# SAFETY DATA SHEET



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

**Product Identifier**

**Material Name: Furosemide Injection (Hospira, Inc.)**

**Trade Name:** Not established
**Chemical Family:** Not determined

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

**Intended Use:** Pharmaceutical active

**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**

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

**Hospira UK Limited**
**Horizon**
**Honey Lane**
**Hurley**
**Maidenhead, SL6 6RJ**
**United Kingdom**
**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
P281 - Use personal protective equipment as required
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

**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**

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|---|---|---|---|---|
| Furosemide | 54-31-9 | 200-203-6 | Repr. 2 (H361d) | 1 |
| HYDROCHLORIC ACID | 7647-01-0 | 231-595-7 | Skin Corr.1B (H314)<br>STOT SE 3 (H335) | ** |
| SODIUM HYDROXIDE | 1310-73-2 | 215-185-5 | Skin Corr. 1A (H314) | ** |

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|---|---|---|---|---|
| Water for Injection | 7732-18-5 | 231-791-2 | Not Listed | * |

**Additional Information:**
* Proprietary
** to adjust pH
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

**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:** May include oxides of nitrogen and sulfur and products of chlorine

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

**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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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 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**

**HYDROCHLORIC ACID**
**ACGIH Ceiling Threshold Limit:** 2 ppm

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| **Australia PEAK** | 5 ppm<br>7.5 mg/m$^3$ |
| **Austria OEL - MAKs** | 5 ppm<br>8 mg/m$^3$ |
| **Belgium OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Bulgaria OEL - TWA** | 5 ppm<br>8.0 mg/m$^3$ |
| **Cyprus OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Czech Republic OEL - TWA** | 8 mg/m$^3$ |
| **Estonia OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Germany - TRGS 900 - TWAs** | 2 ppm<br>3 mg/m$^3$ |
| **Germany (DFG) - MAK** | 2 ppm<br>3.0 mg/m$^3$ |
| **Greece OEL - TWA** | 5 ppm<br>7 mg/m$^3$ |
| **Hungary OEL - TWA** | 8 mg/m$^3$ |
| **Ireland OEL - TWAs** | 5 ppm<br>8 mg/m$^3$ |
| **Italy OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Japan - OELs - Ceilings** | 2 ppm<br>3.0 mg/m$^3$ |
| **Latvia OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Lithuania OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Luxembourg OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Malta OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Netherlands OEL - TWA** | 8 mg/m$^3$ |
| **Poland OEL - TWA** | 5 mg/m$^3$ |
| **Portugal OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Romania OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Slovakia OEL - TWA** | 5 ppm<br>8.0 mg/m$^3$ |
| **Slovenia OEL - TWA** | 5 ppm<br>8 mg/m$^3$ |
| **Spain OEL - TWA** | 5 ppm<br>7.6 mg/m$^3$ |
| **Switzerland OEL -TWAs** | 2 ppm<br>3.0 mg/m$^3$ |
| **Vietnam OEL - TWAs** | 5 mg/m$^3$ |

**SODIUM HYDROXIDE**

| | |
|---|---|
| **ACGIH Ceiling Threshold Limit:** | 2 mg/m$^3$ |
| **Australia PEAK** | 2 mg/m$^3$ |
| **Austria OEL - MAKs** | 2 mg/m$^3$ |

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| **Bulgaria OEL - TWA** | 2.0 mg/m$^3$ |
| **Czech Republic OEL - TWA** | 1 mg/m$^3$ |
| **Estonia OEL - TWA** | 1 mg/m$^3$ |
| **France OEL - TWA** | 2 mg/m$^3$ |
| **Greece OEL - TWA** | 2 mg/m$^3$ |
| **Hungary OEL - TWA** | 2 mg/m$^3$ |
| **Japan - OELs - Ceilings** | 2 mg/m$^3$ |
| **Latvia OEL - TWA** | 0.5 mg/m$^3$ |
| **OSHA - Final PELS - TWAs:** | 2 mg/m$^3$ |
| **Poland OEL - TWA** | 0.5 mg/m$^3$ |
| **Slovakia OEL - TWA** | 2 mg/m$^3$ |
| **Slovenia OEL - TWA** | 2 mg/m$^3$ |
| **Sweden OEL - TWAs** | 1 mg/m$^3$ |
| **Switzerland OEL -TWAs** | 2 mg/m$^3$ |

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.

**Furosemide**

**Pfizer Occupational Exposure Band (OEB):** OEB 3 (control exposure to the range of 10ug/m$^3$ to < 100ug/m$^3$)

**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:** | No data available. |
| **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:** 9.0 (8.0-9.3)
**Melting/Freezing Point (°C):** No data available
**Boiling Point (°C):** No data available.
**Partition Coefficient: (Method, pH, Endpoint, Value)**
**Furosemide**
No data available
**SODIUM HYDROXIDE**
No data available
**HYDROCHLORIC ACID**
No data available
**Water for Injection**
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

**Flammablity:**
- **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

**Polymerization:** No data available

## 10. STABILITY AND REACTIVITY

**Reactivity:** No data available
**Chemical Stability:** Stable at normal conditions
**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**
**Short Term:** Ingestion may cause lowering of blood pressure. Accidental or incidental ingestion of large amounts may cause nausea, abdominal discomfort, headache or dizziness. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

## 11. TOXICOLOGICAL INFORMATION

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

**Furosemide**
Rat Oral LD 50 2600 mg/kg
Mouse Sub-tenon injection (eye) Minimum Symptomatic Dose 400mg/kg

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

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Furosemide**
13 Week(s) Rat Oral 300 mg/kg LOAEL
13 Week(s) Mouse Oral 600 mg/kg LOAEL
6 Month(s) Dog Oral 10 mg/kg/day LOAEL
2 Year(s) Rat Oral 30 mg/kg/day LOAEL

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Furosemide**
Reproductive & Fertility Rat Oral 2.9 mg/kg/day LOAEL Fertility
Embryo / Fetal Development Rabbit Oral 25 mg/kg LOAEL Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development Rat Oral 12.5 mg/kg/day LOAEL Teratogenic
Embryo / Fetal Development Mouse Oral 1250 mg/kg/day LOAEL Fetotoxicity, Teratogenic

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

**Furosemide**
Bacterial Mutagenicity (Ames) Negative
*In Vitro* Micronucleus Human Lymphocytes Positive
Mammalian Cell Mutagenicity Mouse Lymphoma Positive

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

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

**Furosemide**
2 Year(s) Male Rat Oral 15 mg/kg/day LOEL Tumors
104 Month(s) Female Mouse Oral 17.5 LOEL Tumors
2 Year(s) Female Rat Oral, in feed 700 ppm NOEL Not carcinogenic
104 Month(s) Male Mouse Oral, in feed 1400 ppm NOEL Not carcinogenic

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

**Furosemide**
**IARC:** Group 3 (Not Classifiable)

**HYDROCHLORIC ACID**
**IARC:** Group 3 (Not Classifiable)

## 11. TOXICOLOGICAL INFORMATION

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated.

**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.**

This material is not regulated for transportation / carriage.

## 15. REGULATORY INFORMATION

**Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

**Furosemide**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **Australia (AICS):** | Present |

## 15. REGULATORY INFORMATION

| | |
|---|---|
| **Standard for the Uniform Scheduling for Drugs and Poisons:** | Schedule 4 |
| **EU EINECS/ELINCS List** | 200-203-6 |

**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 |

**HYDROCHLORIC ACID**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | 1.0 % |
| **CERCLA/SARA Hazardous Substances and their Reportable Quantities:** | 5000 lb<br>2270 kg |
| **CERCLA/SARA - Section 302 Extremely Hazardous TPQs** | 500 lb |
| **CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs** | 5000 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<br>Schedule 6 |
| **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<br>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<br>Schedule 6 |
| **EU EINECS/ELINCS List** | 215-185-5 |

## 16. OTHER INFORMATION

**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
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:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** New data sheet.

**Revision date:** 31-Mar-2017

Product Stewardship Hazard Communication
**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**