



AMIODARONE HYDROCHLORIDE INJECTION, 50MG/ML SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product name: Amiodarone Hydrochloride Injection, 50mg/mL

Intended Use Of The Product

Use of the substance/preparation: Pharmaceutical. Antiarrhythmic drug. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, And Telephone Of The Responsible Party

Supplier:

Mylan Institutional LLC
1718 Northrock Court
Rockford, IL 61003 USA
800.848.0462

www.mylan.com

Manufacturer:

Mylan Teoranta
Galway, Ireland

Emergency Telephone Number

Emergency number : +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Classification Of The Substance Or Mixture

Classification (GHS-US)

Eye Irrit. 2B H320
Repr. 2 H361
STOT SE 1 H370

Label Elements

GHS-US labeling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H320 - Causes eye irritation
H361 - Suspected of damaging fertility or the unborn child
H370 - Causes damage to organs

Precautionary statements (GHS-US) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
P264 - Wash hands, forearms, and exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P321 - Specific treatment (see section 4).
P337+P313 - If eye irritation persists: Get medical advice/attention.

P405 - Store locked up.
P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

Other Hazards

Other hazards not contributing to the classification: Cardiac effects. Amiodarone Hydrochloride Injection may cause a worsening of existing arrhythmias or precipitate a new arrhythmia. Refer to product insert for complete adverse drug interactions.

Unknown acute toxicity (GHS US) Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Polyoxyethylene 20 sorbitan monooleate	(CAS No.) 9005-65-6	7 - 13	Eye Irrit. 2B, H320 STOT SE 1, H370
2-Butyl-3-benzofuryl 4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride	(CAS No.) 19774-82-4	3 - 7	Repr. 2, H361 STOT SE 2, H371
Benzyl alcohol	(CAS No.) 100-51-6	1 - 5	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 3 (Inhalation: vapour), H331

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

Description Of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: If accidental ingestion occurs, flush mouth out with water and get medical attention.

Most Important Symptoms And Effects Both Acute and Delayed

General: Irritation to eyes, skin and respiratory tract.

Inhalation: Inhalation of vapor and/or mist may cause respiratory irritation.

Skin Contact: May cause skin irritation.

Eye Contact: Causes eye irritation.

Ingestion: Abdominal pain. Gastrointestinal irritation. May be harmful if swallowed.

Injection: The most common adverse effects reported include fever, bradycardia, congestive heart failure, heart arrest, hypotension, ventricular tachycardia, abnormal liver function, nausea.

Chronic symptoms: May cause damage to heart, liver, and kidneys.

Indication Of Any Immediate Medical Attention And Special Treatment Needed

If exposed or concerned, get medical advice and attention. In the event of an accidental injection, call a poison center and go immediately to the nearest emergency room.

5. FIREFIGHTING MEASURES

Extinguishing Media

Suitable extinguishing media: Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂).

Unsuitable extinguishing media: Do not use a heavy water stream. Use of a heavy stream of water may spread fire.

Special Hazards Arising From The Substance Or Mixture

Fire hazard: Not considered flammable but may burn at high temperatures.

Explosion hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice For Firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂), nitrogen oxides, chlorine gas.

Other information: Refer to Section 9 for flammability properties.

6.**ACCIDENTAL RELEASE MEASURES****Personal Precautions, Protective Equipment And Emergency Procedures**

General measures: Avoid all eye and skin contact and do not breathe vapor and mist. Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Do not touch or walk through spilled material.

For Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Ventilate area. If possible, stop flow of product.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods And Material For Containment And Cleaning Up

Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference To Other Sections

See Heading 8, Exposure Controls and Personal Protection.

7.**HANDLING AND STORAGE**

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Precautions For Safe Handling

Hygiene measures: Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions For Safe Storage, Including Any Incompatibilities

Storage conditions: Keep away from heat and direct sunlight. Store in unopened containers. Store locked up.

Storage temperature: 20-25°C (68-77°F)

Specific End Use(s)

Pharmaceutical

8.**EXPOSURE CONTROLS/PERSONAL PROTECTION****Control Parameters**

No Occupational Exposure Limits have been established for this product or its components.

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Safety glasses. Protective clothing. Gloves.

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

9.**PHYSICAL AND CHEMICAL PROPERTIES****Information On Basic Physical And Chemical Properties**

Physical state	: Liquid
Appearance	: Clear, pale-yellow
Odor	: Not available
Odor threshold	: Not available
pH	: Not available
Relative evaporation rate (butyl acetate=1)	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flash point	: Not available

Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Lower flammable limit	: Not available
Upper flammable limit	: Not available
Vapor pressure	: Not available
Relative vapor density at 20 °C	: Not available
Relative density	: Not available
Specific gravity	: Not available
Solubility	: Not available
Log Pow	: Not available
Log Kow	: Not available
Viscosity, kinematic	: Not available
Viscosity, dynamic	: Not available
Explosion data - sensitivity to mechanical impact	: Not available
Explosion data - sensitivity to static discharge	: Not available

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.

Chemical Stability Stable at standard temperature and pressure.

Possibility Of Hazardous Reactions Hazardous polymerization will not occur.

Conditions To Avoid Extremely high or low temperatures.

Incompatible Materials Strong bases. Strong oxidizers. Strong acids.

Hazardous Decomposition Products Carbon oxides (CO, CO₂). Nitrogen oxides. Chlorine gas.

11. TOXICOLOGICAL INFORMATION

Information On Toxicological Effects - Product

Acute toxicity: Not classified

LD50 and LC50 Data: Not available

Skin corrosion/irritation: Not classified

Serious eye damage/irritation: Causes eye irritation.

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Teratogenicity: Not available

Carcinogenicity: Not classified

Specific target organ toxicity (repeated exposure): Not classified

Reproductive toxicity: Suspected of damaging fertility or the unborn child.

Specific target organ toxicity (single exposure): Causes damage to organs.

Aspiration hazard: Not classified

Information On Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

Polyoxyethylene 20 sorbitan monooleate (9005-65-6)	
LD50 oral rat	37.605 g/kg
2-Butyl-3-benzofuryl 4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride (19774-82-4)	
LD50 oral rat	> 3 g/kg
Benzyl alcohol (100-51-6)	
LD50 oral rat	1230 mg/kg
LD50 dermal rat	1700 mg/kg
LD50 dermal rabbit	2000 mg/kg
LD50 Intravenous Rat	53 mg/kg
LC50 inhalation rat (mg/l)	8.8 mg/l (Exposure time: 4 h)
Polyoxyethylene 20 sorbitan monooleate (9005-65-6)	
National Toxicity Program (NTP) Status	1
Benzyl alcohol (100-51-6)	
National Toxicity Program (NTP) Status	1
Polyoxyethylene 20 sorbitan monooleate (9005-65-6)	
LOAEL (oral,rat)	20 mg/kg body weight

2-Butyl-3-benzofuryl 4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride (19774-82-4)	
LOAEL (oral,rat)	1000 mg/kg body weight (liver, blood)

12. ECOLOGICAL INFORMATION

Toxicity

Benzyl alcohol (100-51-6)	
LC50 fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
EC50 other aquatic organisms 1	35 mg/l (Exposure time: 3 h - Species: Anabaena variabilis)
LC50 fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

Persistence And Degradability Not available

Bioaccumulative Potential

Benzyl alcohol (100-51-6)	
Log Pow	1.1

13. DISPOSAL CONSIDERATIONS

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.
Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

In accordance with ICAO/IATA/DOT/TDG
UN Number Not regulated for transport
UN Proper Shipping Name Not regulated for transport

15. REGULATORY INFORMATION

US Federal regulations

Polyoxyethylene 20 sorbitan monooleate (9005-65-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

US State regulations

2-Butyl-3-benzofuryl 4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride (19774-82-4)	
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.
U.S. - California - Proposition 65 - Reproductive Toxicity - Female	WARNING: This product contains chemicals known to the State of California to cause (Female) reproductive harm.
U.S. - California - Proposition 65 - Reproductive Toxicity - Male	WARNING: This product contains chemicals known to the State of California to cause (Male) reproductive harm.

Benzyl alcohol (100-51-6)

U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Water Quality - Ground Water Quality Criteria
U.S. - New Jersey - Water Quality - Practical Quantitation Levels (PQLs)
U.S. - Pennsylvania - RTK (Right to Know) List

Canadian regulations

Amiodarone Hydrochloride Injection, 50mg/mL

WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects
	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects



Polyoxyethylene 20 sorbitan monooleate (9005-65-6)

Listed on the Canadian DSL (Domestic Substances List) inventory.
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Benzyl alcohol (100-51-6)

Listed on the Canadian DSL (Domestic Substances List) inventory.
Listed on the Canadian Ingredient Disclosure List

WHMIS Classification	Class B Division 3 - Combustible Liquid Class D Division 2 Subdivision B - Toxic material causing other toxic effects
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This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

16. OTHER INFORMATION

- Indication of changes** : 02/04/2014
- Data sources** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
- Other information** : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

GHS Full Text Phrases:

Acute Tox. 3 (Inhalation:vapour)	Acute toxicity (inhalation:vapour) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Irrit. 2B	Serious eye damage/eye irritation Category 2B
Flam. Liq. 4	Flammable liquids Category 4
Repr. 2	Reproductive toxicity Category 2
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
STOT SE 2	Specific target organ toxicity (single exposure) Category 2
H302	Harmful if swallowed
H312	Harmful in contact with skin
H331	Toxic if inhaled
H361	Suspected of damaging fertility or the unborn child
H370	Causes damage to organs
H371	May cause damage to organs

Party Responsible For The Preparation Of This Document:

Mylan Global Environmental, Health, and Safety Department
Phone Number: 304-599-2595

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

North America Mylan Pharmaceuticals