
 <b>Pharmaceutical Division</b>	<b>Bumetanide Injection, USP</b>		<b>Safety Data Sheet (SDS)</b>	
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### Section 1 - Identification

- (a) **Product Identifier:** Bumetanide Injection, USP
- (b) **Product Code:** 70860-405  
70860-406
- Common/Trade Name:** Bumetanide Injection
- Chemical Name:** 3-(butylamino)-4-phenoxy-5-sulfamoylbenzoic acid
- Chemical Family:** Diuretic
- (c) **Product Use:** Pharmaceutical, Injectable
- 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

(a)	<b>Classification:</b>	Not Classified
(b)	<b>Signal Word:</b>	Not classified
	<b>Hazard Statement</b>	Not classified.
	<b>Symbols</b>	Not applicable
	<b>Precautionary Statement(s)</b>	Not applicable
(c)	<b>Description of Hazards</b>	None Known
(d)	<b>Unknown Acute Toxicity</b>	N/A

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### Section 3 – Composition / Information on Ingredients


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
3-(butylamino)-4-phenoxy-5-sulfamoylbenzoic acid	Bumetanide, USP	0.25 mg/mL	28395-03-1	N/A
Sodium Chloride	Sodium Chloride	8.5 mg/mL	7647-14-5	N/A
Ammonium Acetate	Ammonium Acetate	4 mg/mL	631-61-8	N/A
Edetate Disodium	Edetate Disodium	0.1 mg/mL	6381-92-6	N/A
Benzyl Alcohol	Benzyl Alcohol	0.01 mL/mL	100-51-6	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s. to pH	1310-73-2	N/A
Water for Injection	Water for Injection	q.s. to 1 mL	7732-18-5	N/A

### Section 4 – First Aid Measures

- Eye Exposure:** Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.
- Skin Exposure:** Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
- Ingestion:** Clean mouth with water and drink afterwards plenty of water
- Inhalation:** Move to fresh air. If discomfort occurs, get medical attention.
- Notes to Physician:** None.

### Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Dry chemical, CO<sub>2</sub>, alcohol-resistant foam or water spray.
- (b) **Hazardous Decomposition Products:** Decomposition products may include the following materials:  
carbon dioxide carbon monoxide

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- (c) **Special Protective Equipment / Precautions:** Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

### Section 6 - Accidental Release Measures

**Spill:** Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor.

**Release to Air:** No information available.

**Release to Water:** No information available.

### Section 7 - Handling and Storage


**General 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.  
**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

**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.] Protect from light.

### Section 8 - Exposure Controls / Personal Protection

- (a) **Exposure Limits:** None  
**Engineering Controls**

**Ventilation:** No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.


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**(b) Individual Protection Measures**

Respiratory Protection:	Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
Eye Protection:	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles.
Skin Protection:	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other Protective Equipment	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Section 9 - Physical and Chemical Properties**

<b>(a) Appearance</b>	Clear, colorless liquid
<b>(b) Odor</b>	Odorless
<b>(c) Odor Threshold</b>	Not available
<b>(d) pH</b>	6.8 to 7.8
<b>(e) Melting Point:</b>	Not available
<b>(f) Initial Boiling Point:</b>	Not available
<b>(g) Flash Point</b>	Not available
<b>(h) Evaporation Rate:</b>	Not available
<b>(i) Flammability</b>	Not available
<b>(j) Upper Lower Flammability or Explosion Limits</b>	Not available
<b>(k) Vapor Pressure:</b>	Not available
<b>(l) Vapor Density:</b>	Not available
<b>(m) Relative Density</b>	Not available
<b>(n) Solubility(ies)</b>	Soluble
<b>(o) Partition Coefficient: n-octanol/water</b>	Not available
<b>(p) Auto-ignition Temperature</b>	Not available
<b>(q) Decomposition Temperature</b>	Not available
<b>(r) Viscosity</b>	Not available

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### Section 10 - Stability and Reactivity

<b>(a) Reactivity</b>	No specific test data related to reactivity available for this product or its ingredients.
<b>(b) Chemical Stability</b>	The product is stable.
<b>(c) Possibility of Hazardous Reactions</b>	Under normal conditions of storage and use, hazardous reactions will not occur.
<b>(d) Conditions to Avoid</b>	Not established
<b>(e) Incompatible Materials</b>	Reactive or incompatible with the following materials: oxidizing materials and acids.
<b>(f) Hazardous Decomposition Products</b>	Under normal conditions of storage and use, hazardous decomposition products should not be produced.


### Section 11 - Toxicological Information

<b>(a) Likely Routes of Exposure</b>	Inhalation, skin and eye contact, and ingestion.
<b>(b) Symptoms related to the physical, chemical and toxicological characteristics</b>	<p><b>Eye contact:</b> No known significant effects or critical hazards.</p> <p><b>Inhalation:</b> No known significant effects or critical hazards.</p> <p><b>Skin contact:</b> No known significant effects or critical hazards</p> <p><b>Ingestion:</b> No known significant effects or critical hazards.</p>
<b>(c) Delayed and immediate effects and also chronic effects from short and long term exposure</b>	<p><b>Eye contact:</b> No known significant effects or critical hazards.</p> <p><b>Inhalation:</b> No known significant effects or critical hazards.</p> <p><b>Skin contact:</b> No known significant effects or critical hazards.</p> <p><b>Ingestion:</b> No known significant effects or critical hazards.</p>

**(c) Acute Toxicity**

Based on available data, the classification criteria are not met.

Component	Type	Route	Species	Dosage
Benzyl Alcohol	LD <sub>50</sub>	Oral	Rat	1230 mg/kg
	LD <sub>50</sub>	Dermal	Rabbit	2000 mg/kg

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**(d) Hazardous Chemical Listings**


NTP: Not Listed  
IARC: Not Listed  
OSHA: Not Listed

**Section 12 - Ecological Information**

<b>(a)</b>	<b>Ecotoxicity</b>	Aquatic Toxicity:				
		<b>Species</b>	<b>Method</b>	<b>End Point</b>	<b>Duration</b>	<b>Result</b>
		Fathead Minnow	NPDES	LC-50	96 hours	460-770mg/l
		Bluegill	NPDES	LC-50	96 hours	10mg/L
		<i>Daphnia Magna</i> (Water Flea)	Surrogate	ErC50	48 hours	23-400 mg/l
<b>(b)</b>	<b>Persistence and degradability</b>	There is no data available				
<b>(c)</b>	<b>Bioaccumulative potential</b>	There is no data available				
<b>(d)</b>	<b>Mobility in soil</b>	Not available				
<b>(e)</b>	<b>Other Adverse Effects</b>	There is no data available				

**Section 13 - Disposal Considerations**

**Waste Disposal:** The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

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**Section 14 - Transport Information**

DOT, IMDG and IATA Classification

(a)	<b>UN Number</b>	Not regulated
(b)	<b>UN Proper Shipping Name</b>	Not available
(c)	<b>Transport Hazard Class(es)</b>	Not available
(d)	<b>Packing Group</b>	Not available
(e)	<b>Environmental Hazards</b>	No.
(f)	<b>Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</b>	Not available
(g)	<b>Special Precautions</b>	<b>Transport within user's premises:</b> always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**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 – Not regulated
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 313 - Not on this list

**Section 16 - Other Information**

As of the date of effectiveness, 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


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**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
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
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
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted



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UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System