MATERIAL SAFETY DATA SHEET

Product Name: Labetalol Hydrochloride Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address  
Hospira Inc.  
275 North Field Drive  
Lake Forest, Illinois USA  
60045

Emergency Telephone  
CHEMTREC: North America: 800-424-9300;  
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency  
224-212-2000

Product Name  
Labetalol Hydrochloride Injection

Synonyms  
5-[1-hydroxy-2-[(1-methyl-3-phenylpropyl) amino] ethyl]-salicylamide monohydrochloride

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name  
Labetalol Hydrochloride

Chemical Formula  
C_{19}H_{24}N_{2}O_{3}• HCl

Preparation  
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.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labetalol Hydrochloride</td>
<td>0.5</td>
<td>32780-64-6</td>
<td>CV5376000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labetalol Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview  
Labetalol Hydrochloride Injection is a solution containing labetalol hydrochloride, an adrenergic receptor blocking agent with selective alpha1- and nonselective beta-adrenergic receptor blocking actions. Clinically, it is indicated for control of blood pressure in severe hypertension. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Possible target organs include the cardiovascular system, gastrointestinal system, respiratory system and liver.

Occupational Exposure Potential  
Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms  
None known from workplace exposure. In clinical use, the most common adverse effects include hypotension, scalp tingling, nasal congestion, muscle weakness, dyspnea, tremor and urinary retention. Ventricular arrhythmia, edema or fluid retention, bradycardia, hypotension,
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syncope, chest pain, atrioventricular (AV) conduction delay, and AV block have also been reported. Adverse nervous system effects may include drowsiness or tiredness, dizziness or lightheadedness, headache, fatigue, lethargy, and nightmares or vivid dreams. Adverse respiratory effects of labetalol have included dyspnea, wheezing, bronchospasm, and nasal congestion. Elevated liver function test results, including reversible increases in serum aminotransferase concentrations; jaundice (including cholestatic jaundice); and hepatitis have been reported in some patients. The most frequent adverse gastrointestinal effects associated with labetalol therapy are nausea, dyspepsia, and vomiting. Less commonly observed adverse effects include impairment of male sexual function and liver injury. Hypotension, bradycardia, hypoglycemia, and respiratory depression have been reported in infants of mothers who were treated with labetalol for hypertension during pregnancy. FDA Pregnancy Category C.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to this material; pre-existing respiratory, cardiovascular, or liver ailments.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this aqueous product.

Fire & Explosion Hazard
None anticipated for this aqueous product.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
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7. HANDLING AND STORAGE

Handling
No special handling required under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions
No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m3</th>
<th>ppm</th>
<th>µg/m3</th>
<th>Note</th>
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<tbody>
<tr>
<td>Labetalol Hydrochloride</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
</tr>
</tbody>
</table>

Respiratory protection
Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection
If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection
Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls
Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State
Liquid

Color
Clear, Colorless to light yellow

Odor
NA

Odor Threshold:
NA

pH:
3.0 to 4.5

Melting point/Freezing point:
NA

Initial Boiling Point/Boiling Point Range:
NA

Evaporation Rate:
NA

Flammability (solid, gas):
NA

Upper/Lower Flammability or Explosive Limits:
NA

Vapor Pressure:
NA
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Vapor Density: NA
Specific Gravity: NA
Solubility: Soluble in water
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Not determined.

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
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<tbody>
<tr>
<td>Labetalol Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>2114, &gt;2000 1450, 600 1250 &gt;1500</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Mouse</td>
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<td>Rabbit</td>
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<td></td>
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<td></td>
<td>Dog</td>
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<tr>
<td>Labetalol Hydrochloride</td>
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<td>LD50</td>
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<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>41</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. In clinical use, rashes have developed in some patients during labetalol therapy. Facial erythema, and reversible alopecia have also occurred. Hypersensitivity (e.g., rash, urticaria, pruritus, angioedema, dyspnea) and anaphylactoid reactions have been reported rarely in patients.
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Reproductive Effects

In repeat dose studies in male rats, the copulation rate was decreased at an oral dosage of 300 mg/kg/day. In perinatal studies in rats, decreased fetal viability and size was observed at maternal oral dosages of 150 mg/kg/day (equivalent to 9000 mg/day in a 60 mg female). Teratogenic studies have been performed with labetalol in rats and rabbits at oral doses up to approximately 6 and 4 times the maximum recommended human dose (MRHD), respectively. No reproducible evidence of fetal malformations was observed. Increased fetal resorptions were seen in both species at doses approximating the MRHD. A teratology study performed with labetalol in rabbits at intravenous doses up to 1.7 times the MRHD revealed no evidence of drug-related harm to the fetus. Oral administration of labetalol to rats during late gestation through weaning at doses of 2 to 4 times the MRHD caused a decrease in neonatal survival.

Mutagenicity

Studies with labetalol, using dominant lethal assays in rats and mice, and exposing microorganisms according to modified Ames tests, showed no evidence of mutagenesis.

Carcinogenicity

There was no evidence of carcinogenesis in mice treated orally for 18 months at 200 mg/kg/day or in rats treated orally for 113-116 weeks at 225 mg/kg/day.

Target Organ Effects

Possible target organs include the cardiovascular system, gastrointestinal system, respiratory system and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Not determined for product.

Persistence/Biodegradability

Not determined for product.

Bioaccumulation

Not determined for product.

Mobility in Soil

Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal

All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal

Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:

Not regulated

IMDG STATUS:

Not regulated

ICAO/IATA STATUS:

Not regulated

Transport Comments:

None
15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
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<tbody>
<tr>
<td>Labetalol Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
</tbody>
</table>

RCRA Status: Not Listed

U.S. OSHA Classification

Possible Irritant

GHS Classification

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class: Not Applicable

Hazard Category: Not Applicable

Signal Word: Not Applicable

Symbol: Not Applicable

Prevention:
P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement: Not Applicable

Response:
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Labetalol Hydrochloride.

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases:
S23 - Do not breathe vapor.
S24 - Avoid contact with skin.
S25 - Avoid contact with eyes.
S37/39 - Wear suitable gloves and eye/face protection.
## 16. OTHER INFORMATION:

<table>
<thead>
<tr>
<th>Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value</td>
</tr>
<tr>
<td>CAS Chemical Abstracts Service Number</td>
</tr>
<tr>
<td>CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td>DOT US Department of Transportation Regulations</td>
</tr>
<tr>
<td>EEL Employee Exposure Limit</td>
</tr>
<tr>
<td>IATA International Air Transport Association</td>
</tr>
<tr>
<td>LD50 Dosage producing 50% mortality</td>
</tr>
<tr>
<td>NA Not applicable/Not available</td>
</tr>
<tr>
<td>NE Not established</td>
</tr>
<tr>
<td>NIOSH National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
</tr>
<tr>
<td>Prop 65 California Proposition 65</td>
</tr>
<tr>
<td>RCRA US EPA, Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RTECS Registry of Toxic Effects of Chemical Substances</td>
</tr>
<tr>
<td>SARA Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>STEL 15-minute Short Term Exposure Limit</td>
</tr>
<tr>
<td>TSCA Toxic Substance Control Act</td>
</tr>
<tr>
<td>TWA 8-hour Time Weighted Average</td>
</tr>
</tbody>
</table>

MSDS Coordinator: Hospira GEHS  
Date Prepared: 10/12/2011  
Obsolete Date: 10/21/2008

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