
	Sagent Pharmaceuticals, Inc.		
	Document Type Safety Data Sheet (SDS)	Document Title Labetalol Hydrochloride Injection, USP	
	Document No. MSDS-0126	Version 1.0	Effective Date 10 Oct 2021

Section 1 - Identification

- (a) **Product Identifier:** Labetalol Hydrochloride Injection, USP
- (b) **NDC:** 25021-317-20, 25021-317-40
- Common/Trade Name:** Labetalol Hydrochloride
- Chemical Name:** 5-[1-hydroxy-2-[(1-methyl-3-phenylpropyl) amino] ethyl]-salicylamide monohydrochloride
- Chemical Family:** Adrenergic receptor blocking agent
- (c) **Product Use:** Pharmaceutical product used as a cardiovascular drug
- Product Type:** Regulated Prescription Drug
- Container Information:** Pre-filled vial
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** GHS classification - Reproductive Toxicity: Category 2
- (b) **Signal Word,** Warning.
- Hazard statement(s),**
- Symbol(s), and/or**
- Precautionary statement(s):**
- Precautionary Statements
- Prevention:**
- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- Response:**
- P308 + P313 - IF exposed or concerned: Get medical attention/advice.
- Storage:**
- P405 - Store locked up
- Disposal:**
- P501 - Dispose of contents/container in accordance with all local and national regulations
- (c) **Description of Hazards:** H361F – Suspected for damaging fertility

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(d) Unknown Acute Toxicity: N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Labetalol Hydrochloride	Labetalol Hydrochloride	N/A	32780-64-6	N/A
Sodium Hydroxide	Sodium Hydroxide	N/A	1310-73-2	N/A
Water for Injection	Water	N/A	7732-18-5	N/A
Dextrose	Dextrose	N/A	14431-43-7	N/A
Methylparaben	Methylparaben	N/A	99-76-3	N/A
Citric acid monohydrate	Citric acid monohydrate	N/A	5949-29-1	N/A
Propylparaben	Propylparaben	N/A	94-13-3	N/A
Edetate disodium	Edetate disodium	N/A	139-33-3	N/A

Section 4 - First Aid Measures


Eye Exposure: Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.

Skin Exposure: Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.

Inhalation: Move to fresh air if discomfort occurs, get medical attention.

Notes to Physician: See patient package insert in shipping carton for complete information.

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Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Use water or an ABC multi-purpose extinguisher.
- (b) **Hazardous Combustion Products:** Not determined
- (c) **Special Protective Equipment / Precautions:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

Section 6 - Accidental Release Measures

- Spill:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
- Release to Air:** N/A
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

- General Handling:** When handling pharmaceutical products, avoid all contact with skin, eyes, nostrils and mouth. Avoid inhalation of dust, fumes, mist, and/or vapors associated with the product. Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases.
- Storage Conditions:** Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Protect from freezing and light. Retain in carton until time of use.


Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Labetalol Hydrochloride	OSHA	N/A	N/A

(b) Engineering Controls

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Ventilation: Good general ventilation should be sufficient to control airborne levels.

(c) Individual Protection Measures

Respiratory Protection:	Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.
Eye Protection:	Safety glasses
Skin Protection:	Work uniform or laboratory coat.
Other Protective Equipment:	Protective Latex or Nitrile gloves
Additional Exposure Precautions:	Wash hands following use. No eating, drinking, or smoking while handling this product.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Clear colorless to light yellow color solution
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	3.0-4.5
(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)	Soluble in water

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(o)	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


(a)	Reactivity	No data available
(b)	Chemical Stability	Stable under normal conditions
(c)	Possibility of Hazardous Reactions	None known
(d)	Conditions to Avoid	None known
(e)	Incompatible Materials	None known
(f)	Hazardous Decomposition Products	None known

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, Inhalation, skin, eye
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	N/A

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Propylparaben	LD ₅₀	Oral	Mouse	6332 mg/kg
Propylparaben	LD ₅₀	Sub-tenon injection (eye)	Mouse	200 mg/kg
Edetate sodium	LD ₅₀	Oral	Rat	2000-2200 mg/kg
Labetalol Hydrochloride	LD ₅₀	Oral	Rat	2114 mg/kg
Labetalol Hydrochloride	LD ₅₀	Oral	Mouse	600mg/kg
Labetalol Hydrochloride	LD ₅₀	Oral	Rabbit	1250mg/kg

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Labetalol Hydrochloride	LD ₅₀	Intravenous	Rat	53mg/kg
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(e) Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

NIOSH: No

(f) Mutagenicity: There is no data available.

(g) Carcinogenicity (Duration, Species, Route, Dose, End Point, Effect(s):

Labetalol Hydrochloride

18 Month(s) Mouse Oral 200 mg/kg/day NOAEL not carcinogenic

113-116 Week(s) Rat Oral 225 mg/kg/day NOAEL not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

(h) Reproductive Toxicity (Duration, Species, Route, Dose, End Point, Effect(s):

Labetalol Hydrochloride

Reproductive & Fertility Rat Oral 50 mg/kg/day LOAEL Fertility

Embryo / Fetal Development Rat Oral 125 mg/kg/day NOAEL not Teratogenic,

Embryotoxicity

Embryo / Fetal Development Rabbit Oral 4 times human dose NOAEL not Teratogenic

(i) Teratogenic:

Adverse reproductive effects were observed in human males during therapeutic use.


Section 12 - Ecological Information

(a)	Ecotoxicity	No data available
(b)	Persistence and degradability	No data available
(c)	Bioaccumulative potential	No data available
(d)	Mobility in soil	No data available
(e)	Other Adverse Effects	No data available

Section 13 - Disposal Considerations

Dispose of waste in accordance with all applicable laws and regulations.

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Section 14 - Transport Information

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

DOT: Not dangerous goods.

IATA: Not dangerous goods.

IMDG: Not dangerous goods.

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent use. 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:

TSCA: Sect. 8(b)

Water for Injection – Present

Methylparaben - Present

Propylparaben – Present

Edetate sodium – Present

Sodium hydroxide - Present

CERCLA: There is no data available.

SARA 302: There is no data available.


SARA 313: Not listed.

CA Prop 65: Not listed.

Section 16 - Other Information

As of the date of issuance, 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

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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:
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Schaumburg, IL 60195
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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
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
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
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program

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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)