## 1. PRODUCT AND COMPANY IDENTIFICATION

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Cordarone Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Name</td>
<td>Not available</td>
</tr>
<tr>
<td>Chemical Name</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Amiodarone HCl</td>
</tr>
<tr>
<td>Product Use</td>
<td>Pharmaceutical product</td>
</tr>
<tr>
<td>Classification</td>
<td>Cardiovascular Drug</td>
</tr>
<tr>
<td>Supplier</td>
<td>Wyeth</td>
</tr>
<tr>
<td></td>
<td>P.O. Box 8299</td>
</tr>
<tr>
<td></td>
<td>Philadelphia, PA 19101 USA.</td>
</tr>
<tr>
<td></td>
<td>Telephone: 1-610-688-4400</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Pharmaceutical tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available</td>
</tr>
</tbody>
</table>

### Potential Physical Hazards

Powders and solids are presumed to be combustible.

### Potential Health Effects

- **Eyes**: Not available
- **Skin**: Not available
- **Inhalation**: Not available
- **Ingestion**: The most common effects may include dizziness, lightheadedness or fainting, trouble in walking, numbness or tingling in fingers or toes, trembling or 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.

  Please see Patient Package Insert for further information.

### 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>200 mg/tablet</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>.? mg/tablet</td>
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</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.

**Aggravated Medical Conditions**
Known sensitivity to product; cardiogenic shock; severe sinus-node dysfunction.

### 5. FIRE-FIGHTING MEASURES

**Flammable Properties**
Presumed to be a combustible particulate solid.

**Extinguishing Media**
- Suitable Extinguishing Media
  - Use water spray, foam, dry chemical or carbon dioxide.
- Unsuitable Extinguishing Media
  - 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

Common Name
Amiodarone HCl

Exposure Guideline
100 mcg/m³

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
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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pharmaceutical tablet</td>
</tr>
<tr>
<td>Color</td>
<td>Pink</td>
</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility</td>
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</tr>
<tr>
<td>Partition Coefficient (n-octanol/water)</td>
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</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash Point</td>
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</tr>
<tr>
<td>Melting Point</td>
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</tr>
<tr>
<td>Flammability Limits in Air</td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td>Explosion Limits</td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Water Solubility</td>
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</tr>
<tr>
<td>Evaporation Rate</td>
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</tr>
<tr>
<td>Vapor Density</td>
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</tr>
<tr>
<td>Autoignition Temperature Method</td>
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</tr>
<tr>
<td>Upper</td>
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</tr>
<tr>
<td>Lower</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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

Multiple Dose Toxicity

Amiodarone HCl
No Toxicologic Effect
See Carcinogenicity

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.

Amiodarone HCl
Target Organ(s) of Toxicity
No data available
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
<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Fire Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Sudden Release of Pressure Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Prepared By</th>
<th>Wyeth Department of Environment, Health &amp; Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Format</td>
<td>This MSDS was prepared in accordance with ANSI Z400.1-2004.</td>
</tr>
<tr>
<td>List of References</td>
<td>See Patient Package Insert for more information.</td>
</tr>
<tr>
<td>Revision Summary</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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End of MSDS