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Section 1 - Identification

- (a) **Product Identifier:** Amiodarone Hydrochloride Injection (3 mL Pre-Filled Syringe)
- (b) **Product Code:** 25021-302
- Common/Trade Name:** Amiodarone Hydrochloride
- Chemical Name:** (2-butyl-3-benzo-furanyl)[4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl]methanone hydrochloride.
- Chemical Family:** Antiarrhythmic
- (c) **Product Use:** Class III Antiarrhythmic used in treating heartbeat irregularities.
- Product Type:** Regulated Prescription Drug
- Container Information:** Plastic Syringe
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618


Section 2 - Hazards Identification

- a) **Classification:** **US OSHA Classification:** Target Organ Toxin, Possible Irritant

NFPA Rating

Health Hazard	2
Fire Hazard	0
Reactivity Hazard	0

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Signal Word:	- Not Available
<u>GHS Precautionary Statements:</u>	
<ul style="list-style-type: none"> - P260: Do not breathe dust/fume/gas/mist/vapors/spray - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell. 	

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(d) Unknown Acute Toxicity: N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(2-butyl-3-benzo-furanyl)[4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl]methanone hydrochloride.	Amiodarone Hydrochloride	5% (w/v)	19774-82-4	N/A
Phenylmethanol	Benzyl Alcohol	2% (w/v)	100-51-6	N/A
Polyoxyethylene (20) sorbitan monooleate	Polysorbate 80	10% (w/v)	9005-65-6	N/A
Water	Water for injection	83% (w/v)	7732-18-5	N/A

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.

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Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Water spray or multi-purpose ABC extinguisher.
- (b) **Hazardous Combustion Products:** None.
- (c) **Special Protective Equipment / Precautions:** 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.

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.
- 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.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Amiodarone Hydrochloride	OSHA	PEL	NE

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	ACGIH -----	TLV STEL	NE NE
Benzyl Alcohol	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Polysorbate 80	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Water for Injection	OSHA ACGIH -----	PEL TLV STEL	NE NE NE

(b) Engineering Controls


Ventilation: Handle product in a well ventilated area.

(c) Individual Protection Measures

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.
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.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Pale yellow liquid
(b)	Odor	No Odor
(c)	Odor Threshold	None
(d)	pH	Not Available
(e)	Melting Point:	Not Applicable

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(f)	Initial Boiling Point:	Approx. 100°C
(g)	Flash Point	Not Applicable
(h)	Evaporation Rate:	Approx to water
(i)	Flammability	Not anticipated for this product
(j)	Upper Lower Flammability or Explosion Limits	Not Available
(k)	Vapor Pressure:	Approx to water
(l)	Vapor Density:	Approx to water
(m)	Relative Density	Approx to water
(n)	Solubility(ies)	Soluble in water
(o)	Partition Coefficient: n-octanol/water	Not Available
(p)	Auto-ignition Temperature	Not Applicable
(q)	Decomposition Temperature	Not Available
(r)	Viscosity	Not Available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not Reactive
(b)	Chemical Stability	Stable at normal temperature and pressures.
(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur
(d)	Conditions to Avoid	Storage near oxidizers and water reactive materials.
(e)	Incompatible Materials	Strong oxidizers or water-reactive materials.
(f)	Hazardous Decomposition Products	Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, carbon dioxide and sulfur oxides.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Under normal use, Amiodarone presents little hazard. It may be absorbed through the skin or via inhalation of aerosols or accidentally ingested.
(b)	Symptoms related to the physical, chemical and toxicological	Amiodarone is a drug generally considered a class III antiarrhythmic used in treating heart

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	characteristics	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.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Possible irritation to skin and respiratory tract.

(d) 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
Amiodarone Hydrochloride	LD ₅₀	IP	Mouse	450 mg/kg

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

(e) Hazardous Chemical Listings


NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

(a)	Ecotoxicity	Not determined for product.
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		<p>LC50(96 hr) = 460 mg/L in Pimephales promelas for benzyl alcohol</p> <p>LC50 = 640 mg/L in Leuciscus idus for benzyl alcohol</p> <p>EC50(24 hr) = 400 mg/L in Daphnia magna for benzyl alcohol</p> <p>EC50 = 95 mg/L in Chlorella pyrenoidosa for benzyl alcohol</p>
(b)	Persistence and degradability	Not determined for product. Benzyl alcohol was degraded over 90% in a 28-day biodegradation assay in sewage sludge.
(c)	Bioaccumulative potential	Not established
(d)	Mobility in soil	Not established
(e)	Other Adverse Effects	Not established

Section 13 - Disposal Considerations

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


Section 14 - Transport Information

(a)	UN Number	Not Available
(b)	UN Proper Shipping Name	Not Available
(c)	Transport Hazard Class(es)	Not Available
(d)	Packing Group	Not Available
(e)	Environmental Hazards	Not Available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
(g)	Special Precautions	Not Available

DOT: Not regulated

ICAO/IATA: Not regulated

IMDG: Not regulated

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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 (Benzyl Alcohol and Polysorbate 80 are listed)

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

Massachusetts Right to Know Components – None

Rhode Island Right to Know Components – None

Florida Right to Know Components – None

California Prop. 65 Components – Amiodarone hydrochloride

OSHA: Target Organ Toxin, Possible Irritant

GHS Classification: Does not apply

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 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 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:

Sagent Pharmaceuticals, Inc.

1901 N. Roselle Rd, Suite 700


Schaumburg, IL 60195

847-908-1600

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

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
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
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMDG	International Maritime Dangerous Goods
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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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

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RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
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)
WHMIS	Workplace Hazardous Materials Information System