



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 17-May-2018

Version: 2.0

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Labetalol Hydrochloride Injection, USP (Hospira Inc.)

**Trade Name:** Labetalol Hydrochloride Injection, USP

**Chemical Family:** Not determined

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as cardiovascular drug

### 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

Hospira UK Limited  
Horizon  
Honey Lane  
Hurley  
Maidenhead, SL6 6RJ  
United Kingdom

### Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

### Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Reproductive Toxicity: Category 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  
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

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### 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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Labetalol Hydrochloride	32780-64-6	251-211-1	Repr 2 (H361f)	0.5
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Methylparaben	99-76-3	202-785-7	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Dextrose	14431-43-7	Not Listed	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Edetate disodium	139-33-3	205-358-3	Not Listed	*
Citric acid monohydrate	5949-29-1	Not Listed	Not Listed	**

#### 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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

##### Eye Contact:

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

##### Skin Contact:

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

##### 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.

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

### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.  
**Medical Conditions Aggravated by Exposure:** None known

### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

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

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

**Fire / Explosion Hazards:** Not applicable

### Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including 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

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** 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

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.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.  
**Specific end use(s):** Pharmaceutical drug product

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Labetalol Hydrochloride

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

#### SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m <sup>3</sup>
Australia PEAK	2 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	2.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
Estonia OEL - TWA	1 mg/m <sup>3</sup>
France OEL - TWA	2 mg/m <sup>3</sup>
Greece OEL - TWA	2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Japan - OELs - Ceilings	2 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	2 mg/m <sup>3</sup>
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	2 mg/m <sup>3</sup>

#### Exposure Controls

<b>Engineering Controls:</b>	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.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</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>Eyes:</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>Skin:</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.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless to light yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Water Solubility:** Soluble  
**pH:** 3.0-4.5  
**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available.  
**Partition Coefficient: (Method, pH, Endpoint, Value)**  
**Water for Injection**  
No data available  
**Dextrose**  
No data available  
**Methylparaben**  
No data available  
**Propylparaben**  
No data available  
**Citric acid monohydrate**  
No data available  
**SODIUM HYDROXIDE**  
No data available  
**Edetate disodium**  
No data available  
**Labetalol Hydrochloride**  
No data available  
**Decomposition Temperature (°C):** No data available.  
**Evaporation Rate (Gram/s):** No data available  
**Vapor Pressure (kPa):** No data available  
**Vapor Density (g/ml):** No data available  
**Relative Density:** No data available  
**Viscosity:** No data available

#### Flammability:

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** None  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

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

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### 11. TOXICOLOGICAL INFORMATION

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

#### 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

##### **Edetate disodium**

Rat Oral LD50 2000-2200 mg/kg

##### **Labetalol Hydrochloride**

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

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

##### **Citric acid monohydrate**

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

#### 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

#### Reproduction & Development 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

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

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

##### **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

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

### 12. ECOLOGICAL INFORMATION

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

**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.

### 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.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Labetalol Hydrochloride  
CERCLA/SARA 313 Emission reporting

Not Listed

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### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	251-211-1

#### Methylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

#### Propylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

#### SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
	454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	215-185-5

#### Dextrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

#### Edetate disodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-358-3

#### Citric acid monohydrate



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### 15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage  
Reproductive toxicity-Cat.2; H361f - Suspected of damaging fertility

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

**Reasons for Revision:** Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity.

**Revision date:** 17-May-2018  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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.

**End of Safety Data Sheet**