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Section 1 - Identification


- (a) **Product Identifier:** Furosemide Injection
- (b) **NDC:** 70860-302
- Common/Trade Name:** Furosemide Injection, LASIX®
- Chemical Name:** 4-chloro-N-furfuryl-5-sulfamoylanthranilic acid
- Chemical Family:** Diuretic: Anthranilic Acid Derivative
- (c) **Product Use:** Treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome.
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154


Section 2 - Hazards 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.

- (a) **Classification:** U.S. OSHA GHS Classification

	Hazard Class	Hazard Category
Physical Hazards	Not classified	Not classified
Health Hazards	STOT-RE	2

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
	<u>Signal Word:</u> Warning

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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Hazard Statements:</u>	May cause damage to organs through prolonged or repeated exposure
<u>Precautionary Statements:</u>	<p>Prevention Do not breathe vapor or spray. Wash hands thoroughly after handling.</p> <p>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.</p>

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Furosemide USP	Furosemide	10.0 mg/mL	54-31-9	N/A
Sodium chloride	Sodium Chloride	7.5 mg/mL	7647-14-5	N/A
Sodium hydroxide	Sodium hydroxide	q.s. to pH	1310-73-2	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s. to pH	7647-01-0	N/A
Water for Injection, USP	Water for Injection, USP	q.s. to 1mL	7732-18-5	N/A
Nitrogen	Nitrogen	q.s.	7727-37-9	N/A

Section 4 - First Aid Measures

Eye Exposure: 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.

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- Skin Exposure:** 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.
- Ingestion:** Remove from source of exposure. If 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.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

- (a) **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.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
- (b) **Hazardous Combustion Products:** Nitrogen oxides (NO_x)
Carbon oxides
Sulfur oxides
Chlorine compounds
- (c) **Special Protective Equipment / Precautions:** No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Section 6 - Accidental Release Measures

- Personal precautions, protective equipment and emergency procedures:** **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.

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Release to Air:

Avoid release to the environment.
 Prevent further leakage or spillage if safe to do so.
 Prevent spreading over a wide area (e.g., by containment or oil barriers).
 Retain and dispose of contaminated wash water.
 Local authorities should be advised if significant spillages cannot be contained.

Release to Water:

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Section 7 - Handling and Storage

General Handling:

Do not breathe mist or vapors.
 Do not swallow.
 Avoid contact with eyes.
 Avoid prolonged or repeated contact with skin.
 Wash skin thoroughly after handling.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
 Do not eat, drink or smoke when using this product.
 Take care to prevent spills, waste and minimize release to the environment.


Hygiene Measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

When using do not eat, drink or smoke.
 Wash contaminated clothing before re-use.
 The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage Conditions:

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature.]

Do not store with strong oxidizing agents, organic peroxides, explosives, or gasses.

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Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Furosemide	OSHA	PEL	NE
	ACGIH	TLV	NE
	AIHA	WEEL	

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

(b) Engineering Controls


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

(c) Individual Protection Measures

Respiratory Protection:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Eye Protection:	Safety goggles with side-shields or goggles.
Skin Protection:	Impervious clothing, uniform, or lab coat.
Other Protective Equipment:	Chemical resistant gloves.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Aqueous solution
(b)	Odor	N/A
(c)	Odor Threshold	N/A
(d)	pH	8.0-9.3
(e)	Melting Point:	N/A
(f)	Initial Boiling Point:	N/A
(g)	Flash Point	N/A

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(h)	Evaporation Rate:	N/A
(i)	Flammability	N/A
(j)	Upper Lower Flammability or Explosion Limits	N/A
(k)	Vapor Pressure:	N/A
(l)	Vapor Density:	N/A
(m)	Relative Density	N/A
(n)	Solubility(ies)	N/A
(o)	Partition Coefficient: n-octanol/water	N/A
(p)	Auto-ignition Temperature	N/A
(q)	Decomposition Temperature	N/A
(r)	Viscosity	N/A

Section 10 - Stability and Reactivity

(a)	Reactivity	Not classified as a reactivity hazard
(b)	Chemical Stability	Stable under standard use and storage conditions.
(c)	Possibility of Hazardous Reactions	Can react with strong oxidizers.
(d)	Conditions to Avoid	Strong oxidants.
(e)	Incompatible Materials	Strong acids/alkalis, strong oxidizing/reducing agents.
(f)	Hazardous Decomposition Products	No hazardous decomposition products are known.

Section 11 Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, Inhalation, skin, eye
(b)	Symptoms related to the physical, chemical and toxicological	None anticipated from normal handling of this product.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	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).


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	<p>Mutagenicity Furosemide was devoid of 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.</p> <p>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.</p>
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(d) Acute Toxicity

Product formulation is not classified based on available information. Information for the active ingredient is as follows:

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

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(e) Hazardous Chemical Listings

NTP: Not Listed **IARC:** Group 3 – Not classifiable

OSHA: Not Listed as to carcinogenicity to humans

Section 12 - Ecological Information

(a)	Ecotoxicity	No applicable ecological information found.
(b)	Persistence and degradability	No applicable ecological information found.
(c)	Bioaccumulative potential	No applicable ecological information found.
(d)	Mobility in soil	No applicable ecological information found.
(e)	Other Adverse Effects	No applicable ecological information found.

Section 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.

Contaminated packaging

Dispose of container and unused product in accordance with federal, state, and local regulations.

Section 14 - Transport Information


(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

IMDG: Not Regulated

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA – Exempt
 CERCLA - Not on this list
 SARA 313 - Not on this list
 SARA 302 – Not on this list
 RCRA listed – Not listed
 US PROP 65 (Calif.) – Not listed

Section 16 - Other Information


As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:


Athenex Pharmaceutical Division
 10 N. Martingale Road, Suite 230
 Schaumburg, IL 60173
 847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)

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CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity

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TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS047

Revision: 02

Title: Furosemide Injection

Effective Date: 21 Sep 2021

All dates and times are in Eastern Standard Time.

SDS Revision

Change Request

Name/Signature	Title	Date	Meaning/Reason
Emily Berdyck (EBERDYCK)	Quality Assurance Supervisor	20 Sep 2021, 02:00:30 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (EXT-JANDRE)	Regulatory Affairs Consultant	21 Sep 2021, 09:04:23 AM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Amy Diviak (AMYDIVIAK)	Quality Systems Director	21 Sep 2021, 11:15:40 AM	Approved

Review: SDS047 02 Furosemide Injection

Review

Name/Signature	Title	Date	Meaning/Reason
John Andre (EXT-JANDRE)	Regulatory Affairs Consultant	06 Sep 2022, 09:37:24 AM	Reviewed