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

Product Identifier

Material Name: Palonosetron Injection (Hospira, Inc.)
Trade Name: Palonosetron Injection
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product for the treatment of 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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Non-hazardous 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
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>
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</thead>
<tbody>
<tr>
<td>Palonosetron hydrochloride</td>
<td>135729-62-3</td>
<td>Not Listed</td>
<td>Acute Tox. 4 (H302)</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>
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<tr>
<td>Citric acid monohydrate</td>
<td>5949-29-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Sodium citrate, dihydrate</td>
<td>6132-04-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
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<tr>
<td>Disodium EDTA (dihydrate)</td>
<td>6381-92-6</td>
<td>Not Listed</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: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

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 Identification and/or Section 11 - Toxicological Information.

Medical Conditions: None known

Aggravated by Exposure: None

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Water, dry powder or foam extinguishers are recommended.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.
SAFETY DATA SHEET

Material Name: Palonosetron Injection (Hospira, Inc.)
Revision date: 14-Dec-2017

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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. Cleanup 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 hands and any exposed skin after removal of PPE. 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 drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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 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
Latvia OEL - TWA 0.5 mg/m³
OSHA - Final PELS - TWAs: 2 mg/m³
Poland OEL - TWA 0.5 mg/m³
Slovakia OEL - TWA 2 mg/m³
Slovenia OEL - TWA 2 mg/m³
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### HYDROCHLORIC ACID

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden OEL - TWAs</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>ACGIH Ceiling Threshold Limit:</td>
<td>2 ppm</td>
</tr>
<tr>
<td>Australia PEAK</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Belgium OEL - TWA</td>
<td>5 ppm</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
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</tr>
<tr>
<td></td>
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<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm</td>
</tr>
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<td></td>
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</tr>
<tr>
<td>Germany (DFG) - MAK</td>
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<tr>
<td></td>
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<tr>
<td>Greece OEL - TWA</td>
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<td></td>
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<tr>
<td>Hungary OEL - TWA</td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
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</tr>
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<td>Latvia OEL - TWA</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Lithuania OEL - TWA</td>
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<tr>
<td></td>
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<tr>
<td>Luxembourg OEL - TWA</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Netherlands OEL - TWA</td>
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<tr>
<td>Poland OEL - TWA</td>
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<tr>
<td>Portugal OEL - TWA</td>
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</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
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<td>Romania OEL - TWA</td>
<td>5 ppm</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Slovakia OEL - TWA</td>
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<tr>
<td></td>
<td>8.0 mg/m³</td>
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<tr>
<td>Slovenia OEL - TWA</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
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<tr>
<td></td>
<td>7.6 mg/m³</td>
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<td>Switzerland OEL - TWAs</td>
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<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Palonosetron hydrochloride
Pfizer Occupational Exposure Band (OEB):

OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

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: Solution
Color: Colorless
Odor: No data available
Odor Threshold: No data available
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 3.3 - 4.0
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value) No data available
Water for Injection No data available
Citric acid monohydrate No data available
Sodium citrate, dihydrate No data available
Palonosetron hydrochloride
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Disodium EDTA (dihydrate)
No data available

HYDROCHLORIC ACID
No data available

SODIUM HYDROXIDE
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: No data available
 Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
 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: Active ingredient may be harmful if swallowed. May cause irritation (based on components).
Long Term: May cause effects on central nervous system through prolonged or repeated exposure.
Known Clinical Effects: Adverse effects associated with therapeutic use include headache, and constipation. May cause irregular heartbeat (cardiac arrhythmia), hypersensitivity reactions.

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

Palonosetron hydrochloride
Rat Oral LD50 500 mg/kg

HYDROCHLORIC ACID
Rat Oral LD50 238-277 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)
11. TOXICOLOGICAL INFORMATION

Citric acid monohydrate
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Palonosetron hydrochloride
Fertility  Rat  Oral30 mg/kg/day  NOAEL  Fertility
Embryo / Fetal Development  Rat  Oral 18 mg/kg/day  NOAEL  Fetotoxicity
Reproductive & Fertility  Rat  Oral 60 mg/kg/day  NOEL  No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Palonosetron hydrochloride
In Vitro  Bacterial Mutagenicity (Ames)  Not specified  Negative
In Vivo  Unscheduled DNA Synthesis  Rat Hepatocyte  Negative
In Vivo  Micronucleus  Mouse  Negative
In Vitro  Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Positive

HYDROCHLORIC ACID
Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vivo  Micronucleus  Rat  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Palonosetron hydrochloride
104 Week(s)  Rat  Oral 60 mg/kg/day  NOAEL  Not carcinogenic

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:  The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below.

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

Citric acid monohydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

Sodium citrate, dihydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

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:
  - EU EINECS/ELINCS List: 231-791-2

Palonosetron hydrochloride
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
**15. REGULATORY INFORMATION**

<table>
<thead>
<tr>
<th>Standard for the Uniform Scheduling for Drugs and Poisons:</th>
<th>Schedule 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU EINECS/ELINCS List</td>
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</table>

**SODIUM HYDROXIDE**

<table>
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<tr>
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<td>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</td>
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<td>215-185-5</td>
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**Disodium EDTA (dihydrate)**

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</thead>
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<td>Australia (AICS):</td>
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</tr>
<tr>
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</table>

**HYDROCHLORIC ACID**

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<th>1.0 %</th>
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<td>CERCLA/SARA - Section 302 Extremely Hazardous TPQs</td>
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</tr>
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<td>California Proposition 65</td>
<td>Not Listed</td>
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<tr>
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<td>Schedule 5</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>231-595-7</td>
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</table>

**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

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

**Revision date:** 14-Dec-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