SAFETY DATA SHEET

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

Product Identifier

Material Name: Bumetanide Injection, USP (Hospira Inc.)
Trade Name: Bumetanide Injection, USP
Chemical Family: Sulfonamide

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

Intended Use: Pharmaceutical product used as diuretic

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

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

Note: No data available
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>Bumetnide</td>
<td>28395-03-1</td>
<td>249-004-6</td>
<td>Not Listed</td>
<td>0.025</td>
</tr>
</tbody>
</table>

PZ03077
SAFETY DATA SHEET

Material Name: Bumetanide Injection, USP (Hospira Inc.)
Revision date: 25-Jul-2016

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>SODIUM HYDROXIDE</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr. 1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>Edetate disodium</td>
<td>139-33-3</td>
<td>205-358-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>BENZYL ALCOHOL</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Acute Tox. 4 (H302)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4 (H332)</td>
<td>1</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: 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. 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.
Incompatible Materials: None known
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
Sweden OEL - TWAs 1 mg/m³
Switzerland OEL - TWAs 2 mg/m³

SODIUM CHLORIDE
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**BENZYL ALCOHOL**

<table>
<thead>
<tr>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer OEL TWA-8 Hr</td>
<td>10 ppm</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>40 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>45 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>240 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.

**Bumetanide**

**Pfizer Occupational Exposure Band (OEB):** OEB 4 (control exposure to the range of 1ug/m³ to <10ug/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 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>Soluble</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Bumetanide</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Decomposition Temperature (°C):</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENZYL ALCOHOL</td>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
</tr>
<tr>
<td>Edetate disodium</td>
<td>Relative Density:</td>
<td>No data available</td>
</tr>
<tr>
<td>SODIUM HYDROXIDE</td>
<td>Viscosity:</td>
<td>No data available</td>
</tr>
<tr>
<td>Ammonium Acetate</td>
<td>Flammability:</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity:</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Stability:</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td>None</td>
</tr>
<tr>
<td>Oxidizing Properties:</td>
<td>None known</td>
</tr>
<tr>
<td>Conditions to Avoid:</td>
<td>None known</td>
</tr>
<tr>
<td>Incompatible Materials:</td>
<td>None known</td>
</tr>
<tr>
<td>Hazardous Decomposition Products:</td>
<td>Thermal decomposition products include oxides of carbon, nitrogen, and sulfur.</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include muscle cramps, headache, dizziness, nausea, decrease in blood pressure (hypotension).

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

<table>
<thead>
<tr>
<th>Rat</th>
<th>Oral</th>
<th>LD50</th>
<th>&gt; 6000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>4625mg/kg</td>
</tr>
</tbody>
</table>

PZ03077
11. TOXICOLOGICAL INFORMATION

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

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

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

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

**Carcinogen Status:**

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

12. ECOLOGICAL INFORMATION

**Environmental Overview:**

Environmental properties have not been investigated.

**Toxicity:**

**Aquatic Toxicity:** (Species, Method, End Point, Duration, Result)
SAFETY DATA SHEET

Material Name: Bumetanide Injection, USP (Hospira Inc.)
Revision date: 25-Jul-2016

Version: 1.0

BENZYL ALCOHOL
Fathead Minnow NPDES LC-50 96 Hours 460 - 770 mg/L
Bluegill NPDES LC-50 96 Hours 10 mg/L
Daphnia Magna (Water Flea) Surrogate ErC50 48 Hours 23 - 400 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

Bumetnide
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List 249-004-6

Ammonium Acetate
CERCLA/SARA 313 Emission reporting Not Listed

PZ03077
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Hydroxide</td>
<td>Not Listed</td>
<td>5000 lb</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>211-162-9</td>
</tr>
<tr>
<td>Edetate disodium</td>
<td>Not Listed</td>
<td>1000 lb</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>205-358-3</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>Not Listed</td>
<td>454 kg</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-791-2</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

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

Material Name: Bumetanide Injection, USP (Hospira Inc.)
Revision date: 25-Jul-2016

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

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

Revision date:
25-Jul-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