SAFETY DATA SHEET

Product Name: METRONIDAZOLE - Metronidazole Injection, Solution

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
METRONIDAZOLE - Metronidazole Injection, Solution

Synonyms
2-methyl-5-nitroimidazole-1-ethanol

2. HAZARD(S) IDENTIFICATION

Emergency Overview
METRONIDAZOLE - Metronidazole Injection, Solution contains metronidazole, a synthetic antibacterial and antiprotozoal agent indicated for the treatment of serious infections caused by susceptible organisms. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and potentially carcinogenic. Based on clinical use, possible target organs include the nervous system, gastrointestinal system, kidneys and skin.

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>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Hazards</th>
<th>Hazard Class</th>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenicity</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

Label Element(s)

<table>
<thead>
<tr>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Warning</td>
<td>Suspected of causing cancer</td>
</tr>
</tbody>
</table>

Precautionary Statement(s)

Prevention
Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe vapor or spray
Wash hands thoroughly after handling

Response
If exposed or concerned: Get medical advice/attention. Get medical advice/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: METRONIDAZOLE - Metronidazole Injection, Solution

3. COMPOSITION/INFORMATION ON INGREDIENTS

<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>Metronidazole</td>
<td>0.5</td>
<td>443-48-1</td>
<td>NI5600000</td>
</tr>
</tbody>
</table>

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride; dibasic sodium phosphate (anhydrous) and citric acid (anhydrous) are added as buffers.

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>Metronidazole</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 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>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>A sterile, nonpyrogenic, isotonic, buffered solution in water</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>5.8 (4.5 to 7.0)</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>Metronidazole is a crystalline powder sparingly soluble in water</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>
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 (CO\textsubscript{x}) and nitrogen oxides (NO\textsubscript{x}).

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>
</tr>
</thead>
<tbody>
<tr>
<td>Metronidazole</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>3000</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3800</td>
<td>mg/kg</td>
<td>Mouse</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 serious adverse reactions reported in patients treated with metronidazole injection have been convulsive seizures, encephalopathy, aseptic meningitis, optic and peripheral neuropathy, the latter characterized mainly by numbness or paresthesia of an extremity. Other adverse effects may include nausea, rash, fever, reversible neutropenia, diarrhea, abdominal cramping, headache, anorexia, vomiting and a sharp, unpleasant metallic taste, dysuria, cystitis, polyuria, incontinence, a sense of pelvic pressure, and darkened urine. Urticaria, erythematous rash, Stevens-Johnson Syndrome, flushing, nasal congestion, dryness of the mouth may also occur.

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. During clinical use, urticaria, erythematous rash, Stevens-Johnson Syndrome, flushing, nasal congestion, dryness of the mouth have been reported in some patients.

Reproductive Effects
Reproduction studies have been performed in rats at doses up to five times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to metronidazole. Metronidazole administered intraperitoneally to pregnant mice at approximately the human dose caused fetotoxicity; when administered orally to pregnant mice, no fetotoxicity was observed. Metronidazole crosses the placental barrier and enters the fetal circulation rapidly. FDA Pregnancy Category B.
11. TOXICOLOGICAL INFORMATION: continued

**Mutagenicity**
Metronidazole has shown mutagenic activity in a number of *in vitro* assay systems, but studies in mammals (*in vivo*) failed to demonstrate a potential for genetic damage.

**Carcinogenicity**
Metronidazole has shown evidence of carcinogenic activity in studies involving chronic, oral administration in mice and rats, but similar studies in the hamster gave negative results.

**Carcinogen Lists**
- IARC: Not listed
- NTP: Group 2 - Reasonably Anticipated to be a Human Carcinogen.
- 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, kidneys 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.

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US TSCA Status</strong></td>
<td>Exempt.</td>
</tr>
<tr>
<td><strong>US CERCLA Status</strong></td>
<td>Not listed</td>
</tr>
<tr>
<td><strong>US SARA 302 Status</strong></td>
<td>Not listed</td>
</tr>
<tr>
<td><strong>US SARA 313 Status</strong></td>
<td>Not listed</td>
</tr>
<tr>
<td><strong>US RCRA Status</strong></td>
<td>Not listed</td>
</tr>
<tr>
<td><strong>US PROP 65 (Calif.)</strong></td>
<td>This product is, or contains a material, known to the State of California to cause cancer.</td>
</tr>
</tbody>
</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>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Prevention**

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Wear protective gloves/protective clothing/eye protection/face protection  
Do not breathe vapor or spray  
Wash hands thoroughly after handling

**Response**

If exposed or concerned: Get medical advice/attention. 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>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symbol</td>
<td>NA</td>
</tr>
<tr>
<td>Indication of Danger</td>
<td>NA</td>
</tr>
<tr>
<td>Risk Phrases</td>
<td>NA</td>
</tr>
</tbody>
</table>
| Safety Phrases    | 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>Definition</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>STOT - SE</td>
<td>Specific Target Organ Toxicity – Single Exposure</td>
</tr>
<tr>
<td>STOT - RE</td>
<td>Specific Target Organ Toxicity – Repeated Exposure</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:** October 19, 2012  
**Date Revised:** June 02, 2014

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