



MATERIAL SAFETY DATA SHEET

ISOPROTERENOL HYDROCHLORIDE INJECTION USP 0.2MG/ML

1. IDENTIFICATION

Material Identification	:	Isoproterenol Hydrochloride Injection USP 0.2mg/ml			
Active ingredient	:	3,4-Dihydroxy- α -[(isopropylamino)methyl] benzyl alcohol hydrochloride			
Molecular Formula	:	C ₁₁ H ₁₇ NO ₃ . Hcl	Molecular Weight	:	247.72 g/mol
CAS Number	:	51-30-9			
Product Use	:	Beta 1/Beta 2 Adrenergic Agonist			
Manufactured by	:	Micro Labs Limited Plot no. 113-116, KIADB, Bommasandra Industrial Area, Bommasandra-Jigani Link Road, Anekal taluk, Bangalore-560099, Karnataka, India	Manufactured for	:	Armas Pharmaceuticals Inc. 151 Route 33 East, Suite 203, Manalapan, NJ 07726
Emergency Contact	:	+91-80-27839033			

2. HAZARDS IDENTIFICATION

Label Elements

Signal	:	Not classified as hazardous substance
Physical hazards	:	Not classified
Classification of the substance	:	Not classifiable
Hazard statements	:	Non-hazardous in accordance with international standards for workplace safety.
Precautionary statements	:	Non-hazardous in accordance with international standards for workplace safety.
Supplementary Information	:	Not listed as hazardous substance under OSHA guidelines.
Hazard(s) not otherwise classified (HNOC)	:	Not known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS #	EINECS #	% w/w	Label Elements EU classification (67/548/EEC) GHS & EU classification (1272/2008 EC) Risk phrases/Hazard statements
Active Pharmaceutical Ingredient				
Isoproterenol Hydrochloride				EU 67/548/EEC: Not listed under European Union Legislation
3,4-Dihydroxy- α -[(isopropylamino)methyl] benzyl alcohol hydrochloride	51-30-9	200-089-8	Proprietary	GHS & EU 1272/2008: Not listed as hazardous substance.



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Chemical Name	CAS #	EINECS #	% w/w	Label Elements EU classification (67/548/EEC) GHS & EU classification (1272/2008 EC) Risk phrases/Hazard statements
Excipients				
Edetate Disodium (Inj. Grade)	6381-92-6	205-358-3	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Acute toxicity, Category 4, Inhalation, Specific target organ toxicity- repeated exposure, Category 2, Inhalation, Respiratory tract Hazard codes: H332, H373 Hazard symbol/Pictogram: GHS07, GHS08
Sodium Chloride Inj. Grade	7647-14-5	231-598-3	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Not Classified
Trisodium Citrate dihydrate (Inj. Grade)	6132-04-3	Not listed	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Not a hazardous substance or mixture
Anhydrous Citric Acid (Inj. Grade)	77-92-9	201-069-1	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Eye irritation, Category 2, Hazard codes: H319 Hazard symbol/Pictogram: GHS08
Sodium Hydroxide (Inj. Grade)	1310-73-2	215-185-5	Proprietary	EU 67/548/EEC: Classification: Corrosive Risk phrase code: R35 Hazard symbol: C GHS & EU 1272/2008: Classification: Category 1/1A Hazard codes: H290, H314 Hazard symbol/Pictogram: GHS05



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Hydrochloric Acid (Inj. Grade)	7647-01-0	231-595-7	Proprietary	EU 67/548/EEC: Classification: Corrosive Risk phrase code: R34, R37 Hazard symbol: C, Xi GHS & EU 1272/2008: Classification: Category 1/1B Hazard codes: H290, H314, H335 Hazard symbol/Pictogram: GHS05, GHS07
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Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eyes Contact	:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact	:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation	:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Notes to physician: Blood pressure and ECG may be monitored and the following treatment used, as appropriate: tachycardia in asthmatic patients may be treated with cardio-selective beta-blockers (metoprolol or atenolol, but used cautiously since cardio-selectivity may not be absolute). Non-asthmatics may be treated with propranolol; blood pressure may be regulated with rapid-acting vasodilators (nitrites, sodium nitroprusside) or alpha-blocking agents (quinidine, phentolamine).
Protection of First-Aiders:	:	Use personal protective equipment.
Signs and Symptoms:	:	None known from workplace exposures. In clinical use, adverse reactions may include nervousness, increased heart rate, palpitations, flushing, chest pain, restlessness, insomnia, anxiety, tension, fear and excitement. Manifestations of acute over dosage include chest pain, dizziness, headache, irregular heartbeat, fast or pounding heartbeat, nausea or vomiting, restlessness, weakness, flushing, or decreased diastolic pressure. Direct application of isoproterenol to the eye can cause a decrease in intraocular pressure and even an increase in heart rate.
Medical Conditions Aggravated by Exposure:	:	Pre-existing hypersensitivity to sympathomimetic amines; pre-existing central nervous system, respiratory system, or cardiovascular system disorders such as cardiac arrhythmias associated with tachycardia.
Notes to Physician:	:	Seek product package insert for complete information.



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Occupational exposure potential	:	Clinically, isoproterenol hydrochloride is available as an inhalation medication for the treatment of asthma. It is systemically bioavailable via the pulmonary route. Other studies suggest that isoproterenol has some potential to be absorbed through the skin. Avoid dust or aerosol generation and avoid skin contact.
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5. FIRE FIGHTING MEASURES

Flammability	:	None anticipated for this aqueous product.
Fire & Explosion Hazard	:	None anticipated for this aqueous product.
Extinguishing media	:	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	:	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental precautions	:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and material for containment and cleaning up	:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for safe handling	:	Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Handling	:	No special handling required under conditions of normal product use. Do not breathe aerosol; avoid contact with skin and eyes.
Storage	:	No special storage required for hazard control. For product protection, follow temperature storage recommendations noted on the product case label, the primary container label, or the product insert.



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Special precautions	:	Protect from light, oxidizing materials, and extreme heat.
Specific end use(s)	:	Pharmaceutical drug product for patients

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls	:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section. It is recommended that all operations be fully enclosed and no air recirculated.
Personal Protective Equipment	:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection	:	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Hands	:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eye Protection	:	Eye protection is normally not required during intended use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Skin protection	:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)



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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	:	Solution for Injection
Color	:	Clear, colorless solution
Appearance	:	Isoproterenol Hydrochloride Injection USP 0.2mg/ml: Clear, colorless to slightly yellow colour solution. Free from any visible particles.
Molecular Formula	:	C ₁₁ H ₁₇ NO ₃ . Hcl
Molecular Weight	:	247.72 g/mol

10. STABILITY AND REACTIVITY

Reactivity	:	Not determined.
Chemical stability	:	Stable under standard use and storage conditions. Solutions become pink to brownish-pink on standing exposed to air and almost immediately when made alkaline.
Hazardous reactions	:	Not determined.
Conditions to Avoid	:	To minimize decomposition, protect from light.
Incompatible Materials	:	Not determined.
Hazardous decomposition products	:	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.
Hazardous Polymerization	:	Not anticipated to occur with this material.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity	:	Isoproterenol Hydrochloride:			
		Type	Route	Species	Dosage
		LD50	Oral	Rat	2221 mg/kg
		LD50	Oral	Mouse	1260 mg/kg
		LD50	Oral	Rabbit	3070 mg/kg
		LD50	Oral	Dog	600 mg/kg
		LD50	Intravenous	Rat	26.9 mg/kg
		LD50	Intravenous	Mouse	77 mg/kg
		LD50	Intravenous	Rabbit	27 mg/kg
		LD50	Intravenous	Dog	50 mg/kg
		Sodium Chloride:			
		LD50	Oral	Rat	3g/kg
		LD50	Oral	Mouse	4g/kg
		LD50	Dermal	Rat	>10g/kg
		Hydrochloric Acid:			
LD50	Oral	Rat	238-277 mg/kg		



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Skin Irritation/ Corrosion	:	Inadvertent contact with skin may produce irritation with redness and discomfort. This material has some potential to be absorbed through skin and mucus membranes.
Eye irritation/ Corrosion	:	Inadvertent contact with the eyes may produce irritation with redness, tearing and pain.
Germ cell mutagenicity	:	Isoproterenol was negative in the Ames test for mutagenicity in the presence and absence of metabolic activation. In an in vitro chromosomal aberration assay, Isoproterenol hydrochloride was negative in the absence of metabolic activation but positive in the presence of metabolic activation.
Carcinogenicity	:	Long-term studies in animals to evaluate the carcinogenic potential of Isoproterenol hydrochloride have not been conducted.
Aspiration Hazard	:	None anticipated from normal handling of this material.
Dermal or Respiratory Sensitization	:	Not anticipated from normal handling of this product.
Reproductive Effects	:	Reproduction studies have been performed in rats and rabbits with Isoproterenol at aerosol doses (30 minutes per day for 12 days) up to 15 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Isoproterenol. In another study, pregnant rats were given Isoproterenol hydrochloride intraperitoneally at dosages of 0, 20, 40 or 80 mg/kg/day in sterile 0.9% saline on gestational days 6 through 15. Although these dosages produced some evidence of fetal and maternal toxicity, there was no evidence for teratogenicity in this study.
IARC:	:	Not considered to be a carcinogen.
NTP:	:	Not considered to be a carcinogen.
OSHA:	:	Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Toxicity:	:	No data available
Persistence and degradability	:	No data available
Bio-accumulative potential	:	No data available
Mobility in soil	:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods	:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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14. TRANSPORTATION INFORMATION

Environmental hazards	:	Not regulated
Special precautions for user	:	Not regulated
Transport hazard class(es)	:	Not regulated
Packing group	:	Not regulated
IATA UN number	:	Not regulated

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.

15. REGULATORY / STATUTORY INFORMATION

Seveso regulation (Directive 96/82/EC)	:	Not listed
Candidate list (art. 59-REACH):	:	Not listed
Ozone depletion substance (2000/2037/EC)	:	Not listed
Import/export dangerous chemical (2008/689/EC)	:	Not listed

16. OTHER INFORMATION

Date of preparation: 27/07/21

The information contained in this Material Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

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End of Safety Data Sheet