



Date: 20.06.2019

SAFETY DATA SHEET**SECTION 1 – IDENTIFICATION OF THE PRODUCT & THE COMPANY**

Product Name : Labetalol Hydrochloride Injection USP (5 mg/ mL)

Manufacturers Name and Address : **Gland Pharma Limited**
Survey No.: 143–148, 150&151
Near Gandimaisamma Cross Roads,
D.P.Pally, Quthubullapur Mandal
Ranga Reddy District
Hyderabad- 500043
Telangana, India

Telephone Number for Info : +91-40-30510999

SECTION 2 – HAZARDS IDENTIFICATION**Classification of the Substance or Mixture**

GHS – Classification : Reproductive Toxicity: Category 2

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

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Component	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)	To adjust pH
Dextrose	14431-43-7	Not Listed	Not Listed	Proprietary
Methylparaben	99-76-3	202-785-7	Not Listed	Proprietary



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Citric acid monohydrate	5949-29-1	Not Listed	Not Listed	To adjust pH
Propylparaben	94-13-3	202-307-7	Not Listed	Proprietary
Edetate disodium	139-33-3	205-358-3	Not Listed	Proprietary

SECTION 4 – FIRST AID MEASURES

Description of First Aid measure

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.

Inhalation Remove to fresh air and keep patient at rest. Seek medical attention immediately.

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

SECTION 5 – FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire

Fire / Explosion Hazards: Not applicable



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Advice for Fire-Fighters: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 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. Clean up operations should only be undertaken by trained personnel.

SECTION 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.



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SECTION 8 –CONTROL MEASURES/PERSONAL PROTECTION

Control Parameters

Labetalol Hydrochloride Band (OEB) :	OEB 2 (control exposure to the range of 100ug/m ³ to < 1000ug/m ³)
Exposure Controls	
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.
Personal Protective Equipment :	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
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.)
Eyes :	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.)
Skin :	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.)
Respiratory protection :	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor



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	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.).
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SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical State	:	Liquid
Odor	:	No data available
Molecular Formula	:	Mixture
Color	:	Colorless to light yellow
Odor Threshold	:	No data available
Molecular Weight	:	Mixture
pH	:	3.0-4.5
Solubility	:	Soluble in water
Melting point/Freezing point	:	No data available
Boiling Point Range	:	No data available
Partition Coefficient (Method, pH, Endpoint, Value) Water	:	No data available
Decomposition Temperature (°C)	:	No data available
Evaporation Rate (Gram/s)	:	
Vapor Pressure (kPa)	:	No data available
Vapor Density (g/ml)	:	No data available
Relative Density	:	No data available
Viscosity	:	No data available

Flammability:

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



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SECTION 10 – STABILITY AND REACTIVITY

- Reactivity** : No data available
- Chemical Stability** : Stable under normal conditions of use..
- Possibility of Hazardous Reactions:**
- Oxidizing Properties** : No data available
- Conditions to avoid** : No data available
- Incompatibilities Materials:** No data available.
- Hazardous Decomposition products:** No data available

SECTION 11 – TOXICOLOGICAL INFORMATION

Information on Toxicological Effects 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), fatigue, low blood pressure on standing (orthostatic hypotension), abnormal ejaculation, impotence.

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

Labetalol Hydrochloride

- Rat Oral LD 50 : 2114 mg/kg
Mouse Oral LD 50 : 600 mg/kg
Rabbit Oral LD 50 : 1250 mg/kg
Rat Intravenous LD 50 : 50 mg/kg
Mouse Intravenous LD 50 : 47 mg/kg
Rabbit Intravenous LD 50 : 41 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

- | | | | | |
|----------------------------|--------|--------------------|-------|-----------------|
| Embryo / Fetal Development | Rat | Oral 125 mg/kg/day | NOAEL | Not teratogenic |
| Embryo / Fetal Development | Rabbit | 4 times human dose | NOAEL | Not Teratogenic |
| Reproductive & Fertility | Rat | Oral 50 mg/kg/day | LOAEL | Fertility |



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Genetic Toxicity: (Study Type, Cell Type/Organism, Result)maximum dose **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

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

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview : The environmental characteristics of this mixture have not been fully evaluated. 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.

SECTION 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

SECTION 14 – TRANSPORTATION INFORMATION

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

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



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SECTION 15 – REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class: None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR

Labetalol Hydrochloride

CERCLA/SARA 313 Emission reporting	:	Not Listed
California Proposition 65	:	Not Listed
EU EINECS/ELINCS List	:	251-211-1
Australia (AICS)	:	Present

SECTION 16 – OTHER DATA

Data Sources	:	Publicly available toxicity information.
Revision date	:	18-Feb-2017
Prepared by	:	Gland Pharma Limited

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.