SAFETY DATA SHEET

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

Product Identifier

Material Name: Sufentanil Citrate Injection, USP CII (Hospira Inc.)
Trade Name: Sufentanil Citrate Injection, USP CII
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product used as analgesic

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

Emergency telephone number:
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: 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: Sufentanil Citrate Injection, USP CII (Hospira Inc.)
Revision date: 22-May-2018

Version: 1.1

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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<tbody>
<tr>
<td>Sufentanil Citrate</td>
<td>60561-17-3</td>
<td>262-295-4</td>
<td>Acute Tox 2 (H300)2 (H361d)</td>
<td>0.005</td>
</tr>
<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>
<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: Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.

Skin Contact: Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

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: Move to fresh air If discomfort occurs, get medical attention.

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

Advice for Fire-Fighters
SAFETY DATA SHEET

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
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.

**HYDROCUTIC ACID**

**ACGIH Ceiling Threshold Limit:** 2 ppm
**Australia PEAK**
5 ppm
7.5 mg/m³
**Austria OEL - MAKs**
5 ppm
8 mg/m³
**Belgium OEL - TWA**
5 ppm
8 mg/m³
**Bulgaria OEL - TWA**
5 ppm
8.0 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

PZ03109
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Unit</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Greece OEL - TWA</td>
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<td></td>
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<td>Ireland OEL - TWAs</td>
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### SODIUM HYDROXIDE

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<tr>
<th>Country</th>
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<tr>
<td></td>
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<tr>
<td></td>
<td>mg/m³</td>
<td>2</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.

**Sufentanil Citrate**

Pfizer Occupational Exposure Band (OEB): OEB 5 (control exposure to <1ug/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. It is recommended that all operations be fully enclosed and no air recirculated.

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

**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:** Impervious disposable 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 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

**Physical State:** Liquid

**Odor:** No data available.

**Molecular Formula:** Mixture

**Color:** Colorless

**Odor Threshold:** No data available.

**Molecular Weight:** Mixture

**Solvent Solubility:** No data available

**Water Solubility:** Soluble

**pH:** 3.5-6

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available.

**Partition Coefficient:** (Method, pH, Endpoint, Value)

**HYDROCHLORIC ACID**

No data available

**SODIUM HYDROXIDE**

No data available

**Sufentanil Citrate**

No data available

**Water for Injection**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available
SAFETY DATA SHEET

Material Name: Sufentanil Citrate Injection, USP CII (Hospira Inc.)
Revision date: 22-May-2018

Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: 0.9961
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.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.
Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include drowsiness, nausea, decrease in blood pressure (hypotension), increase in blood pressure (hypertension), respiratory depression, musculoskeletal system rigidity, decreased heart rate (bradycardia).

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

HYDROCHLORIC ACID
- Rat Oral LD50 238-277 mg/kg

Sufentanil Citrate
- Rat IV LD50 17.9 mg/kg
- Mouse IV LD50 18.7 mg/kg
- Dog IV LD50 10.1-19.5 mg/kg

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

Sufentanil Citrate
- Embryo / Fetal Development Rat No route specified 2.5 times human dose LOAEL Embryotoxicity
- Embryo / Fetal Development Rabbit No route specified 2.5 times human dose LOAEL Embryotoxicity

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

HYDROCHLORIC ACID

PZ03109
11. TOXICOLOGICAL INFORMATION

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

PZ03109
15. REGULATORY INFORMATION

Sufentanil Citrate

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 262-295-4

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: 500 lb
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs: Not Listed
- 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

SODIUM HYDROXIDE

- CERCLA/SARA 313 Emission reporting: Not Listed
- 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

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
SAFETY DATA SHEET

Material Name: Sufentanil Citrate Injection, USP CII (Hospira Inc.)
Revision date: 22-May-2018

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
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Data Sources:
Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision:
Updated Section 5 - Fire Fighting Measures. Updated Section 10 - Stability and Reactivity.

Revision date:
22-May-2018

Prepared by:
Product Stewardship Hazard Communication
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