SAFETY DATA SHEET

Product Name: Furosemide Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	Furosemide Injection
Synonyms	4-chloro-*N*-furfuryl-5-sulfamoylanthranilic acid

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Furosemide Injection is a solution containing furosemide, a loop diuretic with a rapid onset of action. It is used in the treatment of edema associated with heart failure, including pulmonary edema, with renal and hepatic disorders, and to treat hypertension. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the gastrointestinal system, nervous system, blood and kidneys.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	STOT – RE	2

Label Element(s)

Pictogram

Signal Word

Warning

Hazard Statement(s)

May cause damage to organs through prolonged or repeated exposure

Precautionary Statement(s)

Prevention

Do not breathe vapor or spray.
Wash hands thoroughly after handling.

Response

Get medical attention if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Furosemide
Chemical Formula $C_{12}H_{11}ClN_2O_5S$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Furosemide	1	54-31-9	CB2625000

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride. Contains sodium hydroxide and may contain hydrochloric acid for pH adjustment

4. FIRST AID MEASURES

Eye Contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/ supportive care as necessary.

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability None anticipated for this aqueous product.

Fire & Explosion Hazard None anticipated for this aqueous product.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required for hazard control under conditions of normal product use.

Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Furosemide	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

Respiratory Protection Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin Protection If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye Protection Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Furosemide Injection is a sterile solution intended for intramuscular or intravenous administration
Odor	NA
Odor Threshold	NA
pH	9.0 (8.0 to 9.3).
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Furosemide is a white to off-white odorless crystalline powder. It is practically insoluble in water, sparingly soluble in alcohol, freely soluble in dilute alkali solutions and insoluble in dilute acids
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), sulfur oxides (SOx), and hydrogen chloride.
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Furosemide	100	LD50	Oral	2600 2000 800 2000	mg/kg mg/kg mg/kg mg/kg	Rat Mouse Rabbit Dog
Furosemide	100	LD50	Intravenous	800 308 400 >400	mg/kg mg/kg mg/kg mg/kg	Rat Mouse Rabbit Dog

LD 50: Dosage that produces 50% mortality.

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. In clinical use, the most common adverse effect is fluid and electrolyte imbalance including hyponatremia, hypokalemia, and hypochloremic alkalosis, particularly after large doses or prolonged use. Signs of electrolyte imbalance include headache, hypotension, muscle cramps, dry mouth, thirst, weakness, lethargy, drowsiness, restlessness, oliguria, cardiac arrhythmias, pancreatitis, jaundice and other gastrointestinal disturbances. It may provoke hyperglycemia and glycosuria. Other adverse effects may include blurred vision, yellow vision, dizziness, headache, and orthostatic hypotension. Skin rashes and photosensitivity reactions may be severe; hypersensitivity reactions may include interstitial nephritis and vasculitis; fever has also been reported. Bone marrow depression may occur; there have been reports of agranulocytosis, thrombocytopenia, and leucopenia. Tinnitus and deafness may occur, in particular during rapid high-dose parenteral furosemide.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	None anticipated from normal handling of this product.
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. In clinical use, skin rashes and photosensitivity reactions may be severe; hypersensitivity reactions may include interstitial nephritis and vasculitis; fever has also been reported.

11. TOXICOLOGICAL INFORMATION: continued

Reproductive Effects

None anticipated from normal handling of this product. Furosemide produced no impairment of fertility in male or female rats, at 100 mg/kg/day (the maximum effective diuretic dose in the rat and 8 times the maximal human dose of 600 mg/day).

The effects of furosemide on embryonic and fetal development and on pregnant dams were studied in mice, rats and rabbits. Furosemide caused unexplained maternal deaths and abortions in the rabbit at the lowest dose of 25 mg/kg (2 times the maximal recommended human oral dose of 600 mg/day). In another study, a dose of 50 mg/kg (4 times the maximal recommended human oral dose of 600 mg/day) also caused maternal deaths and abortions when administered to rabbits between Days 12 and 17 of gestation. In a third study, none of the pregnant rabbits survived an oral dose of 100 mg/kg. Data from the above studies indicate fetal lethality that can precede maternal deaths. The results of the mouse study and one of the three rabbit studies also showed an increased incidence and severity of hydronephrosis (distention of the renal pelvis and, in some cases, of the ureters) in fetuses derived from treated dams as compared with the incidence in fetuses from the control group.

Furosemide has been shown to cause unexplained maternal deaths and abortions in rabbits at 2, 4, and 8 times the maximal recommended human oral dose. FDA Pregnancy Category C.

Mutagenicity

Furosemide was not mutagenic activity in various strains of *Salmonella typhimurium* when tested in the presence or absence of an *in vitro* metabolic activation system, and questionably positive for gene mutation in mouse lymphoma cells in the presence of rat liver S9 at the highest dose tested. Furosemide did not induce sister chromatid exchange in human cells *in vitro*, but other studies on chromosomal aberrations in human cells *in vitro* gave conflicting results. In Chinese hamster cells it induced chromosomal damage but was questionably positive for sister chromatid exchange. Studies on the induction by furosemide of chromosomal aberrations in mice were inconclusive. The urine of rats treated with this drug did not induce gene conversion in *Saccharomyces cerevisiae*.

Carcinogenicity

Furosemide was tested for carcinogenicity by oral administration in one strain of mice and one strain of rats. A small but significantly increased incidence of mammary gland carcinomas occurred in female mice at a dose 17.5 times the maximum human dose of 600 mg. There were marginal increases in uncommon tumors in male rats at a dosage of 15 mg/kg (slightly greater than the maximum human dose) but not at 30 mg/kg.

Carcinogen Lists

IARC: IARC Group 3 - Not classifiable as to carcinogenicity to humans.

NTP: Not listed

OSHA: Not listed

Specific Target Organ Toxicity – Single Exposure

NA

Specific Target Organ Toxicity – Repeat Exposure

Based on clinical use, possible target organs include the gastrointestinal system, nervous system, blood and kidneys.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Not determined for product.

Persistence/Biodegradability

Not determined for product.

Bioaccumulation

Not determined for product.

Mobility in Soil

Not determined for product.

Notes:

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt.
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

15. REGULATORY INFORMATION: continued

GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Do not breathe vapor or spray.
Wash hands thoroughly after handling.

Response

Get medical attention if you feel unwell

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s) NA
Symbol NA
Indication of Danger NA
Risk Phrases NA
Safety Phrases S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with eyes
S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

16. OTHER INFORMATION: continued

MSDS Coordinator: Hospira GEHS
Date Prepared: October 18, 2012
Date Revised: June 02, 2014

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