



Cordarone Intravenous

Preparation Date 20-Aug-2007

Revision Date 20-Aug-2007

Revision Number 1

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 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.

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects There is no known ecological information for this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Amiodarone HCl	19774-82-4	50 mg/ml
Benzyl Alcohol	100-51-6	20.2 mg/ml
Inactive Ingredients	Not applicable	.? mg/tablet

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	
Suitable Extinguishing Media	Use alcohol-resistant 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	Exposure Guideline
Amiodarone HCl	100 mcg/m ³
Benzyl Alcohol	15 ppm (Germany)
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

Appearance	Biopharmaceutical liquid	Physical State	Liquid
Color	Yellow	Odor	Not available
Odor Threshold	Not available		
pH	3.5 - 4.5		
Specific Gravity	Not available	Water Solubility	Not available
Solubility	Not applicable	Evaporation Rate	Not available
Partition Coefficient (n-octanol/water)	Not available	Vapor Density	Not available
Vapor Pressure	Not applicable		
Boiling Point	Not available	Autoignition Temperature Method	Not available
Flash Point	Not available		None
Melting Point	Not applicable		
Flammability Limits in Air	Upper Not available	Lower Not available	
Explosion Limits	Upper Not available	Lower Not available	

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 Dose/Species/Study Length:	See Carcinogenicity
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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 <i>in vitro</i> and <i>in vivo</i> 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 <i>in vitro</i> or <i>in vivo</i>
Reproductive Toxicity	Not reprotoxic.
Developmental Toxicity	Not developmentally toxic.

Amiodarone HCl

Target Organ(s) of Toxicity No data available

Benzyl Alcohol

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 INFORMATIONUSAFederal 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 VonKananel email Aug 3, 2007
Revision Summary	Changes to Section 11

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