MATERIAL SAFETY DATA SHEET

Product Name: Cimetidine 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                | Cimetidine Hydrochloride Injection |
| Synonyms                    | N#-cyano-N-methyl-N#-[2-[[5-(methyl-1H-imidazol-4-yl)methyl]thio]-ethyl]-guanidine |

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Active Ingredient Name</th>
<th>Cimetidine Hydrochloride</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Formula</td>
<td>C10H16N6S•HCl</td>
</tr>
<tr>
<td>Preparation</td>
<td>Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include benzyl alcohol which is added as a bacteriostatic preservative, and sodium chloride. Sodium hydroxide and/or hydrochloric acid are added for pH adjustment</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>Cimetidine Hydrochloride</td>
<td>≤15</td>
<td>70059-30-2</td>
<td>MF0035100</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

<table>
<thead>
<tr>
<th>Carcinogen List</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance</td>
<td>IARC</td>
<td>NTP</td>
<td>OSHA</td>
</tr>
<tr>
<td>Cimetidine Hydrochloride</td>
<td>3</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview Cimetidine Hydrochloride Injection is a solution containing cimetidine hydrochloride, an anti-histamine that inhibits the effects of histamine mediated by H2-receptors including gastric acid secretion and pepsin output. Clinically, cimetidine is used to inhibit gastric acid secretion. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, potential target organs include the gastrointestinal system, central nervous system and liver.

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 known from occupational exposures. In clinical use, adverse may include diarrhea and other gastrointestinal disturbances, dizziness, tiredness, headache, and rashes. Myalgia and arthralgia can occur. Altered liver function tests have occurred and there have been rare reports...
of hepatotoxicity. Reversible confusional states, especially in the elderly or in seriously ill patients have occasionally occurred. Other adverse effects reported rarely include hypersensitivity reactions and fever, reversible alopecia, blood disorders, acute pancreatitis, interstitial nephritis, hallucinations and depression, and cardiovascular disorders including bradycardia, tachycardia, and heart block. Rapid intravenous injection has been associated with cardiac arrest and arrhythmias; transient hypotension has also been seen. Gynecomastia and a decrease in sperm count have occurred in men receiving large doses over long periods of time. Galactorrhea has occurred in women.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to cimetidine or related materials; pre-existing gastrointestinal, cardiovascular, central nervous system or liver effects.

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 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 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 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
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container label, or the product insert.

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Exposure Guidelines</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component</td>
<td>Type</td>
</tr>
<tr>
<td>Cimetidine Hydrochloride</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>Appearance/Physical State</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Clear, sterile aqueous 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>5.4 (3.8 to 6.0)</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>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>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>
</tbody>
</table>

10. STABILITY AND REACTIVITY
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>Cimetidine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral, IV</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Cimetidine</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>5000 mg/kg</td>
<td>Rat</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2550 mg/kg</td>
<td>Mouse</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;8640 mg/kg</td>
<td>Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4000 mg/kg</td>
<td>Hamster</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2600 mg/kg</td>
<td>Dog</td>
<td></td>
</tr>
<tr>
<td>Cimetidine</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>106 mg/kg</td>
<td>Rat</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>150 mg/kg</td>
<td>Mouse</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>164 mg/kg</td>
<td>Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>206 mg/kg</td>
<td>Dog</td>
<td></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. 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. Rarely, hypersensitivity reactions have been reported during the clinical use of this product.

Reproductive Effects
Reproduction studies have been performed in rats, rabbits and mice at doses up to 40 times the normal human dose and have shown no evidence of impaired fertility or harm to the fetus due to cimetidine. Cimetidine has demonstrated a weak anti-androgenic effect. In animal studies this was manifested as reduced prostate and seminal vesicle weights. However, there was no impairment of mating performance or fertility, nor any harm to the fetus in these animals at doses 8 to 48 times the full therapeutic dose of cimetidine, as compared with controls. In human studies, cimetidine has been shown to have no effect on
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Spermatogenesis, sperm count, motility, morphology or in vitro fertilizing capacity.

Mutagenicity

The mutagenic potential of cimetidine hydrochloride has not been evaluated.

Carcinogenicity

In a 24-month toxicity study conducted in rats, at dosage levels of 150, 378 and 950 mg/kg/day (approximately 8 to 48 times the recommended human dose), there was a small increase in the incidence of benign Leydig cell tumors in each dose group; when the combined drug-treated groups and control groups were compared, this increase reached statistical significance. In a subsequent 24 month study, there were no differences between the rats receiving 150 mg/kg/day and the untreated controls. However, a statistically significant increase in benign Leydig cell tumor incidence was seen in the rats that received 378 and 950 mg/kg/day. These tumors were common in control groups as well as treated groups and the difference became apparent only in aged rats.

Target Organ Effects

Based on clinical use, potential target organs include the gastrointestinal system, central nervous system and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Not determined for product. For cimetidine:

IC50: > 1000 mg/L, 3 Hours, Residential sludge
IC50: > 105 mg/L, 72 Hours, Selenastrum capricornutum, green algae, measured
NOEL: 105 mg/L, 72 Hours, Selenastrum capricornutum, green algae, measured
EC50: 760 mg/L, 48 Hours, Daphnia pulex, static test
NOEL: 230 mg/L, 48 Hours, Daphnia pulex, static test
EC50: > 1000 mg/L, 96 Hours, Static test, Adult Lepomis macrochirus, bluegill sunfish
NOEL: 1000 mg/L, 96 Hours, Static test, Adult Lepomis macrochirus, bluegill sunfish


Persistence/Biodegradability

Not determined for product. The active pharmaceutical ingredient is chemically stable in water at neutral pH. Half-Life, Neutral: > 1 months, measured, deionized water.

The active pharmaceutical ingredient is chemically unstable in water when exposed to light. Half-Life, aqueous: 2 to 200 hours, measured, lake water UV/Visible spectrum: 216 nm at pH 7. Aqueous photolysis may be a significant depletion mechanism.

The active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment. Aerobic – Inherent, Percent Degradation: 50 %, 3 days, Batch activated sludge (BAS), Activated sludge.

The active pharmaceutical ingredient may adsorb to sludges and other biomass. Soil Sediment Sorption 3.03 to 3.62, Measured (log Koc).

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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

ADR/ADG/ DOT STATUS: Not regulated
IMDG STATUS: Not regulated
ICAO/IATA STATUS: Not regulated
Transport Comments: None

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>Cimetidine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>RCRA Status</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.S. OSHA Classification</td>
<td>Target Organ Toxin</td>
<td></td>
<td></td>
<td></td>
<td></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 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 Not Applicable
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Statement

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 Cimetidine Hydrochloride.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable

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: 09/07/2011
Obsolete Date: 10/21/2008
Product Name: Cimetidine Hydrochloride Injection

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