handling
For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage
No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Exposure Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone HCl</td>
<td>100 mcg/m³</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>15 ppm (Germany)</td>
</tr>
</tbody>
</table>

Engineering Controls
No special precautions required.

Personal Protective Equipment

- **Eye/face Protection**: Avoid contact with skin and eyes. Provide eye protection based on a risk assessment.
- **Skin Protection**: For prolonged or repeated exposure use protective gloves. No special protective clothing required under typical conditions of use.
- **Respiratory Protection**: No personal respiratory protective equipment normally required.
- **General Hygiene Considerations**: When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
- **Other**: Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Biopharmaceutical liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Yellow</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>3.5 - 4.5</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition Coefficient</td>
<td>Not available</td>
</tr>
<tr>
<td>(n-octanol/water)</td>
<td></td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability Limits</td>
<td>Upper Not available</td>
</tr>
<tr>
<td>in Air</td>
<td></td>
</tr>
<tr>
<td>Explosion Limits</td>
<td>Upper Not available</td>
</tr>
<tr>
<td></td>
<td>Lower Not available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>Not available</td>
</tr>
<tr>
<td>Autoignition Temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Method</td>
<td>None</td>
</tr>
</tbody>
</table>

Revision Date: 20-Aug-2007  
Cordarone Intravenous
10. STABILITY AND REACTIVITY

Chemical Stability
Stable at room temperature.

Conditions to Avoid
No data available

Materials to Avoid
No materials to be especially mentioned.

Hazardous Decomposition Products
None under normal use.

Possibility of Hazardous Reactions
None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Amiodarone HCl
- LD50 Oral: >3000 mg/kg rats and mice
  >5000 mg/kg dogs
- Acute Dermal Irritation: Not applicable
- Primary Eye Irritation: Not applicable
- Sensitization: Not applicable

Benzyl Alcohol
- LD50 Oral: No data available
- Acute Dermal Irritation: Not available
- Primary Eye Irritation: Not available
- Sensitization: Not applicable

Multiple Dose Toxicity

Amiodarone HCl
- No Toxicologic Effect: See Carcinogenicity
- Dose/Species/Study Length:

Maximum Tolerated Dose (MTD), Oral

Amiodarone HCl
- Carcinogenicity: Long-term toxicity studies in rats showed a dose-related increase in the incidence of thyroid tumors.
- Genetic Toxicity: No evidence of mutagenicity was observed in a battery of in vitro and in vivo assays.
- Reproductive Toxicity: Reproduction studies in male and female rats have revealed evidence of reduced fertility.
- Developmental Toxicity: Developmental toxicity studies conducted indicate that this compound caused embryotoxic effects including increased fetal resorption and growth retardation in mice and rats.

Benzyl Alcohol
- Carcinogenicity: No studies to assess the carcinogenic potential have been performed.
- Genetic Toxicity: Not genotoxic in vitro or in vivo
- Reproductive Toxicity: Not reprotoxic.
- Developmental Toxicity: Not developmentally toxic.
12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information Not available
Ecotoxicity Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.
U.S. Department of Transport (DOT) Not regulated
Canadian Transport of Dangerous Goods (TDG) Not regulated
International Civil Aviation Organization (ICAO) Not regulated
International Air Transport Association (IATA) Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO) Not regulated
Transport of Dangerous Goods by Rail (RID) Not regulated
Transport of Dangerous Goods by Road (ADR) Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN) Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status
This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.
SARA 311/312 Hazardous Categorization

- Acute Health Hazard: No
- Chronic Health Hazard: No
- Fire Hazard: No
- Sudden Release of Pressure Hazard: No
- Reactive Hazard: No

This product does not contain any HAPs.

State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

Canada
Not classified

WHMIS Hazard Class
Non-controlled

European Union
In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By: Wyeth Department of Environment, Health & Safety
Format: This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References: Goldman to VonKanenel email Aug 3, 2007
Revision Summary: Changes to Section 11

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End of MSDS