MATERIAL SAFETY DATA SHEET

Product Name: METOCLOPRAMIDE Metoclopramide 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:
METOCLOPRAMIDE Metoclopramide Hydrochloride Injection

Synonyms:
4-amino-5-chloro-N-[2-(diethylamino)ethyl]-2-methoxybenzamide monohydrochloride monohydrate

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name:
Metoclopramide Hydrochloride Monohydrate

Chemical Formula:
C_{14}H_{22}ClN_{3}O_{2} \cdot HCl \cdot H_{2}O

Preparation:
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride. Sodium hydroxide and/or hydrochloric acid 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>Metoclopramide Hydrochloride</td>
<td>0.5</td>
<td>54143-57-6</td>
<td>NA</td>
</tr>
<tr>
<td>Monohydrate</td>
<td></td>
<td></td>
<td></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>Metoclopramide Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Monohydrate</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Emergency Overview:
METOCLOPRAMIDE - Metoclopramide Hydrochloride Injection is a solution containing metoclopramide hydrochloride, a selective dopamine antagonist that increases gut motility. It stimulates the motility of the upper gastrointestinal tract without affecting gastric, biliary, or pancreatic secretion and increases gastric peristalsis, leading to accelerated gastric emptying. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the central nervous system, gastrointestinal system and possibly the endocrine system.

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.
Product Name: METOCLOPRAMIDE Metoclopramide Hydrochloride Injection

Signs and Symptoms

None known from occupational exposure. In clinical use, the most frequent side effects (that occur in about 10% of patients) include restlessness, drowsiness, fatigue and lassitude. Extrapyramidal symptoms are also observed in 1 of 500 patients receiving doses in the range of 30-40 mg/day. Other side effects include insomnia, headache, dizziness, endocrine disturbances (e.g., galactorrhea, gynecomastia, menstrual disorders), cardiovascular effects, rare hepatotoxicity and allergic reactions. A single dose of metoclopramide produces a prominent elevation in maternal serum prolactin in pregnant women. Metoclopramide can also increase milk production in lactating/nursing women. Hyper-prolactinemia may be associated with menstrual disturbances and infertility in women. Amenorrhea and galactorrhea have been reported in women and impotency has been reported in men.

Medical Conditions

Pre-existing hypersensitivity to this material; pre-existing central nervous system, gastrointestinal system or endocrine 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 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.
Product Name: METOCLOPRAMIDE Metoclopramide Hydrochloride Injection

**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>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Component</strong></td>
<td><strong>Type</strong></td>
</tr>
<tr>
<td>Metoclopramide Hydrochloride Monohydrate</td>
<td>Not Applicable</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

<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>2.5 to 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>Metoclopramide hydrochloride is a white or practically white, crystalline, odorless or practically odorless powder. It is very soluble in water, freely soluble in alcohol, sparingly soluble in chloroform, practically insoluble in ether.</td>
</tr>
</tbody>
</table>
Product Name: METOCLOPRAMIDE Metoclopramide Hydrochloride Injection

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 vapor.
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>Metoclopramide Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>750</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>270</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td>Metoclopramide Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>50</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>33</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>30</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.
Reproductive Effects Reproduction studies performed in rats, mice, and rabbits by the IV, IM, subcutaneous (SC), and oral routes at maximum levels ranging from 12 to 250 times the human dose have demonstrated no impairment of fertility or significant harm to the fetus due to metoclopramide. In some patients, metoclopramide can elevate levels of the hormone prolactin. Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating drugs, the clinical significance of elevated serum prolactin levels is unknown for most patients.
Mutagenicity An Ames mutagenicity test performed on metoclopramide was negative.
Carcinogenicity A 77-week study was conducted in rats with oral doses up to about 40 times the maximum recommended human daily dose. Metoclopramide elevated prolactin levels and the elevation persisted during chronic administration. An
increase in mammary neoplasms has been found in rodents after chronic administration of prolactin-stimulating neuroleptic drugs and metoclopramide. Neither clinical studies nor epidemiologic studies conducted to date, however, have shown an association between chronic administration of these drugs and mammary tumorigenesis; the available evidence is too limited to be conclusive at this time.

Target Organ Effects
Based on clinical use, possible target organs include the central nervous system, gastrointestinal system and possibly the endocrine 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. 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

DOT STATUS Not regulated
ICAO/IATA STATUS: Not regulated
IMDG STATUS: Not regulated
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>Metoclopramide Hydrochloride Monohydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**US 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**
- 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 Metoclopramide Hydrochloride Monohydrate.

**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>
<th></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>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
</tr>
</tbody>
</table>

MSDS Coordinator: Hospira GEHS  
Date Prepared: 10/18/2011  
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.