

3. HAZARDS IDENTIFICATION

Ingestion:	Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Liver function effects (may include increased levels of SGOT, SGPT, serum LDH, jaundice). Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Respiratory effects (may include shortness of breath, bronchospasms, laryngospasms, respiratory depression). Loss of vision. Hypothyroidism. Hyperthyroidism.
Skin contact:	May cause irritation and/or allergic reactions.
Eye contact:	May cause irritation and/or allergic reactions.

4. FIRST AID MEASURES

Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
Skin contact:	In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Notes to physician:	See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available
Flash point:	Not determined
Autoignition temperature:	Not available.
Flammable limits	Not available.
in air-lower (%):	
Flammable limits	
in air-upper (%):	Not available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).
Environmental precautions:	No information available.
Methods for cleaning up:	For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.

Storage:**Technical measures**

Store at room temperature between 20°C and 25°C (68°F and 77°F). Protect from light.

/Storage conditions:

Avoid excessive heat. Protect from freezing.

Incompatible products:

No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Amiodarone Hydrochloride 19774-82-4	None	None	None	None	None	None
Sulfobutylether beta-cyclodextrin sodium 182410-00-0	None	None	None	None	None	None
Dextrose, anhydrous 50-99-7	None	None	None	None	None	None
Citric Acid Anhydrous 77-92-9	None	None	None	None	None	None
Sodium Citrate, dihydrate 6132-04-3	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures:

No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:**Respiratory protection:**

No personal respiratory protective equipment normally required.

Hand protection:

Use chemical resistant, impervious gloves.

Skin and body protection:

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits).

Eye protection:

Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:

Liquid

Appearance:

Aqueous solution

Color:

Clear, colorless to light yellow.

Odor:

Not available.

pH:

3.3 - 3.9

Molecular weight:

Not applicable.

9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling point/range:	Not available.
Melting point/range:	Not available.
Density:	Not available.
Vapor pressure:	Not available.
Evaporation rate:	Not available.
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Viscosity:	Not available.
% Volatile by Volume:	Not available.

10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Polymerization:	Not applicable
Hazardous decomposition products:	Carbon oxides.
Materials to avoid:	Not available.

11. TOXICOLOGICAL INFORMATION

Component	LD50 Dermal	LC50 Inhalation	LD50 Oral
Amiodarone Hydrochloride 19774-82-4	-	-	3 g/kg (rat)
Sulfobutylether beta-cyclodextrin sodium 182410-00-0	-	-	-
Dextrose, anhydrous 50-99-7	-	-	25800 mg/kg (rat)
Citric Acid Anhydrous 77-92-9	-	-	3000 mg/kg (rat)
Sodium Citrate, dihydrate 6132-04-3	-	-	-
Water 7732-18-5	-	-	90 mL/kg (rat)

Acute toxicity: Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Liver function effects (may include increased levels of SGOT, SGPT, serum LDH, jaundice). Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Respiratory effects (may include shortness of breath, bronchospasms, laryngospasms, respiratory depression). Hypothyroidism. Hyperthyroidism. Loss of vision. May cause skin and eye irritation.

Chronic toxicity: Target Organs: Heart. Liver. Lung.

Carcinogenic effects: May be carcinogenic based on animal data.

Mutagenic effects: Not mutagenic in a standard battery of genetic toxicological tests.

Reproductive toxicity: May impair fertility based on animal data. Teratogenic at maternally toxic doses.

FDA Pregnancy Category D

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Amiodarone Hydrochloride 19774-82-4	None.	None.	None.	None.
Sulfobutylether beta-cyclodextrin sodium 182410-00-0	None.	None.	None.	None.
Dextrose, anhydrous 50-99-7	None.	None.	None.	None.
Citric Acid Anhydrous 77-92-9	120 mg/L EC50 72 h	1516 mg/L LC50 Lepomis macrochirus 96 h	None.	= 14 mg/L EC50 Photobacterium phosphoreum
Sodium Citrate, dihydrate 6132-04-3	None.	None.	None.	1800 - 3200mg/LEC50 Pseudomonas fluorescens 8h
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:
 DOT shipping name: None
 UN Number: None
 DOT Packing Group: None
 DOT Hazard class: None

TDG (Canada):
 TDG Proper shipping name: None
 TDG UN/NA Number: None
 TDG Packing Group: None
 TDG Hazard class: None

ADR/RID:
 ADR Official Transport Name: None
 ADR Proper shipping name: None
 ADR UN/NA number: None
 ADR Hazard Class: None

ICAO / IATA:
 IATA Proper shipping name: None
 IATA UN Number: None
 IATA Primary Hazard: None
 IATA Packing group: None
 ICAO ERG Code: None

IMO / IMDG:
 IMDG Proper Shipping Name: None
 IMDG Hazard Class and Division: None
 IMDG Packing Group: None
 IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:
TSCA Inventory List - OTHER REGULATIONS: The product is exempt from TSCA, it is FDA Regulated
Japanese Inventory (ENCS) This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Amiodarone Hydrochloride	<0.2	Not Listed	Not Listed	Not Listed	Not Listed
Sulfobutylether beta-cyclodextrin sodium	<2	Not Listed	Not Listed	Not Listed	Not Listed
Dextrose, anhydrous	<5	Not Listed	Not Listed	Not Listed	Not Listed
Citric Acid Anhydrous	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Citrate, dihydrate	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Water	>93	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop. 65	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:

Product id: 1237301

Product name: Nexterone® (Amiodarone HCl) Premixed Injection

Amiodarone Hydrochloride	Present	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sulfobutylether beta-cyclodextrin sodium	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Dextrose, anhydrous	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Citric Acid Anhydrous	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Citrate, dihydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

This product contains component(s) known to the State of California to cause developmental harm.

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product does not comply with EINECS

Risk Phrases:
NONE

Safety Phrases:
NONE

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s)?:
None

Additional information:
Not Available.

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End of safety data sheet: