1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Metoclopramide Injection (Hospira, Inc.)

Trade Name: Not established
Synonyms: Metoclopramidum
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used for nausea and vomiting (antiemetic)

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous
SAFETY DATA SHEET

Material Name: Metoclopramide Injection (Hospira, Inc.)
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3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoclopramide</td>
<td>364-62-5</td>
<td>206-662-9</td>
<td>Acute Tox 4 (H302)</td>
<td>0.5</td>
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<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr.1A (H314)</td>
<td>**</td>
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<tr>
<td>HYDROCHLORIC ACID</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Skin Corr.1B (H314)</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3 (H335)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: If irritation occurs or persists, get medical attention. Rinse thoroughly with plenty of water, also under the eyelids.

Skin Contact: Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Due to the nature of this material first aid is not normally required.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

Fire / Explosion Hazards: Not applicable
SAFETY DATA SHEET

Material Name: Metoclopramide Injection (Hospira, Inc.)
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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:
Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical product used for nausea and vomiting (antiemetic)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Metoclopramide
Pfizer OEL TWA-8 Hr: 40 µg/m³

Sodium chloride
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

Sodium hydroxide
ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK 2 mg/m³
Austria OEL - MAKs 2 mg/m³
Bulgaria OEL - TWA 2.0 mg/m³
Czech Republic OEL - TWA 1.0 mg/m³
Estonia OEL - TWA 1 mg/m³
France OEL - TWA 2 mg/m³
Greece OEL - TWA 2 mg/m³
Hungary OEL - TWA 2 mg/m³
Japan - OELs - Ceilings 2 mg/m³

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latvia OEL - TWA</td>
<td>0.5</td>
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<tr>
<td>OSHA - Final PELS - TWAs</td>
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</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>0.5</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
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</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>1</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2</td>
</tr>
</tbody>
</table>

### HYDROCHLORIC ACID

<table>
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<tr>
<td>ACGIH Ceiling Threshold Limit:</td>
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</tr>
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</tr>
<tr>
<td>Belgium OEL - TWA</td>
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<tr>
<td>Bulgaria OEL - TWA</td>
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<td>Cyprus OEL - TWA</td>
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<td>Czech Republic OEL - TWA</td>
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<td>Estonia OEL - TWA</td>
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<td>Germany - TRGS 900 - TWAs</td>
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<tr>
<td>Germany (DFG) - MAK</td>
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<tr>
<td>Greece OEL - TWA</td>
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<td>Hungary OEL - TWA</td>
<td>8</td>
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<tr>
<td>Ireland OEL - TWAs</td>
<td>8</td>
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<td>Japan - OELs - Ceilings</td>
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<td>Latvia OEL - TWA</td>
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<td>Lithuania OEL - TWA</td>
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<td>Luxembourg OEL - TWA</td>
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<td>Portugal OEL - TWA</td>
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</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>8</td>
</tr>
</tbody>
</table>

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Material Name: Metoclopramide Injection (Hospira, Inc.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls:
Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:
Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:
Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid solution
Odor: No data available.
Molecular Formula: Mixture

Color: Clear, colorless
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)
Metoclopramide
No data available
Water for injection
No data available
Sodium chloride
No data available
Sodium hydroxide
No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

HYDROCHLORIC ACID

No data available

Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- Oxidizing Properties: None
- Conditions to Avoid: None known
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.
Known Clinical Effects: Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances. As with all antipsychotic agents, tardive dyskinesia may appear. This syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth, or jaw. Hypersensitivity reactions may also occur in susceptible individuals.

Acute Toxicity: (Species, Route, End Point, Dose)

Metoclopramide
- Rat Oral LD 50 750 mg/kg
- Mouse Oral LD 50 270 mg/kg
- Rat Intraperitoneal LD 50 114 mg/kg

Sodium chloride
- Rat Oral LD50 3000 mg/kg
- Mouse Oral LD50 4000 mg/kg

Sodium hydroxide

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11. TOXICOLOGICAL INFORMATION

**Irritation / Sensitization:** (Study Type, Species, Severity)

- Sodium chloride
  - Eye Irritation: Rabbit, Moderate
  - Skin Irritation: Rabbit, Mild

- Sodium hydroxide
  - Eye Irritation: Rabbit, Severe
  - Skin Irritation: Rabbit, Severe

**Reproduction & Developmental Toxicity:** (Study Type, Species, Route, Dose, End Point, Effect(s))

- **Metoclopramide**
  - Embryo / Fetal Development: Rat, Oral, 10 mg/kg/day, NOEL, Not teratogenic
  - Embryo / Fetal Development: Rabbit, Oral, 10 mg/kg/day, NOEL, Not Teratogenic
  - Embryo / Fetal Development: Mouse, Oral, 10 mg/kg/day, NOEL, Not Teratogenic
  - Embryo / Fetal Development: Rabbit, Intravenous, 10 mg/kg, NOEL, Not Teratogenic

- **Genetic Toxicity:** (Study Type, Cell Type/Organism, Result)
  - HYDROCHLORIC ACID
    - Bacterial Mutagenicity (Ames): Salmonella, Negative
    - In Vivo Micronucleus: Rat, Negative

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

**HYDROCHLORIC ACID**

**IARC:** Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Metoclopramide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 3
- Schedule 4
- EU EINECS/ELINCS List: 206-662-9

Water for injection
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 231-791-2

Sodium chloride
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-598-3

Sodium hydroxide
- CERCLA/SARA 313 Emission reporting: Not Listed
15. REGULATORY INFORMATION

| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 1000 lb |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |
| EU EINECS/ELINCS List | 215-185-5 |

**HYDROCHLORIC ACID**

| CERCLA/SARA 313 Emission reporting | 1.0 % |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 5000 lb |
| CERCLA/SARA - Section 302 Extremely Hazardous TPQs | 2270 kg |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 500 lb |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |
| EU EINECS/ELINCS List | 231-595-5 |

16. OTHER INFORMATION

**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
- Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
- Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

**Data Sources:** Safety data sheets for individual ingredients. Publicly available toxicity information.

**Revision date:** 04-Jan-2017

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet