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

Product Name
Neostigmine Methylsulfate Injection

Synonyms
Dimethylcarbamate of (m-hydroxyphenyl) trimethylammonium methylsulfate; Benzenaminium, 3-(((dimethylamino)carbonyl)oxy)-N,N,N-trimethyl-, methyl sulfate.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Neostigmine Methylsulfate

Chemical Formula
C_{12}H_{19}N_{2}O_{2} \cdot CH_{3}SO_{4}

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include methyl paraben and propyl paraben; sodium hydroxide may be added to adjust the pH.

<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>Neostigmine Methylsulfate</td>
<td>0.05 – 0.1</td>
<td>51-60-5</td>
<td>CY1225000</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>Neostigmine Methylsulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Neostigmine Methylsulfate Injection is a solution containing neostigmine methylsulfate, a synthetic quaternary ammonium compound that produces cholinergic effects by competing with acetylcholine for acetylcholinesterase. Clinically, it is used in the diagnosis and symptomatic treatment of myasthenia gravis. It is also used after surgery to reverse the effects of non-depolarizing neuromuscular blocking agents and to prevent postoperative distention and urinary retention. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potent drug. Based on clinical use, possible target organs include the eyes, central and parasympathetic nervous system, glands, kidneys, heart, lungs, gastrointestinal tract, and uterus.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. However, limited information suggests that dilute solutions of neostigmine methylsulfate have some potential for skin and eye absorption. Avoid liquid aerosol generation and skin contact.
Product Name: Neostigmine Methylsulfate Injection

Signs and Symptoms
No signs or symptoms from occupational exposure are known. In clinical use, adverse events include nausea, vomiting, gastrointestinal upset, cramps, visual impairment, diarrhea, dizziness, headaches, drowsiness, sweating, increased salivation, decreased blood pressure, cardiac changes, bronchospasm, bronchorrhea, rash, excessive urination, spasms, bone and joint pain, flushing, allergic reactions, muscle weakness, premature delivery.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to neostigmine methylsulfate; preexisting eye, heart, muscle, urinary bladder, cardiovascular system, respiratory system, or gastrointestinal system ailments; late pregnancy.

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 firefighting 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 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 storage required for hazard control. For product protection, follow
Product Name: Neostigmine Methylsulfate Injection

storage recommendations noted on the product case label, the primary container label, or the product insert.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neostigmine Methylsulfate</td>
<td>Not Applicable</td>
<td>mg/m3 ppm µg/m3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A N/A N/A</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>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>5.0 - 6.5</td>
</tr>
<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>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Very soluble in water and soluble in alcohol</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
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 sulfur oxides (SOx).

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>
</tr>
</thead>
<tbody>
<tr>
<td>Neostigmine Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>7.5 - 10.0</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Neostigmine Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>0.16</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.25</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Neostigmine Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>0.23</td>
<td>mg/kg</td>
<td>Mouse</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 tearing and redness.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
Studies in animals to evaluate the effects of neostigmine methylsulfate on fertility or development have not been conducted. Intravenous administration of anticholinesterase agents to pregnant women near term may cause uterine irritability and premature labor.

Mutagenicity
Studies to evaluate the genotoxic potential of neostigmine methylsulfate have not been conducted.

Carcinogenicity
Studies in animals to evaluate the carcinogenic potential of neostigmine methylsulfate have not been conducted.

Target Organ Effects
Based on clinical use, possible target organs include the eyes, central and parasympathetic nervous system, glands, kidneys, heart, lungs, gastrointestinal tract, and uterus.
### 12. ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Toxicity</td>
<td>Not determined for product</td>
</tr>
<tr>
<td>Persistence/Biodegradability</td>
<td>Not determined for product</td>
</tr>
<tr>
<td>Bioaccumulation</td>
<td>Not determined for product</td>
</tr>
<tr>
<td>Mobility in Soil</td>
<td>Not determined for product</td>
</tr>
</tbody>
</table>

### 13. DISPOSAL CONSIDERATIONS

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste Disposal</td>
<td>All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.</td>
</tr>
<tr>
<td>Container Handling and Disposal</td>
<td>Dispose of container and unused contents in accordance with federal, state and local regulations.</td>
</tr>
</tbody>
</table>

### 14. TRANSPORTATION INFORMATION

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT STATUS</td>
<td>Not regulated</td>
</tr>
<tr>
<td>IMDG STATUS:</td>
<td>Not regulated</td>
</tr>
<tr>
<td>ICAO/IATA STATUS:</td>
<td>Not regulated</td>
</tr>
</tbody>
</table>

### 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>Neostigmine Methylsulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCRA Status</td>
<td>Not Listed</td>
</tr>
<tr>
<td>U.S. OSHA Classification</td>
<td>Target Organ Toxin Possible Irritant</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:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Class</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Hazard Category</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Signal Word</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Symbol</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
Product Name: Neostigmine Methylsulfate Injection

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 Neostigmine Methylsulfate.

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:

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: 11/14/2011
Obsolete Date: 10/21/2008
Product Name: Neostigmine Methylsulfate Injection

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