MATERIAL SAFETY DATA SHEET

Product Name: Pontocaine Hydrochloride (Tetracaine Hydrochloride, USP)

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
Pontocaine Hydrochloride (Tetracaine Hydrochloride, USP)

Synonyms
Pontocaine Hydrochloride; Tetracaine Hydrochloride Injection, USP; 2-(Dimethylamino) ethyl p-(butylamino) benzoate monohydrochloride

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Tetracaine Hydrochloride

Chemical Formula
C_{15}H_{24}N_{2}O_{2} • HCl

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% in the Pontocaine Hydrochloride product include sodium chloride and chlorobutanol. The 2% solution of Pontocaine Hydrochloride is also colored with FD&C Blue #1 to prevent accidental use for injection. Hazardous ingredients present at less than 1% in the Tetracaine Hydrochloride Injection, USP, product include sodium chloride and acetone sodium bisulfite.

<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>Tetracaine Hydrochloride</td>
<td>2</td>
<td>136-47-0</td>
<td>DG4900000</td>
</tr>
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</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>Tetracaine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Pontocaine Hydrochloride (Tetracaine Hydrochloride, USP) contains tetracaine hydrochloride, an ester-type local anesthetic, indicated for topical anesthesia of the eyes, skin, mouth and throat. Tetracaine Hydrochloride Injection, USP, contains tetracaine hydrochloride supplied as a 1% solution indicated for prolonged spinal anesthesia. In the workplace, this material should be considered a potent drug, and potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the nerves, central nervous system, respiratory system, eyes, cardiovascular system and possibly the skin.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Published reports have indicated that similar local anesthetics have some potential to be
Product Name: Pontocaine Hydrochloride (Tetracaine Hydrochloride, USP)

absorbed through intact skin and through mucus membranes. Avoid liquid aerosol generation and skin contact.

**Signs and Symptoms**

Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. In normal clinical use, adverse effects may include fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anemia, back pain, post-operative pain and fetal distress. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal, edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other ester-type local anesthetics may occur.

**Medical Conditions Aggravated by Exposure**

Pre-existing hypersensitivity to tetracaine or other local anesthetics. Pre-existing nervous system or cardiovascular ailments. Pre-existing ailments in the following organs: central nervous system, eyes, respiratory system, cardiovascular system and possibly skin.

### 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 from this aqueous product.

**Fire & Explosion Hazard**

None anticipated from 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.

7. HANDLING AND STORAGE

Handling
No special handling required for hazard control

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m3</th>
<th>ppm</th>
<th>µg/m3</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracaine 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 dusts or 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 dust or 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Clear, Colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
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<tr>
<td>pH:</td>
<td>3.2 to 6.0</td>
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<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
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</table>
Product Name: Pontocaine Hydrochloride (Tetracaine Hydrochloride, USP)

Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: NA
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 Strong oxidizers, acids
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>Tetracaine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>160</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td>Tetracaine Hydrochloride</td>
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<td>LD50</td>
<td>Intravenous</td>
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<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6.4</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2.2</td>
<td>mg/kg</td>
<td>Rabbit</td>
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<tr>
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<td></td>
<td></td>
<td>4</td>
<td>mg/kg</td>
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<td>Tetracaine Hydrochloride</td>
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<td>LD50</td>
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<td>Rat</td>
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<td>23</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td>Tetracaine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intratracheal</td>
<td>4.4</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. Inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness. During topical use, mild erythema at the site of application is frequently seen with slight edema or pruritus occurring less commonly.
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**Ocular Irritation/Corrosion**
None anticipated from normal handling of this product. During clinical use, a stinging sensation may occur when tetracaine hydrochloride is used in the eye. Inadvertent contact of this product with eyes may produce irritation, numbness, and blurred vision.

**Dermal or Respiratory Sensitization**
None anticipated from normal handling of this product. Inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of tetracaine hydrochloride.

**Reproductive Effects**
Long-term reproduction studies in animals with tetracaine hydrochloride have not been conducted.

**Mutagenicity**
Tetracaine hydrochloride was inconclusive in an Ames test for mutagenicity.

**Carcinogenicity**
Long-term studies in animals to evaluate the carcinogenic potential of tetracaine hydrochloride have not been conducted.

**Target Organ Effects**
Based on clinical use, possible target organs include the nerves, central nervous system, respiratory system, eyes, cardiovascular system and possibly the skin.

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>Tetracaine Hydrochloride</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
</tbody>
</table>

**RCRA Status**
- Not Listed

**U.S. OSHA Classification**
- Target Organ Toxin
- 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**
- H00 - 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 Tetracaine 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.
Product Name: Pontocaine Hydrochloride (Tetracaine Hydrochloride, USP)

16. OTHER INFORMATION:

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

MSDS Coordinator: Hospira GEHS
Date Prepared: 11/02/2011
Obsolete Date: 10/21/2008

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