



300 Northfield Road
Bedford, OH 44146
Telephone: (440) 232-3320
-or- (800) 562-4797

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Amiodarone Hydrochloride Injection (3, 9 and 18 mL)

Chemical Names: Amiodarone Hydrochloride

Synonyms: 2-butyl-3-benzofuranyl 4-(2-(diethylamino) ethoxy)-3,5-diiodophenyl ketone hydrochloride; amiodaronum hydrochloride; Methanone, (2-butyl-3-benzofuranyl) (4-(2-(diethylamino)ethoxy)-3,5-diiodophenyl-, hydrochloride; Amiodarone HCl; SKF 331314 A, Trangorex, L 3424, L 3438 labaz, Cordarone®

Manufacturer's Name: BEN VENUE LABORATORIES, INC.

Address: 300 NORTHFIELD ROAD
BEDFORD, OH 44146

Emergency Telephone Number: Chemtrec: 1(800)424-9300

Telephone Number for Info.: (440)232-3320 -or- (800)562-4797

Medical Emergency: Professional Services 1(800)521-5169

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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Amiodarone Hydrochloride	5	9774-82-4	NONE	NONE	20 ug/m ³ (BVL OEL)
Benzyl Alcohol	2	100-51-6	NONE	NONE	NONE
Polysorbate 80	10	9005-65-6	NONE	NONE	NONE
Water for Injection	83	7732-18-5	NONE	NONE	NONE

Amiodarone is a sterile injectable liquid drug provided in a vial.

Section III - HEALTH HAZARD DATA

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.

Health Hazard (Acute & Chronic): 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.

Carcinogenicity: NTP? NO **IARC Monographs?** NONE **OSHA Regulated?** NO

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

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

BVL Hazard Category: 3

BVL Occupational Exposure limit (OEL): 20 ug/m³

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes.

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

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.

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately.

When appropriate and trained in CPR, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not Applicable **LEL:** Not Applicable **UEL:** Not Applicable

Flammable Limits: Not Applicable

Extinguishing Media: Use water or an ABC multi-purpose 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 VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Absorb Amiodarone with absorbent materials and dispose according to local, state, and federal guidelines.

Release to Air: If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation

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

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above.

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.

Precautions to be taken in handling and storing: Store between 15-25 °C. Protect from excessive light and heat. Follow instructions provided in packaging.

Other Precautions: NONE

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not 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.

Ventilation: Handle product in a well-ventilated area.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses

Other Protective Clothing or Equipment: Lab Coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking while handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Liquid

Specific Gravity: Approx. to water

Appearance and Odor: Pale-yellow solution

Melting Point: Approx. 0°C

Boiling Point: Approx. 100°C

Evaporation Rate: Approx. to water

Vapor Pressure: Not available

Solubility in Water: Soluble

Vapor Density: Not available

pH: Not Available

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): Strong oxidizers or water-reactive materials.

Hazardous Decomposition or Byproducts: 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

Section XI - TOXICOLOGICAL INFORMATION

For Amiodarone Hydrochloride (active ingredient) RTECS Number OB1361000

LD₅₀ rat, intravenous = 170 mg/kg

LD₅₀ rat, oral = >3 gm/kg

LD₅₀ rat, intraperitoneal = 610 mg/kg

LD₅₀ mouse, oral = >3 gm/kg

LD₅₀ dog, oral = >5 gm/kg

LD₅₀ dog, intraperitoneal = 5 gm/kg

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

Section XII - ENVIRONMENTAL IMPACT 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 XIII - DISPOSAL INFORMATION

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

Section XIV - TRANSPORTATION INFORMATION

Amiodarone solution USP is not a DOT hazardous material.
Amiodarone is not a DOT Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO

CERCLA listed?: NO

RCRA listed?: NO

Listed on the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). CODE - DFM

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician.
This MSDS does not address the therapeutic use of this material
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company Management.
3. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):
1 = Low Toxicity
2.= Moderate Toxicity
3 = Potent or Toxic
4 = Highly Potent or Toxic
5 = Extremely Potent or Toxic

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