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Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier:	Amiodarone Hydrochloride Injection (3 mL Pre-Filled Syringe)
Product Code:	NDC 25021-302-73
Common/Trade Name:	Amiodarone Hydrochloride
Chemical Name:	(2-butyl-3-benzofuranyl)[4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl]methanone hydrochloride.
Chemical Family:	Antiarrhythmic
Product Use:	Pharmaceutical
Product Type:	Regulated Prescription Drug
Container Information:	Syringe

Section 2 - Composition / Information on Ingredients

Ingredient	%	OSHA PEL	ACGGIH TLV	Other Limits Recommended	CAS No.
Amiodarone Hydrochloride	5	None	None	20 ug/m ³³	19774-82-4
Benzyl Alcohol	2	None	None	None	100-51-6
Polysorbate 80	10	None	None	None	9005-65-6
Water for Injection	83	None	None	None	7732-18-5


Section 3 - Hazards Identification

Primary Physical and Health Hazards:

Amiodarone is a drug generally considered a class III antiarrhythmic used in treating heart beat irregularities. Minimal adverse health effect should occur from routine use under care of a physician with this product. Accidental ingestion may result nausea, vomiting, irregular heart beat, headache, lung damage. Short-term contact may cause dermal irritation.

Routes of Entry:

Under normal use, Amiodarone presents little hazard. It may be absorbed through the skin or via inhalation of aerosols or accidentally ingested.

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Signs & Symptoms of Exposure: Possible irritation to skin and respiratory tract.

Chemical Listed as Carcinogen: **NTP:** No **IARC:** No **OSHA:** No

Medical Conditions Generally Aggravated by Exposure: Hypotension may occur with use.

Section 4 - First Aid Measures

Eye Exposure: Flush eyes with large volumes of water for 15 minutes or more. Seek medical attention if irritation or signs of exposure are noted.

Skin Exposure: Wash skin with cool, soapy water for 15 minutes.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention if any symptoms appear. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

Injection: In cases of accidental injection, wash and disinfect area, seek medical attention.

Inhalation: If difficulty with breathing, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.

Notes to Physician: See patient package insert in shipping carton for complete information.


Section 5 - Fire Fighting Measures

Flash Point Not Applicable

Autoignition Temperature: Not Applicable

Flammable Limits in Air Lower %: Not Applicable
Upper %: Not Applicable

Flammable Limits: Not Applicable

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Extinguishing Media

Water spray or multi-purpose ABC extinguisher.

Special Fire Fighting Procedures:

As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards:

None.

Section 6 - Accidental Release Measures

Spill:

Absorb liquid with absorbent material and dispose according to local, state and federal guidelines.

Release to Air:

If aerosolized, reduce exposures by ventilating area. Clean up immediately to prevent evaporation.

Release to Water:

Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling:


Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

Waste Disposal Method:

Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

Storage Conditions:

Protect from excessive light and heat, protect from freezing. Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Use carton to protect contents from light until used. Follow instructions provided in packaging.

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Section 8 - Exposure Controls / Personal Protection

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting.

Respiratory Protection:	Under normal use, respirators should not be required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.
Eye Protection:	Safety glasses.
Ventilation:	Handle product in a well ventilated area.
Skin Protection:	Work uniform or laboratory coat.
Other Protective Equipment:	Protective Latex or Nitrile gloves
Additional Exposure Precautions:	Wash hands following use. No eating, drinking or smoking when handling this product.

Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Amiodarone Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Benzyl Alcohol	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Polysorbate 80	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

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Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

Section 9 - Physical and Chemical Properties

Physical State:	Liquid	Specific Gravity:	Approx to water
Appearance and Odor:	Pale-yellow solution.	Evaporation Rate:	Approx to water
Boiling Point:	Approx. 100°C	Solubility in Water:	Soluble
Vapor Pressure:	Approx to water	pH:	Not available
Vapor Density:	Approx to water	Molecular Weight	681.78

Section 10 - Stability and Reactivity

Stability:	Stable at normal temperature and pressures.
Incompatibility (Materials to avoid):	Strong oxidizers or water-reactive materials.
Hazardous Decomposition:	Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, carbon dioxide and sulfur oxides.
Hazardous Polymerization:	Will not occur.
Conditions to Avoid:	Storage near oxidizers and water reactive materials.

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Section 11 - Toxicological Information

Signs & Symptoms of Exposure & Overexposure:

IMMEDIATE EFFECTS:

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Possible adverse reactions include: nausea, hypotension, transient fever, asystole/cardiac arrest/electromechanical dissociation (EMD), cardiogenic shock, congestive heart failure, bradycardia, liver function test abnormalities, VT and AV Block.


Occupational exposure has not been fully investigated.

DELAYED EFFECTS:

Hypersensitivity to amiodarone or any of the components of this product. Contraindicated in patients with cardiogenic shock, marked bradycardia, and second or third degree AV block unless a functioning pacemaker is available. In patients with life-threatening arrhythmias, the potential risk of hepatic injury should be weighed against the potential benefit of Amiodarone HCl Injection therapy. The drug may cause worsening of existing arrhythmias or precipitate a new arrhythmia.

Acute Toxicity

Component	Type	Route	Species	Dosage
Amiodarone Hydrochloride	LD ₅₀	Oral	Rat	>3 gm/kg
Amiodarone Hydrochloride	LD ₅₀	IV	Rat	170 mg/kg
Amiodarone Hydrochloride	LD ₅₀	IP	Rat	610 mg/kg
Amiodarone Hydrochloride	LD ₅₀	Oral	Mouse	>3 gm/kg
Amiodarone Hydrochloride	LD ₅₀	Oral	Dog	>5 gm/kg
Amiodarone Hydrochloride	LD ₅₀	IV	Dog	5 gm/kg

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Other: Additional reproductive health data is available from National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section 12 - Ecological Information

Information is currently not available on the environmental impact of Amiodarone. Handle in a manner to prevent spills or releases to the environment.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations. Incineration at an approved, permitted facility is recommended.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

TSCA - *Not on this list*


CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 - *Not on this list*

Section 16 - Other Information


As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an

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adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)