SAFETY DATA SHEET

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

Product Identifier

Material Name: Fentanyl Citrate Injection (Hospira Inc.)
Trade Name: Not established
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as analgesic anesthetic agent

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

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

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
### 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROCHLORIC ACID</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Skin Corr.1B (H314) STOT SE 3 (H335)</td>
<td>**</td>
</tr>
<tr>
<td>Fentanyl Citrate</td>
<td>990-73-8</td>
<td>213-588-0</td>
<td>Acute Tox.2 (H300) Repr.2 (H361fd)</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr.1A (H314)</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 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:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Not applicable

**Advice for Fire-Fighters**

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**
6. ACCIDENTAL RELEASE MEASURES

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
Restrict access to work area. 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 drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
Austria OEL - MAKs 5 ppm
Belgium OEL - TWA 8 mg/m³
Bulgaria OEL - TWA 5 ppm
8 ppm
8 mg/m³
Cyprus OEL - TWA 5 ppm
8 mg/m³
Czech Republic OEL - TWA 8 mg/m³
Estonia OEL - TWA 5 ppm
8 mg/m³
Germany - TRGS 900 - TWAs 2 ppm
3 mg/m³
Germany (DFG) - MAK 2 ppm
3.0 mg/m³
Greece OEL - TWA 5 ppm
7 mg/m³
Hungary OEL - TWA 8 mg/m³
Ireland OEL - TWAs 5 ppm
8 mg/m³

Material Name: Fentanyl Citrate Injection (Hospira Inc.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country/Boundaries</th>
<th>OEL - TWAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 ppm 3.0 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>5 ppm 8.0 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 ppm 7.6 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL-TWAs</td>
<td>2 ppm 3.0 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

Sodium hydroxide

<table>
<thead>
<tr>
<th>OEL Type</th>
<th>OEL Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Ceiling Threshold Limit</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Australia PEAK</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>2.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

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.

Fentanyl Citrate
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). 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 disposable gloves (e.g. Nitrile, etc.) (double 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:
Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Solution</th>
<th>Color:</th>
<th>No data available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
<td>Water Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available.</td>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available.</td>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Fentanyl Citrate No data available</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>No data available</td>
<td>HYDROCHLORIC ACID</td>
<td>No data available</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>No data available</td>
<td>Decomposition Temperature (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
<td>Relative Density:</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity:</td>
<td>No data available</td>
<td>Flammability:</td>
<td>No data available</td>
</tr>
</tbody>
</table>

PZ03031
SAFETY DATA SHEET

Material Name: Fentanyl Citrate Injection (Hospira Inc.)
Revision date: 15-Aug-2016

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: Not determined
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: May be absorbed through the skin and cause systemic effects. May be fatal if swallowed (based on components). Use of this drug is habit forming. Addiction may occur.
Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Animal studies indicate that this material may cause adverse effects on the reproductive system.
Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

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

Fentanyl Citrate
Rat Oral LD50 18 mg/kg
Rat Para-periosteal LD50 990ug/kg
Rat Intraperitoneal LD50 2070ug/kg
Mouse Oral LD50 368mg/kg
Mouse Intravenous LD50 10100ug/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))
11. TOXICOLOGICAL INFORMATION

Fentanyl Citrate
Reproductive & Fertility Rat Subcutaneous 1.25 mg/kg/day LOAEL Fertility
Reproductive & Fertility Rat Intravenous 30 ug/kg LOAEL Fertility, Embryotoxicity
Reproductive & Fertility Rat Subcutaneous 160 ug/kg LOAEL Fertility, Embryotoxicity
Embryo / Fetal Development Rat Oral 500 ug/kg NOAEL Not Teratogenic

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

Fentanyl Citrate
Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Negative
In Vivo Micronucleus Mouse Negative

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 thoroughly 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.
SAFETY DATA SHEET

Material Name: Fentanyl Citrate Injection (Hospira Inc.)
Revision date: 15-Aug-2016
Version: 1.2

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

HYDROCHLORIC ACID
- CERCLA/SARA 313 Emission reporting: 1.0 %
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - 5000 lb
  - 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:
  - 231-595-7

Fentanyl Citrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- U.S. Drug Enforcement Administration:
  - Schedule II Controlled Substance
- Australia (AICS):
  - Present
- EU EINECS/ELINCS List:
  - 213-588-0

Sodium hydroxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - 1000 lb
  - 454 kg
- 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
  - Schedule 6
- EU EINECS/ELINCS List:
  - 215-165-5

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Acute toxicity, oral-Cat.2; H300 - Fatal 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: Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 15-Aug-2016
Prepared by: Product Stewardship Hazard Communication

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