SAFETY DATA SHEET

Product Name: Metoclopramide Injection, USP

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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; Australia - 61-290372994; UK - 44-870-8200418

Hospira, Inc., Non-Emergency  224 212-2000

Product Name  Metoclopramide Injection, USP

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

2. HAZARD(S) IDENTIFICATION

Emergency Overview  Metoclopramide Injection, USP 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.

U.S. OSHA GHS Classification

<table>
<thead>
<tr>
<th>Physical Hazards</th>
<th>Hazard Class</th>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Classified</td>
<td>Not Classified</td>
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<table>
<thead>
<tr>
<th>Health Hazards</th>
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<th>Hazard Category</th>
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<tr>
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</table>

Label Element(s)

<table>
<thead>
<tr>
<th>Pictogram</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Word</td>
<td>NA</td>
</tr>
<tr>
<td>Hazard Statement(s)</td>
<td>NA</td>
</tr>
</tbody>
</table>

Precautionary Statement(s)

Prevention

Do not breathe vapor or spray
Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.

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.
Product Name: Metoclopramide Injection, USP

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Active Ingredient Name</th>
<th>Metoclopramide Hydrochloride Monohydrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Formula</td>
<td>C14H22ClN3O2 • HCl • H2O</td>
</tr>
</tbody>
</table>

<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 Monohydrate</td>
<td>0.5</td>
<td>54143-57-6</td>
<td>NA</td>
</tr>
</tbody>
</table>

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.

### 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 such as carbon dioxide, dry chemical extinguishing powder or foam.

**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 control 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 precautions required for hazard control.
### 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>
</tr>
</thead>
<tbody>
<tr>
<td>Metoclopramide Hydrochloride Monohydrate</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>

Notes:  
OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value  
AIHA WEEL: Workplace Environmental Exposure Level  
EEL: Employee Exposure Limit  
TWA: 8-hour Time Weighted Average.

**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>Clear, colorless, sterile solution</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>4.4 (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>Flash Point</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 (Air =1)</td>
<td>NA</td>
</tr>
<tr>
<td>Relative Density</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>
<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>
<tr>
<td>Viscosity</td>
<td>NA</td>
</tr>
</tbody>
</table>
**Product Name: Metoclopramide Injection, USP**

### 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 metoclopramide hydrochloride 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>750 270 mg/kg</td>
<td>mg/kg</td>
<td>Rat Mouse</td>
</tr>
<tr>
<td>Metoclopramide Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>50 33 30 mg/kg</td>
<td>mg/kg</td>
<td>Rat Mouse Rabbit</td>
</tr>
</tbody>
</table>

LD 50: Dosage that produces 50% mortality.

**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.

**Signs and Symptoms**

None anticipated from normal handling of this product. 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 impotence has been reported in men.

**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. However, 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**

None anticipated from normal handling of this product. 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.
Product Name: Metoclopramide Injection, USP

### 11. TOXICOLOGICAL INFORMATION: continued

**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.

**Carcinogen Lists**

- **IARC:** Not listed
- **NTP:** Not listed
- **OSHA:** Not listed

**Specific Target Organ Toxicity**

- **Single Exposure:** NA
- **Repeat Exposure:** Based on clinical use, possible target organs include the 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.

Notes:

### 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

**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

<table>
<thead>
<tr>
<th>US TSCA Status</th>
<th>Exempt</th>
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</thead>
<tbody>
<tr>
<td>US CERCLA Status</td>
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<tr>
<td>US SARA 302 Status</td>
<td>Not listed</td>
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<tr>
<td>US SARA 313 Status</td>
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<tr>
<td>US RCRA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US PROP 65 (Calif.)</td>
<td>Not listed</td>
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</table>


**GHS/CLP 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>Hazard Class</th>
<th>Hazard Category</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement</th>
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</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Prevention**

Do not breathe vapor or spray. Wash hands thoroughly after handling.

**Response**

Get medical attention if you feel unwell.

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.

**EU Classification***

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

<table>
<thead>
<tr>
<th>Classification(s)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Symbol</td>
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</tr>
<tr>
<td>Indication of Danger</td>
<td>NA</td>
</tr>
<tr>
<td>Risk Phrases</td>
<td>NA</td>
</tr>
<tr>
<td>Safety Phrases</td>
<td>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.</td>
</tr>
</tbody>
</table>

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
- STOT - SE: Specific Target Organ Toxicity – Single Exposure
- STOT - RE: Specific Target Organ Toxicity – Repeated Exposure
- TSCA: Toxic Substance Control Act
- TWA: 8-hour Time Weighted Average
MSDS Coordinator: Hospira GEHS
Date Prepared: October 19, 2012
Date Revised: June 02, 2014

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