SAFETY DATA SHEET

1. Identification

Product Identifier: Labetalol Hydrochloride Injection, USP

Synonyms: Benzamide, 2-hydroxy-5-[1-hydroxy-2-[(1-methyl-3-phenylpropyl)amino]ethyl]-,monohydrochloride

National Drug Code (NDC): 17478-420-20
17478-420-40

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.

Precautionary Statement(s):

P260	Do not breathe dust/fume/gas/mist/vapours/ spray.
P264	Wash hands thoroughly after handling.
P314	Get medical advice/attention if you feel unwell.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/attention.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Labetalol Hydrochloride	36894-69-4	Benzamide, 2-hydroxy-5-[1-hydroxy-2-[(1-methyl-3-phenylpropyl)amino]ethyl]-,monohydrochloride	$C_{19}H_{24}N_2O_3$•HCl	364.87	0.5%

*The formula also contains Methylparaben, 0.80 mg; Propylparaben, 0.10 mg; Anhydrous Dextrose, 45 mg; Edetate Disodium, 0.10 mg; Citric Acid Anhydrous and/or Sodium Hydroxide may be added to adjust pH (3.0 – 4.0), and Water for Injection.

4. First Aid Measures

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: None anticipated from normal handling of this product. In clinical use, the most common adverse effects include hypotension, scalp tingling, nasal congestion, muscle weakness, dyspnea, tremor and urinary retention. Ventricular arrhythmia, edema or fluid retention, bradycardia, hypotension, syncope, chest pain, atrioventricular (AV) conduction delay, and AV block have also been reported. Adverse nervous system effects may include drowsiness or tiredness, dizziness or lightheadedness, headache, fatigue, lethargy, and nightmares or vivid dreams. Adverse respiratory effects of labetalol have included dyspnea, wheezing, bronchospasm, and nasal congestion. Elevated liver function test results, including reversible increases in serum aminotransferase concentrations; jaundice (including cholestatic jaundice); and hepatitis have been reported in some patients. The most frequent adverse gastrointestinal effects associated with labetalol therapy are nausea, dyspepsia, and vomiting Less commonly observed adverse effects include impairment of male sexual function and liver injury. Hypotension, bradycardia, hypoglycemia, and respiratory depression have been reported in infants of mothers who were treated with labetalol for hypertension during pregnancy. FDA Pregnancy Category C.

Medical Conditions Aggravated by Exposure: Diseases that cause low blood pressure, bronchial asthma, cardiac problems such as cardiac failure, cardiogenic shock and bradycardia.

Notes to Physician: Treat supportively and symptomatically.

5. Firefighting Measures

Flammability: None anticipated for this aqueous product.

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or foam as necessary.

Unsuitable Extinguishing Media: Not determined.

Special Fire Fighting Procedures: No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Not determined.

Other Specific Hazards: Not determined.

Special Protective Equipment/ Precautions for Firefighters: 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: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water.

Environmental Precautions: Not data available.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizing agents and acids.

Specific End Use: Pharmaceuticals

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Labetalol Hydrochloride	Not established.

Engineering Controls: Engineering controls are normally not needed during the normal use of this product.

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.

Eyes Protection:	Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Hand Protection:	Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless liquid solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	3.0 – 4.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.

Incompatible Materials: Strong bases and oxidizers.

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 product.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May be absorbed by inhalation.

Ingestion: May be absorbed by ingestion.

Skin Contact: May be absorbed by injection.

Eye Contact: May cause irritation to eyes.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity:

Compound	Percent	Species	Route	Type	Dose
Labetalol Hydrochloride	100%	Rat	Oral	LD_{50}	2,114, >2,000 mg/kg
Labetalol Hydrochloride	100%	Mouse	Oral	LD_{50}	1,400, 600 mg/kg
Labetalol Hydrochloride	100%	Rabbit	Oral	LD_{50}	1,250 mg/kg
Labetalol Hydrochloride	100%	Dog	Oral	LD_{50}	>1,500 mg/kg
Labetalol Hydrochloride	100%	Rat	Intravenous	LD_{50}	50 mg/kg
Labetalol Hydrochloride	100%	Mouse	Intravenous	LD_{50}	47 mg/kg
Labetalol Hydrochloride	100%	Rabbit	Intravenous	LD_{50}	41 mg/kg

LD_{50}: Dosage that produces 50% mortality.

Occupational Exposure Potential: Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.

Dermal or Respiratory Sensitization:	None anticipated from normal handling of this product. In clinical use, rashes have developed in some patients during labetalol therapy. Facial erythema and reversible alopecia have also occurred. Hypersensitivity (e.g., rash, urticaria, pruritus, angioedema, dyspnea) and anaphylactoid reactions have been reported rarely in patients.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Specific Target Organ Toxicity – Single Exposure:	No data available.
Specific Target Organ Toxicity – Repeat Exposure:	Based on clinical use, possible target organs include the cardiovascular system, gastrointestinal system respiratory system and liver.
Reproductive Effects:	None anticipated from normal handling of this product. In repeat dose studies in male rats, the copulation rate was decreased at an oral dosage of 300 mg/kg/day. In perinatal studies in rats, decreased fetal viability and size was observed at maternal oral dosages of 150 mg/kg/day (equivalent to 9000 mg/day in a 60 mg female). Teratogenic studies have been performed with labetalol in rats and rabbits at oral doses up to approximately 6 and 4 times the maximum recommended human dose (MRHD), respectively. No reproducible evidence of fetal malformations was observed. Increased fetal resorptions were seen in both species at doses approximating the MRHD. A teratology study performed with labetalol in rabbits at intravenous doses up to 1.7 times the MRHD revealed no evidence of drug-related harm to the fetus. Oral administration of labetalol to rats during late gestation through weaning at doses of 2 to 4 times the MRHD caused a decrease in neonatal survival.
Carcinogenicity:	There was no evidence of carcinogenesis in mice treated orally for 18 months at 200 mg/kg/day or in rats treated orally for 113-116 weeks at 225 mg/kg/day.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.

Mutagenicity:	Studies with labetalol, using dominant lethal assays in rats and mice, and exposing microorganisms according to modified Ames tests, showed no evidence of mutagenesis.
Aspiration Hazard:	None anticipated from normal handling of this product.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

State Regulations

Toxic Substance Control Act (TSCA):	Exempt.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.
California Proposition 65:	Not listed.

16. Other Information

Made with natural rubber latex.

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