

Document Type:
Safety Data Sheet

Isoproterenol Hydrochloride Injection, USP

Effective Date: SDS No.: **27 FEB 2024** SDS013

Revision No: **01**

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Section 1 - Identification

Product Identifier: Isoproterenol Hydrochloride Injection, USP

Product Code: 83634-303

Common/Trade Name: Isoproterenol Hydrochloride Injection

3,4-Dihydroxy-α-[(isopropylamino)methyl] benzyl alcohol

Chemical Name: hydrochloride

Chemical Family: Synthetic Sympathomimetic Amine

Product Use: Pharmaceutical, Injectable

Product Type: Regulated Prescription Drug

Container Information: Vial

Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL

Distributor: 60173, 847-773-4901

Emergency Telephone: 855-283-6229

Section 2 - Hazards Identification

Classification:	GHS US classification
	Skin Irrit. 2 H315
	Eye Irrit. 2 H319
Signal Word:	Warning
Hazard	H315 - Causes skin irritation
Statement(s)	H319 - Causes serious eye irritation
Symbol(s)	



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Precautionary	P264 - Wash hands, forearms and face thoroughly after handling.
Statement(s)	 P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 - If on skin: Wash with plenty of water. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321 - Specific treatment (see supplemental first aid instruction on this
	label). P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse.
Unknown Acute Toxicity	N/A

Section 3 – Composition / Information on Ingredients

Chemical Name	Common Name / Synonym	Quantity/ mL	CAS No.	Impurities / Stabilizing Additives
3,4-Dihydroxy-α- [(isopropylamino)methyl] benzyl alcohol hydrochloride	Isoproterenol Hydrochloride USP	0.2 mg	51-30-9	N/A
Edetate Disodium USP (dihydrate equivalent to Edetate Disodium anhydrous)	Edetate Disodium USP	0.2 mg (0.22mg dihydrate equivalent to 0.2mg anhydrous)	6381-92-6	N/A
Sodium Chloride USP	Sodium Chloride USP	7.0 mg	7647-14-5	N/A
Sodium Citrate Dihydrate USP	Sodium Citrate Dihydrate USP	2.07 mg	6132-04-3	N/A
Citric Acid Anhydrous	Citric Acid Anhydrous	2.5 mg	77-92-9	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s to adjust pH	1310-73-2	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s to adjust pH	7647-01-0	N/A
Water for Injection	Water for Injection	q.s to 1 mL	7732-18-5	N/A



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Nitrogen	Nitrogen	q.s.	7727-37-9	N/A

Section 4 – First Aid Measures

Eye Exposure:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical

attention immediately.

Skin Exposure:

Remove contaminated clothing. Flush area with large amounts of water. Use

soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with

water. Do not induce vomiting unless directed by medical personnel. Seek

medical attention immediately.

Injection:

See patient package insert in shipping carton for complete information.

Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention

immediately.

Section 5 – Fire-fighting Measures

Extinguishing Media

Use extinguishing media appropriate for surrounding

fire.

Data unavailable

Hazardous

Decomposition

Products:

Special Protective

Equipment / Precautions:

During all fire-fighting activities, wear appropriate protective

equipment, including self-contained breathing apparatus.

Section 6 - Accidental Release Measures

Spill:

Stop the flow of material, if this is without risk. Absorb spillage with suitable absorbent material. Place in a suitable container and dispose

according to local, state and federal regulations.

Release to Air:

Do not breathe dust. Provide adequate ventilation. Wear appropriate

respirator when ventilation is inadequate. Put on appropriate personal

protective equipment.

Release to Water:

Prevent entry to sewers and public waters.



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Section 7 - Handling and Storage

General Handling: Avoid prolonged and repeated contact. Wear appropriate personal

protective equipment. Observe good industrial hygiene practices.

Storage Conditions: Store at 20° to 25°C (68° to 77°F); excursions permitted between 15°

and 30°C (59° and 86°F) [See USP Controlled Room Temperature].

Protect from light.

Section 8 - Exposure Controls / Personal Protection

(a) Control Parameters:

Hydrochloric acid (7647-01-0)				
ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm		
OSHA	OSHA PEL (Ceiling)	7 mg/m ³		
OSHA	OSHA PEL C [ppm]	5 ppm		
IDLH	IDLH [ppm]	50 ppm		
NIOSH	NIOSH REL (Ceiling)	7 mg/m ³		
NIOSH	NIOSH REL C [ppm]	5 ppm		
Sodium hydroxide (1310-73-2)			
ACGIH	ACGIH OEL Ceiling	2 mg/m³		
OSHA	OSHA PEL (TWA) [1]	2 mg/m³		
IDLH	IDLH	10 mg/m ³		
NIOSH	NIOSH REL (Ceiling)	2 mg/m³		
Sodium chloride (76	547-14-5)			
Not applicable				
Isoproterenol Hydr	ochloride (51-30-9)			
Not applicable				
Water (7732-18-5)				
Not applicable				

(b) Engineering Controls

Ventilation: Local exhaust and general ventilation must be adequate to meet

exposure standards.



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(c) Individual Protection Measures

Respiratory Protection:	No protection is ordinarily required under normal conditions of use.	
Eye Protection:	Wear safety glasses or goggles.	
Skin Protection:	Wear suitable working clothes.	
Other Protective Equipment:	No other protection is ordinarily required under normal conditions of use.	

Section 9 – Physical and Chemical Properties

(a)	Appearance	Clear, colorless liquid.
(b)	Odor	Odorless
(c)	Odor Threshold	Not available
(d)	рН	2.5 to 3.5
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Completely Soluble
(0)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

Reactivity	No additional information available
Chemical Stability	The product is stable at normal handling and storage conditions.



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Possibility of Hazardous Reactions	Hazardous polymerization will not occur
Conditions to Avoid	Air contact.
Incompatible Materials	None known.
Hazardous Decomposition Products	None known.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation and skin absorption	
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Inhalation: None anticipated during normal product use. Skin Contact: Causes skin irritation. Eye contact: Causes serious eye irritation. Ingestion: May be harmful if swallowed.	
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Reproductive toxicity: Not classified STOT-single exposure: Not classified STOT-repeated exposure:Not classified Aspiration hazard:Not classified	

(d) Acute Toxicity

Not classified.

Component	Type	Route	Species	Dosage
Hydrochloric acid	LC ₅₀ ATE US	Oral Skin Inhalation Oral Vapors Dust, Mist	Rat Rabbit Rat	500238-277 mg/kg >5010 mg/kg 1.68 mg/l (Exposure time: 1 h) 238 mg/kg body weight 1.68 mg/l/4h 1.68 mg/l/4h
Sodium hydroxide	LD ₅₀ ATE US	Oral Dermal Dermal	Rat Rabbit	140-340 mg/kg 1350 mg/kg 1350 mg/kg
Sodium chloride	LD ₅₀ LC ₅₀ ATE US	Oral Inhalation Oral	Rat Rat	3g/kg >42 g/m³ (Exposure time: 1 h) 3,000,000 mg/kg
Water	LD_{50}	Oral	Rat	>90 ml/kg



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(e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed **OSHA:** Not Listed

Section 12 - Ecological Information

Ecotoxicity

Sodium hydroxide (1310-73-2)	
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss
	[static])
Sodium chloride (7647-14-5)	
LC50 - Fish [1]	5560 – 6080 mg/l (Exposure time: 96 h - Species: Lepomis
	macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 - Fish [2]	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus
	[static])
EC50 - Crustacea [2]	340.7 – 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna
	[Static])
Persistence and degradability	No additional information available.
Bioaccumulative potential	BCF – Fish [1]: No bioaccumulation
Mobility in soil	No additional information available.
Other Adverse Effects	No additional information available.

Section 13 - Disposal Considerations

Waste Disposal: To avoid accidental exposure due to waste handling, place waste residue in a segregated, sealed plastic container. Used syringes, needles, and sharps should not be crushed, clipped, or recapped, but placed directly into an approved sharps container. Dispose of any cleanup materials and waste residue per all applicable laws and regulations, e.g., secure chemical landfill disposal.

Section 14 - Transport Information

Not regulated for transport under USDOT regulations.

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:



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Hydrochloric acid (7647-01-0)			
Listed on the United States TSCA (Toxic Substances Control Act) inventory			
Listed on the United States SARA Section 302	Listed on the United States SARA Section 302		
Subject to reporting requirements of United States	s SARA Section 313		
CERCLA RQ	5000 lb		
SARA Section 302 Threshold Planning Quantity	500 lb (gas only)		
(TPQ)			
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors,		
	gas, fog, and other airborne forms of any		
particle size)			
Sodium hydroxide (1310-73-2)			
Listed on the United States TSCA (Toxic Substant	ices Control Act) inventory		
CERCLA RQ	1000 lb		
Sodium chloride (7647-14-5)			
Listed on the United States TSCA (Toxic Substances Control Act) inventory			
Water (7732-18-5)			
Listed on the United States TSCA (Toxic Substances Control Act) inventory			

Section 16 - Other Information

As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Avenacy 10 N. Martingale Road, Suite 225 Schaumburg, IL 60173 847-773-4901

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances



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ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System