MATERIAL SAFETY DATA SHEET

Product Name: NOVOCAIN - Procaine Hydrochloride Injection, Solution

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
NOVOCAIN - Procaine Hydrochloride Injection, Solution

Synonyms
Benzoic acid, 4-amino-, 2-(diethylamino) ethyl ester, monohydrochloride

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Procaine Hydrochloride

Chemical Formula
C₁₃H₂₀N₂O₂ \cdot HCl

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients which may be present at less than 1% include acetone sodium bisulfite (added as an antioxidant in some products) and chlorobutanol (added as an antimicrobial preservative in some the multiple-dose vials). Some solutions may be made isotonic with sodium chloride and the pH may be adjusted between 3 and 5.5 with sodium hydroxide and/or hydrochloric acid for some products.

<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>Procaine Hydrochloride</td>
<td>\leq 10</td>
<td>51-05-8</td>
<td>DG2275000</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>Procaine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
NOVOCAIN - Procaine Hydrochloride Injection is a solution containing procaine hydrochloride, an ester-type local anesthetic used as an analgesic and as a local anesthetic for pain management. In the workplace, this material should be considered potentially irritating to the skin, eyes and respiratory tract. The product formulation also contains sulfite which may cause an allergic reaction in susceptible people. Based on clinical use, possible target organs include the central nervous system, cardiovascular system, and 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 absorbed through intact skin. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposures. However, 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. 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 atrio-ventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Additional adverse effects have included fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anemia, back pain, post-operative pain and fetal distress.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to materials in this product, or related ester-type anesthetics. Pre-existing nervous system or cardiovascular ailments; pre-existing asthma.

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.
Product Name: NOVOCAIN - Procaine Hydrochloride Injection, Solution

7. HANDLING AND STORAGE

Handling  No special handling required for hazard control 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>
</tr>
</thead>
<tbody>
<tr>
<td>Procaine 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  NA
Odor  NA
Odor Threshold:  NA
pH:  3 to 5.5
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
Vapor Density:  NA
Product Name: NOVOCAIN - Procaine Hydrochloride Injection, Solution

Specific Gravity: NA
Solubility: NA
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA

<table>
<thead>
<tr>
<th>10. STABILITY AND REACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reactivity</strong></td>
</tr>
<tr>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Chemical Stability</strong></td>
</tr>
<tr>
<td>Stable under standard use and storage conditions.</td>
</tr>
<tr>
<td><strong>Hazardous Reactions</strong></td>
</tr>
<tr>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Conditions to avoid</strong></td>
</tr>
<tr>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Incompatibilities</strong></td>
</tr>
<tr>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Hazardous decomposition products</strong></td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>Hazardous Polymerization</strong></td>
</tr>
<tr>
<td>Not anticipated to occur with this product.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>11. TOXICOLOGICAL INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute Toxicity</strong></td>
</tr>
<tr>
<td>Not determined for the product formulation. Information for the ingredients is as follows:</td>
</tr>
</tbody>
</table>

<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>
</tr>
</thead>
<tbody>
<tr>
<td>Procaine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>200</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>175</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Procaine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>38</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>33</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>43</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>51</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>63</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
</tbody>
</table>

| **Aspiration Hazard** |
| None anticipated from normal handling of this product. However, inadvertent inhalation of aerosol from the product formulation may produce irritation with coughing. |

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

| **Ocular Irritation/Corrosion** |
| None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness, tearing, and possible numbness. |

| **Dermal or Respiratory Sensitization** |
| None anticipated from normal handling of this product. The product formulation contains acetone sodium bisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence |
Product Name: NOVOCAIN - Procaine Hydrochloride Injection, Solution

of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Reproductive Effects Studies in animals to evaluate the effects on fertility have not been conducted. Animal reproduction studies have not been conducted with NOVOCAIN.

Mutagenicity Studies to evaluate the mutagenic potential have not been conducted.

Carcinogenicity Long-term studies in animals of most local anesthetics, including procaine hydrochloride, to evaluate the carcinogenic potential have not been conducted.

Target Organ Effects Based on clinical use, possible target organs include the central nervous system, cardiovascular system, and 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>
</tr>
</thead>
<tbody>
<tr>
<td>Procaine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

RCRA Status Not Listed

U.S. OSHA Target Organ Toxin
Product Name: NOVOCAIN - Procaine Hydrochloride Injection, Solution

**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 Procaine Hydrochloride.

Classification(s):  Not Applicable

Symbol:  Not Applicable

Indication of Danger:  Not Applicable

Risk Phrases:  Not Applicable

Safety Phrases:  S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

### 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
Product Name: NOVOCAIN - Procaine Hydrochloride Injection, Solution

RTECS  Registry of Toxic Effects of Chemical Substances
SARA  Supercfund 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: 10/28/2011
Obsolete Date: 10/21/2008

Disclaimer:
The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.