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

Product Identifier

Material Name: Meperidine Hydrochloride Injection, USP CII (for use with PCA) (Hospira Inc.)
Trade Name: Meperidine Hydrochloride Injection, USP CII
Chemical Family: Mixture

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
Reproductive Toxicity: Category 2

Label Elements

Signal Word: Warning
Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

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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

<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>ACETIC ACID</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>Skin Corr. 1A (H314)</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Flam. Liq. 3 (H226)</td>
<td></td>
</tr>
<tr>
<td>Meperidine Hydrochloride</td>
<td>50-13-5</td>
<td>200-013-3</td>
<td>Acute Tox 3 (H301)(H361d)</td>
<td>1</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary

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 eye(s) immediately with plenty of water. 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: 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.
SAFETY DATA SHEET

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5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

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
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 drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

ACETIC ACID

ACGIH Threshold Limit Value (TWA) 10 ppm
ACGIH Threshold Limit Value (STEL) 15 ppm
### EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Concentration 1</th>
<th>Concentration 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia STEL</td>
<td>15 ppm</td>
<td>37 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>25.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>5 ppm</td>
<td>13 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 ppm</td>
<td>13 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>25 mg/m³</td>
<td></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.

Meperidine Hydrochloride

Pfizer Occupational Exposure Band (OEB):

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

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
Odor: No data available.
Physical State: Solution
Odor: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture
Solvent Solubility: No data available
Water Solubility: No data available
pH: 3.5-6.0
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
Meperidine Hydrochloride No data available
Sodium Acetate No data available
ACETIC ACID No data available
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
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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: Not determined
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

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: Use of this drug is habit forming. Addiction may occur.
Long Term: Due to its pharmacological action, exposure to this compound may produce adverse effects on fetal development.
Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include lightheadedness, dizziness, sedation, sweating, nausea, vomiting, constipation, constriction of the pupil (miosis), respiratory depression, respiratory arrest, circulatory failure, symptoms of dependence/withdrawal.

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

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meperidine Hydrochloride</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>170 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>178mg/kg</td>
</tr>
<tr>
<td>Sodium Acetate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>3500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>4960mg/kg</td>
</tr>
<tr>
<td>ACETIC ACID</td>
<td>Mouse</td>
<td>Sub-tenon injection (eye)</td>
<td>LC 50</td>
<td>5620 ppm/1H</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>3310mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Dermal</td>
<td>LD 50</td>
<td>1060uL/kg</td>
</tr>
</tbody>
</table>

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

12. ECOLOGICAL INFORMATION

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

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

ACETIC ACID
Fathead Minnow NPDES LC-50 96 Hours 88 mg/L
Bluegill Sunfish NPDES LC-50 96 Hours 75 mg/L
Goldfish NPDES LC-50 24 Hours 423 mg/L

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

PZ03106
15. REGULATORY INFORMATION

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 |

ACETIC ACID

| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 5000 lb |
| California Proposition 65          | 2270 kg |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS):                  | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 2 |
| EU EINECS/ELINCS List              | 200-580-7 |

Sodium Acetate

| 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              | 204-823-8 |

Meperidine Hydrochloride

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65          | Not Listed |
| EU EINECS/ELINCS List              | 200-013-3 |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Flammable liquids-Cat.3; H226 - Flammable liquid and vapor
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

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

Revision date: 09-Aug-2016

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