



# SAFETY DATA SHEET

Revision date 18-Mar-2023

Version 3

Page 1 / 12

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
**Product Code(s)** PZ03094  
**Trade Name:** Labetalol Hydrochloride Injection, USP  
**Chemical Family:** Not determined

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as cardiovascular drug

### 1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Reproductive toxicity** Category 2 - (H361f)

### 2.2. Label elements

**Signal word** Warning

**Hazard statements** H361f - Suspected of damaging fertility

**Precautionary Statements** 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

# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
 Revision date 18-Mar-2023

Page 2 / 12  
 Version 3

P308 + P313 - IF exposed or concerned: Get medical attention/advice  
 P405 - Store locked up  
 P501 - Dispose of contents/container in accordance with all local and national regulations



## 2.3. Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**Note:**

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Not applicable

### 3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Labetalol Hydrochloride (CAS #: 32780-64-6)	0.5		251-211-1	Repr 2 (H361f)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
Citric acid monohydrate (CAS #: 5949-29-1)	**	-	Not Listed	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335)	Not Listed	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration	EC No	Classification according to	Specific concentration	M-Factor	M-Factor (long-term)
---------------	----------	--------------------	-------	-----------------------------	------------------------	----------	----------------------

# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
 Revision date 18-Mar-2023

Page 3 / 12  
 Version 3

		Number		Regulation (EC) No. 1272/2008 [CLP]	limit (SCL)		
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Propylparaben (CAS #: 94-13-3)	*		202-307-7	Not classified as hazardous	Not Listed	No data available	No data available
Methyl-p-hydroxybenzoate (CAS #: 99-76-3)	*		202-785-7	Not classified as hazardous	Not Listed	No data available	No data available
Edetate disodium (CAS #: 139-33-3)	*		205-358-3	Not classified as hazardous	Not Listed	No data available	No data available
Dextrose (CAS #: 14431-43-7)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Edetate disodium 139-33-3	2000	No data available	No data available	No data available	No data available
Labetalol Hydrochloride 32780-64-6	2114	No data available	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available

**Additional information**

\* Proprietary

\*\* to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Non-hazardous ingredients provided for completeness.

**Section 4: FIRST AID MEASURES**

**4.1. Description of first aid measures**

- Inhalation** Remove to fresh air. Seek immediate medical attention/advice.
- Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
- Skin contact** 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.

# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
Revision date 18-Mar-2023

Page 4 / 12  
Version 3

## 4.2. Most important symptoms and effects, both acute and delayed

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

## 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

## **Section 5: FIRE-FIGHTING MEASURES**

### 5.1. Extinguishing media

**Suitable Extinguishing Media** As for primary cause of fire.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Not applicable.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **Section 6: ACCIDENTAL RELEASE MEASURES**

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

#### **Advice on safe handling**

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

# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
Revision date 18-Mar-2023

Page 5 / 12  
Version 3

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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

## 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

## 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

Refer to available public information for specific member state Occupational Exposure Limits.

#### **Labetalol Hydrochloride**

Pfizer OEL TWA-8 Hr: 200 µg/m<sup>3</sup>

#### **Propylparaben**

Russia

MAC: 10 mg/m<sup>3</sup>

#### **Methyl-p-hydroxybenzoate**

Russia

MAC: 4 mg/m<sup>3</sup>

#### **Edetate disodium**

Russia

MAC: 2 mg/m<sup>3</sup>

#### **Sodium hydroxide**

ACGIH OEL (Ceiling)

2 mg/m<sup>3</sup>

ACGIH TLV

Ceiling: 2 mg/m<sup>3</sup>

Austria

2 mg/m<sup>3</sup>

STEL 4 mg/m<sup>3</sup>

Bulgaria

2.0 mg/m<sup>3</sup>

Czech Republic

1 mg/m<sup>3</sup>

Ceiling: 2 mg/m<sup>3</sup>

Denmark

Ceiling: 2 mg/m<sup>3</sup>

Estonia

1 mg/m<sup>3</sup>

STEL: 2 mg/m<sup>3</sup>

Finland

Ceiling: 2 mg/m<sup>3</sup>

France

2 mg/m<sup>3</sup>

Hungary

1 mg/m<sup>3</sup>

STEL: 2 mg/m<sup>3</sup>

Ireland

STEL: 2 mg/m<sup>3</sup>

Ceiling Limit Value

2 mg/m<sup>3</sup>

Latvia

0.5 mg/m<sup>3</sup>

Poland

STEL: 1 mg/m<sup>3</sup>

0.5 mg/m<sup>3</sup>

Romania

1 mg/m<sup>3</sup>

STEL: 3 mg/m<sup>3</sup>

Slovakia

2 mg/m<sup>3</sup>

Spain

STEL: 2 mg/m<sup>3</sup>

Switzerland

2 mg/m<sup>3</sup>

STEL: 2 mg/m<sup>3</sup>

OSHA PEL

2 mg/m<sup>3</sup>

(vacated) Ceiling: 2 mg/m<sup>3</sup>

United Kingdom

STEL: 2 mg/m<sup>3</sup>

### 8.2. Exposure controls

**Engineering controls** Engineering controls should be used as the primary means to control exposures. General

# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
Revision date 18-Mar-2023

Page 6 / 12  
Version 3

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.

<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	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. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Eye/face protection</b>	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
<b>Hand protection</b>	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.).
<b>Skin and body protection</b>	Impervious 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.).
<b>Respiratory protection</b>	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Liquid
<b>Color</b>	Colorless to light yellow
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture
<b>Property</b>	<b>Values</b>
<b>pH</b>	3.0-4.5
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	Soluble
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available

# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
Revision date 18-Mar-2023

Page 7 / 12  
Version 3

<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## **9.2. Other information**

No information available

### **9.2.1. Information with regard to physical hazard classes**

No information available

**Oxidizing properties** None

### **9.2.2. Other safety characteristics**

No information available

## **Section 10: STABILITY AND REACTIVITY**

### **10.1. Reactivity**

**Reactivity** No data available.

### **10.2. Chemical stability**

**Stability** Stable under normal conditions.

### **Explosion data**

**Sensitivity to Mechanical Impact** No data available.

**Sensitivity to Static Discharge** No data available.

### **10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** No information available.

### **10.4. Conditions to avoid**

**Conditions to avoid** Fine particles (such as dust and mists) may fuel fires/explosions.

### **10.5. Incompatible materials**

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

### **10.6. Hazardous decomposition products**

**Hazardous decomposition products** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**

### **11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

**General Information:** The information included in this section describes the potential hazards of the individual ingredients

**Known Clinical Effects:** The most common adverse effects seen during clinical use of this drug include nausea, vomiting, shortness of breath (dyspnea); tiredness, low blood pressure on standing (orthostatic hypotension), abnormal ejaculation, impotence

**Acute toxicity** Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Based on available data, the classification criteria are not met.

**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization** Based on available data, the classification criteria are not met.

**STOT - single exposure** Based on available data, the classification criteria are not met.

**STOT - repeated exposure** Based on available data, the classification criteria are not met.

**Reproductive toxicity** Classification is based on mixture calculation methods based on component data.

**Germ cell mutagenicity** Based on available data, the classification criteria are not met.

# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
Revision date 18-Mar-2023

Page 8 / 12  
Version 3

**Carcinogenicity** Based on available data, the classification criteria are not met.  
**Aspiration hazard** Based on available data, the classification criteria are not met.

## **Acute Toxicity: (Species, Route, End Point, Dose)**

### **Propylparaben**

Mouse Oral LD 50 6332 mg/kg  
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

### **Methyl-p-hydroxybenzoate**

Mouse Oral LD50 > 8 g/kg  
Rat Oral LD 50 2100 mg/kg

### **Edetate disodium**

Rat Oral LD50 2000-2200 mg/kg

### **Labetalol Hydrochloride**

Rat Oral LD50 2114 mg/kg  
Mouse Oral LD50 600 mg/kg  
Rabbit Oral LD50 1250 mg/kg  
Rat Intravenous LD50 53 mg/kg

### **Sodium hydroxide**

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Edetate disodium	= 2 g/kg ( Rat )	-	-
Labetalol Hydrochloride	= 2114 mg/kg ( Rat )	-	-
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-

## **Irritation / Sensitization: (Study Type, Species, Severity)**

### **Methyl-p-hydroxybenzoate**

Skin irritation Rabbit Non-irritating  
Eye irritation Rabbit Slight  
Skin Sensitization Guinea Pig Negative

### **Citric acid monohydrate**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Moderate

### **Sodium hydroxide**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

## **Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

### **Propylparaben**

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system  
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

### **Methyl-p-hydroxybenzoate**

28 Day(s) Rat Oral 250 mg/kg/day NOAEL Gastrointestinal System, Spleen, Thymus

### **Labetalol Hydrochloride**

1 Year(s) Rat Oral 1 mg/kg/day LOAEL Heart  
1 Year(s) Dog Oral 25 mg/kg/day LOAEL None identified  
1 Month(s) Rat Oral 50 mg/kg/day NOAEL None identified

## **Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Methyl-p-hydroxybenzoate**

Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOEL Maternal toxicity, Developmental toxicity



# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
Revision date 18-Mar-2023

Page 9 / 12  
Version 3

## 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  
**Reproductive Effects** Adverse reproductive effects were observed in human males during therapeutic use.

## Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

### Methyl-p-hydroxybenzoate

*In Vivo* Dominant Lethal Assay Rat Negative

### Labetalol Hydrochloride

Bacterial Mutagenicity (Ames) Bacteria Negative

Dominant Lethal Assay Rat Negative

Dominant Lethal Assay Mouse Negative

## 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

**Carcinogenicity** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 11.2.2. Other information

**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

## 12.1. Toxicity

### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

#### Methyl-p-hydroxybenzoate

*Oryzias latipes* (Japanese Rice Fish) OECD LC50 96 hours 59.5 mg/L

*Daphnia magna* (Water Flea) ISO EC50 48 hours 11.2 mg/L

## 12.2. Persistence and degradability

### Persistence and degradability

### Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

#### Methyl-p-hydroxybenzoate

OECD Activated sludge Ultimate (CO2 Evolution) 89 % After 28 Day(s) Ready

## 12.3. Bioaccumulative potential

### Bioaccumulation

No information available.

## 12.4. Mobility in soil

### Mobility in soil

No information available.

# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
Revision date 18-Mar-2023

Page 10 / 12  
Version 3

## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** No information available.

Chemical name	PBT and vPvB assessment
Propylparaben	The substance is not PBT / vPvB
Methyl-p-hydroxybenzoate	The substance is not PBT / vPvB
Edetate disodium	The substance is not PBT / vPvB PBT assessment does not apply
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
Citric acid monohydrate	The substance is not PBT / vPvB

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. Other adverse effects

No information available.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. 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 wastewater 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.

## Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable  
**Special precautions for user:** Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water  
**CERCLA/SARA Section 313 de minimus %** Not Listed  
**California Proposition 65** Not Listed

# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
 Revision date 18-Mar-2023

Page 11 / 12  
 Version 3

<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present
Propylparaben	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	202-307-7
<b>AICS</b>	Present
Methyl-p-hydroxybenzoate	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	202-785-7
<b>AICS</b>	Present
Edetate disodium	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	205-358-3
<b>AICS</b>	Present
Dextrose	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
Labetalol Hydrochloride	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	251-211-1
Sodium hydroxide	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6
Citric acid monohydrate	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	

### Persistent Organic Pollutants

Not applicable

# SAFETY DATA SHEET

Product Name Labetalol Hydrochloride Injection, USP (Hospira Inc.)  
Revision date 18-Mar-2023

Page 12 / 12  
Version 3

## Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## **Section 16: OTHER INFORMATION**

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### **Full text of H-Statements referred to under section 3**

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage Reproductive toxicity-Cat.2; H361f - Suspected of damaging fertility Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

**Revision date** 18-Mar-2023

**Prepared By** Pfizer Global Environment, Health, and Safety

**Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.**