1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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

Emergency Telephone
CHEMTREC: North America: 800-424-9300; International: 1-703-527-3887
Hospira, Inc., Non-Emergency
224 212-2055

Product Name
Lidocaine Hydrochloride Injection

Synonyms
Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxylidide, 2-(diethylamino)-, hydrochloride

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Lidocaine Hydrochloride

Chemical Formula
C_{14}H_{22}N_{2}O \cdot \text{HCl}

<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>Lidocaine Hydrochloride</td>
<td>≤ 5.0%</td>
<td>73-78-9</td>
<td>AN7600000</td>
</tr>
</tbody>
</table>

Non-hazardous ingredients include Water for Injection; some preparation may contain 7.5% dextrose. Hazardous ingredients present at less than 1% may include sodium chloride; sodium hydroxide and/or hydrochloric acid are used to adjust the pH. Multiple-dose vials contain 0.1% of methylparaben added as preservative.

3. HAZARD INFORMATION

Emergency Overview
Lidocaine Hydrochloride Injection is a solution containing lidocaine hydrochloride, an amide-type local anesthetic used as a local anesthetic for pain management. In the workplace, this product should be considered possibly irritating to the skin, eyes and respiratory tract. Possible target organs include the nervous system and cardiovascular system.

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
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 or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal
3. HAZARD INFORMATION: continued

Signs and Symptoms: edema), tachycardia, sneezing nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to lidocaine or related amide-type anesthetics. Pre-existing nervous system or cardiovascular ailments.

Carcinogen Lists: IARC: Not listed NTP: Not listed OSHA: Not listed

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 any 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 under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow temperature 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.
Product Name: Lidocaine Hydrochloride Injection

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>AIHA WEEL</th>
<th>Hospira EEL*</th>
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</thead>
<tbody>
<tr>
<td>Lidocaine Hydrochloride</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not 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: Clear, colorless liquid.
Odor: Not determined.
Odor Threshold: NA
pH: Between 5.0 and 7.0
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 (Air =1): NA
Evaporation Rate: NA
Specific Gravity: NA
Solubility: Very soluble in water and in alcohol; soluble in chloroform; insoluble in ether.
Log Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA
Product Name: Lidocaine Hydrochloride Injection

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
Strongly alkaline conditions. Methyl vinyl ether; zinc.

Hazardous Decomposition Products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides and 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 active ingredient 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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</thead>
<tbody>
<tr>
<td>Lidocaine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>220</td>
<td>mg/kg</td>
<td>Mouse Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>292</td>
<td>mg/kg</td>
<td>Mouse Mouse</td>
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<td>Lidocaine Hydrochloride</td>
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<td>LD50</td>
<td>Intraperitoneal</td>
<td>122</td>
<td>mg/kg</td>
<td>Rat Mouse</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>63</td>
<td>mg/kg</td>
<td>Mouse Mouse</td>
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<tr>
<td>Lidocaine Hydrochloride</td>
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<td>LD50</td>
<td>Intravenous</td>
<td>21</td>
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<tr>
<td></td>
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<td></td>
<td>15</td>
<td>mg/kg</td>
<td>Rabbit Rabbit</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>25.6</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>24.5</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
</tr>
<tr>
<td>Lidocaine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intratracheal</td>
<td>28</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
</tbody>
</table>
| LD 50: Dosage that produces 50% mortality.

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, 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. However, 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 lidocaine.
11. TOXICOLOGICAL INFORMATION: continued

| Reproductive Effects | In a fertility study in rats, lidocaine given subcutaneously at a dosage of 30 mg/kg (180 mg/m²) to mating pairs did not produce alterations in fertility or general reproductive performance of rats. Subcutaneous administration of lidocaine to pregnant rats at a dosage of to 50 mg/kg did not produce evidence of harm to the fetus. In rabbits, there was no evidence of harm to the fetus at a subcutaneous dosage of 5 mg/kg. Treatment of rabbits with a subcutaneous dosage of 25 mg/kg produced evidence of maternal toxicity and evidence of delayed fetal development, including a non-significant decrease in fetal weight and an increase in minor skeletal anomalies. The effect of lidocaine on post-natal development was evaluated in rats by treating pregnant female rats daily subcutaneously at dosages of 2, 10, and 50 mg/kg from day 15 of pregnancy and up to 20 days post partum. No signs of adverse effects were seen either in dams or in the pups up to and including the dose of 10 mg/kg; however, the number of surviving pups was reduced at 50 mg/kg, both at birth and the duration of lactation period; this effect is most likely secondary to maternal toxicity. A second study evaluated the effects of lidocaine on post-natal development in the rat that included assessment of the pups from weaning to sexual maturity. Rats were treated subcutaneously for 8 months with 10 or 30 mg/kg lidocaine, a treatment duration that included 3 mating periods. There was no evidence of altered post-natal development in any offspring; however, both doses of lidocaine significantly reduced the average number of pups per litter surviving until weaning of offspring from the first 2 mating periods. |
| Mutagenicity | The mutagenic potential of lidocaine was evaluated in the Ames Salmonella reverse mutation assay, an in vitro chromosome aberrations assay in human lymphocytes and in an in vivo mouse micronucleus assay. There was no indication of any mutagenic effect in these studies. |
| Carcinogenicity | Long-term studies in animals to evaluate the carcinogenic potential of most local anesthetics, including lidocaine, have not been conducted. |
| Target Organ Effects | Based on clinical use, possible target organs include the nervous system and the cardiovascular system. |

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 by the waste generator. Further, disposal of all pharmaceuticals 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

**DOT STATUS**
- Not regulated

**Proper Shipping Name**
- NA

**Hazard Class**
- NA

**UN Number**
- NA

**Packing Group**
- NA

**Reportable Quantity**
- NA

**ICAO/IATA STATUS**
- Not regulated

**Proper Shipping Name**
- NA

**Hazard Class**
- NA

**UN Number**
- NA

**Packing Group**
- NA

**Reportable Quantity**
- NA

**IMDG STATUS**
- Not regulated

**Proper Shipping Name**
- NA

**Hazard Class**
- NA

**UN Number**
- NA

**Packing Group**
- NA

**Reportable Quantity**
- NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

**TSCA Status**
- This product is exempt. However, lidocaine hydrochloride is listed on the TSCA inventory.

**CERCLA Status**
- Not listed

**SARA 302 Status**
- Not listed

**SARA 313 Status**
- Not listed

**RCRA Status**
- Not listed

**PROP 65 (Calif.)**
- Not listed

Notes:
TSCA, Toxic Substance Control Act;
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act;
SARA, Superfund Amendments and Reauthorization Act;
Prop 65, California Proposition 65
**Product Name:** Lidocaine Hydrochloride Injection

### 15. REGULATORY INFORMATION: continued

| U.S. OSHA Classification | Possible Irritant  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Target Organ Toxin</td>
</tr>
</tbody>
</table>

**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 | NA  
|--------------|-----|
| Hazard Category | NA  
| Symbol | NA  
| Signal Word | NA  
| Hazard Statement | NA  

**Prevention**  
Do not breathe vapor or spray.

**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 Classifications**  
* Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.*

| Classification(s): | NA  
|-------------------|-----|
| Symbol | NA  

| Indication of Danger | NA  
|----------------------|-----|

| Risk Phrases | NA  
|--------------|-----|

| Safety Phrases | S22: Do not breathe dust  
|               | S23: Do not breathe vapor/spray  
|               | S24: Avoid contact with the skin  
|               | S25: Avoid contact with eyes  
|               | S37/39 Wear suitable gloves and eye/face protection. |
# 16. OTHER INFORMATION

### Notes:

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

**MSDS Coordinator:** Global Occupational Toxicology  
**Date Prepared:** February 22, 2008  
**Date Revised:** November 24, 2010

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