SECTION 1: IDENTIFICATION

Product Identifier		
Material Name	:	Labetalol Hydrochloride Injection
Trade Name	:	Labetalol Hydrochloride Injection
Chemical Family	:	Not determined
Relevant Identified Uses of the Substance or Mixture and Uses Advised Against		
Identified Uses	:	Pharmaceutical product used as a cardiovascular drug.
Supplier Details	:	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.
Emergency Telephone Number	:	+91- 4467901901/02/03

SECTION 2: HAZARDS IDENTIFICATION

Classification of the substance or mixture	:	GHS classification - Reproductive Toxicity: Category 2
Label Elements		
Signal Word	:	Warning
Hazard Statements	:	H361f – Suspected for 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.
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.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name	:	Labetalol Hydrochloride
Chemical Formula	:	$C_{19}H_{24}N_2O_3.HCl$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Labetalol Hydrochloride	0.5	32780-64-6	CV5376000

Non-hazardous ingredients include Water for Injection and dextrose. Hazardous ingredients present at less than 1% include Edetate Disodium. Methylparaben and Propylparaben are added as preservatives. Citric acid monohydrate and Sodium hydroxide are added to adjust the pH range.

SECTION 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.
Inhalation	:	Move to fresh air If discomfort occurs, 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.
Most Important Symptoms/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	:	As for primary cause of fire.
Specific 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
Advise for fire-fighters	:	During all firefighting 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 Materials 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.

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 wastewater 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

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

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.
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 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.)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State	:	Liquid
Color	:	Colorless to light yellow color
Odor	:	No data Available
Odor Threshold	:	No data Available
Molecular Formula	:	Mixture
Molecular Weight	:	Mixture
Solvent Solubility	:	No data available.
Water Solubility	:	Soluble
pH	:	3.0 – 4.5
Melting/Freezing Point	:	No data Available
Boiling Point	:	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		
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
Lower Explosive Limits (Liquid) (% by Vol.)	:	No data Available

SECTION 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

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)

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 Oral50 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

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	:	Environmental properties have not been investigated. Releases to the environment should be avoided.
Toxicity	:	No data available.
Persistence And Degradability	:	No data available.
Bioaccumulative 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: TRANSPORT INFORMATION

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

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

SECTION 15: REGULATORY INFORMATION

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

Citric acid monohydrate		
CERCLA/SARA 313 Emission reporting	:	Not Listed
California Proposition 65	:	Not Listed
Australia (AICS)	:	Present
Australia (AICS)	:	Not Listed
Sodium Hydroxide		
CERCLA/SARA 313 Emission reporting	:	Not Listed
CERCLA/SARA Hazardous Substances	:	1000 lb
and their Reportable Quantities	:	454 kg
California Proposition 65	:	Not Listed
Inventory - United States TSCA - Sect. 8(b)	:	Present
Australia (AICS)	:	Present
Standard for the Uniform Scheduling	:	Schedule 5
for Drugs and Poisons	:	Schedule 6
EU EINECS/ELINCS List	:	215-185-5
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
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 Lis	:	205-358-3

SECTION 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

History:

Issued Date	:	07.03.23
Revision Date	:	Nil
Version	:	00

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

----End of SDS---