WEST-WARD
PHARMACEUTICALS

MATERIAL SAFETY DATA SHEET

AMIODARONE FOR INJECTION, MSDS

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SECTION 1. PRODUCT AND COMPANY INFORMATION

Product Name: Amiodarone Hydrochloride for Injection

Supplier: West-Ward Pharmaceuticals
401 Industrial Way West
Eatontown, NJ 07724
Phone (732 542 1191)
Fax (732 720 6220)

Technical Phone: (800 631 2174)

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

CAS No.	Description	% in final Product
19774-82-4	Amiodarone Hydrochloride	5.00
100-51-6	Benzyl Alcohol	2.02
9005-65-6	Polysorbate 80	10.00
7732-18-5	Water for Injection	QS

Category: Antiarrhythmic

SECTION 3. HAZARDS IDENTIFICATION, EMERGENCY OVERVIEW

Route of Entry: Inhalation, eye/skin contact, or ingestion

Potential Health Effects

Route	ShortTerm Exposure	Long Term Exposure
Inhalation	Irritation	No Info
Skin Contact	Irritation	No Info
Eye Contact	Irritation	No Info
Ingestion	Nausea, vomitting, irregular heartbeat, headache, lung damage	Same as Short Term, Visual disturbances

Chemical List as Carcinogen:

NTP: No
IARC: No
OSHA: No

SECTION 4. FIRST AID MEASURES

Eyes:	Immediately flush eyes with water for at least 15 minutes. Seek medical attention
Skin:	Remove from source of exposure, wash affected area with soap and water, seek medical attention as needed.
Inhalation:	If difficulty breathing, remove from source of exposure and administer oxygen. Seek medical attention. Provide symptomatic/ Supportive care as necessary.
Ingestion:	If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

SECTION 5. FIRE AND EXPLOSION DATA

Fire and explosion Data

Closed Cup Flash Point:	N/A
Open Cup Flash Point	N/A
Fire Point:	N/A
Autoignition:	N/A
Lower Explosion Limit:	N/A
General Hazard:	No unusual fire or explosion hazard is
Fire Fighting Instructions:	Evacuate personnel to safe area. Water spray, dry chemical, carbon dioxide, or foam
Hazardous Combustion Products:	Thermal decomposition may yield toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, and hydrogen chloride

SECTION 6. ACCIDENTAL RELEASE MEASURES

Clean Up:	Wear recommended personal protective equipment. Use appropriate absorbent material to clean affected area. Wipe area with soap and water. Dispose of materials according to the applicable fedral, state and/ or local regulations.

SECTION 7. HANDLING AND STORAGE

General Handling:	When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/ or vapors associated with the
Storage Conditions:	Store at controlled room temperature 20° - 25°C (68° - 77°F). Protect from light and excessive heat. Use carton to protect from light until

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Use Local exhaust ventilation if necessary.

Personal Protective Equipment

Eye protection: Safety glasses or goggles recommended.

Hand protection: Latex rubber gloves recommended.

Respiratory Protection: Under normal use, respirators are not required. If aerosols are generated, an air purifying respirator with HEPA Cartridges (P100) should be worn. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Skin Protection: Disposable garments if direct skin contact is anticipated.

Exposure Limits:

Compound	Issuer	Type	OEL
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
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	...	STEL	NE

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form/ Appearance:	Clear to Pale Yellow Solution
Boiling Point/ Boiling Range:	~100°C (212°F)
Melting Point/ Melting Range:	~0°C
Freezing Point:	N/A
Vapor Pressure:	N/A
Relative Vapor Density:	N/A
Percent Volatiles:	N/A
pH:	N/A
Molecular Weight:	681.78
Solvent Solubility:	Very slightly soluble in water

SECTION 10. STABILITY AND REACTIVITY DATA.

Stability:	Stable
Conditions to Avoid:	Storage near oxidizers and water reactive materials.
Hazardous Polymerization:	Will not occur

SECTION 11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Compound	Type	Route	Species	Dosage
Amiodarone Hydrochloride	LD50	Oral	Rat	>3 gm/kg
	LD50	IV	Rat	170 mg/kg
	LD50	IP	Rat	610 mg/kg
	LD50	Oral	Mouse	>3 gm/kg
	LD50	Oral	Dog	>5 gm/kg
	LD50	IP	Dog	5 gm/kg
Polysorbate 80	LD50	IP	Rat	6804 mg/kg
	LD50	IV	Rat	1790 mg/kg
	LD50	Oral	Mouse	25 mg/kg

Other: Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS)
PREGNANCY CATEGORY D: May cause neonatal hypo-or hyperthyroidism. Amiodarone Hydrochloride Injection should be used during pregnancy only if the potential benefit to the mother justifies the rist to the fetus.

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

Dispose of by incineration at an approved /permitted incinerator. Review local, state, and federal regulations for your regulatory area.

SECTION 14. TRANSPORT INFORMATION

UN/NA Number: N/A
US DOT Hazard Class: N/A
Proper Shipping Name: N/A
Shipping Label: N/A

SECTION 15. REGULATORY INFORMATION

U.S. Regulatory Information: not regulated.

SECTION 16. OTHER INFORMATION

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