



BIONICHEPHARMA

Dedicated to Specialty Injectables

Material Safety Data Sheet

Material Name: Amlodarone Hydrochloride Injection
50mg/mL

*** Section 1 - Chemical Product and Company Identification ***

Manufacturer Information

Bioniche Pharma
272 E Deerpath Road
Suite 304
Lake Forest, IL 60045

Phone: 888-258-4199

Emergency # 888-875-1671

*** Section 2 - Hazards Identification ***

Emergency Overview

May cause eye, skin, gastrointestinal, and/or respiratory tract irritation.

Potential Health Effects: Eyes

May cause irritation.

Potential Health Effects: Skin

May cause irritation.

Potential Health Effects: Ingestion

Not considered a likely route of exposure under normal product use. May cause gastrointestinal irritation if swallowed.

Potential Health Effects: Inhalation

Not considered a likely route of exposure under normal product use. May cause respiratory tract irritation.

HMIS Ratings: Health: 1 Fire: 0 HMIS Reactivity 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

*** Section 3 - Composition / Information on Ingredients ***

CAS #	Component
7732-18-5	Water
9005-65-6	Polyoxyethylene 20 sorbitan monooleate
19774-82-4	2-Butyl-3-benzofuryl 4-[2-(diethylamino)ethoxy]-3,5-diodophenyl ketone hydrochloride
185532-71-2	Benzyl alcohol

*** Section 4 - First Aid Measures ***

First Aid: Eyes

Flush immediately with water for at least 15 minutes. Do not rub eyes.

First Aid: Skin

For skin contact, flush with large amounts of water. If irritation persists, get medical attention.

First Aid: Ingestion

If ingestion of a large amount does occur, seek medical attention.

First Aid: Inhalation

Move person to non-contaminated air. If the affected person is not breathing, apply artificial respiration.

*** Section 5 - Fire Fighting Measures ***

General Fire Hazards

See Section 9 for Flammability Properties.

None

Hazardous Combustion Products

Not determined

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Extinguishing Media

Use extinguishing media appropriate for surrounding fire.

Fire Fighting Equipment/Instructions

Firefighters should wear full protective gear.

NFPA Ratings: Health: 1 Fire: 0 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

*** Section 6 - Accidental Release Measures ***

Containment Procedures

Contain the discharged material.

Clean-Up Procedures

Wear appropriate protective equipment and clothing during clean-up. Use sand or perlite or vermiculite as an absorbent for large spills of this material.

Evacuation Procedures

Isolate area. Keep unnecessary personnel away.

Special Procedures

Avoid contact with skin and eyes.

*** Section 7 - Handling and Storage ***

Handling Procedures

Wash hands after handling and before eating.

Storage Procedures

Keep this material in a cool, well-ventilated place.

*** Section 8 - Exposure Controls / Personal Protection ***

A: Component Exposure Limits

ACGIH, OSHA, and NIOSH have not developed exposure limits for any of this product's components.

Engineering Controls

Use general ventilation and use local exhaust, where possible, in confined or enclosed spaces.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Wear safety glasses; chemical goggles (if splashing is possible).

Personal Protective Equipment: Skin

Use impervious gloves.

Personal Protective Equipment: Respiratory

Not normally needed.

Personal Protective Equipment: General

Eye wash fountain is recommended.

*** Section 9 - Physical & Chemical Properties ***

Appearance:	Clear, pale-yellow	Odor:	None
Physical State:	Liquid	pH:	ND
Vapor Pressure:	ND	Vapor Density:	ND
Boiling Point:	ND	Melting Point:	ND
Solubility (H2O):	Slight	Specific Gravity:	ND
Evaporation Rate:	ND	VOC:	ND
Octanol/H2O Coeff.:	ND	Flash Point:	ND
Flash Point Method:	ND	Upper Flammability Limit (UFL):	ND
Lower Flammability Limit (LFL):	ND	Burning Rate:	ND
Auto Ignition:	ND		

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*** Section 10 - Chemical Stability & Reactivity Information ***

Chemical Stability

This is a stable material.

Chemical Stability: Conditions to Avoid

None

Incompatibility

Not Determined

Hazardous Decomposition

Not Determined

Possibility of Hazardous Reactions

Will not occur.

*** Section 11 - Toxicological Information ***

Acute Dose Effects

A: General Product Information

No information available for the product.

B: Component Analysis - LD50/LC50

Water (7732-18-5)

Oral LD50 Rat: >90 mL/kg

Polyoxyethylene 20 sorbitan monooleate (9005-65-6)

Oral LD50 Rat: 34500 µL/kg

2-Butyl-3-benzofuryl 4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride (19774-82-4)

Oral LD50 Rat: >3 g/kg

Carcinogenicity

A: General Product Information

No information available for the product.

B: Component Carcinogenicity

None of this product's components are listed by ACGIH, IARC, OSHA, NIOSH, or NTP.

*** Section 12 - Ecological Information ***

Ecotoxicity

A: General Product Information

No information available for the product.

B: Component Analysis - Ecotoxicity - Aquatic Toxicity

No ecotoxicity data are available for this product's components.

*** Section 13 - Disposal Considerations ***

US EPA Waste Number & Descriptions

Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

Disposal Instructions

All wastes must be handled in accordance with local, state and federal regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

*** Section 14 - Transportation Information ***

US DOT Information

Shipping Name: Not Regulated

*** Section 15 - Regulatory Information ***

US Federal Regulations

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Component Analysis

None of this products components are listed under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), or CERCLA (40 CFR 302.4).

State Regulations

Component Analysis - State

None of this product's components are listed on the state lists from CA, MA, MN, NJ, PA, or RI.

The following statement(s) are provided under the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):

WARNING! This product contains a chemical known to the state of California to cause reproductive/developmental effects.

Component Analysis - WHMIS IDL

No components are listed in the WHMIS IDL.

Additional Regulatory Information

Component Analysis - Inventory

Component	CAS #	TSCA	CAN	EEC
Water	7732-18-5	Yes	DSL	EINECS
Polyoxyethylene 20 sorbitan monooleate	9005-65-6	Yes	DSL	No
2-Butyl-3-benzofuryl 4-[2-(diethylamino)ethoxy]-3,5-diodophenyl ketone hydrochloride	19774-82-4	No	No	EINECS
Benzyl alcohol	185532-71-2	No	No	No

*** Section 16 - Other Information ***

Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial, and local laws.

Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration., NJTSR = New Jersey Trade Secret Registry.