



300 Northfield Road  
 Bedford, OH 44146  
 Telephone: (440) 232-3320  
 -or- (800) 562-4797

**MATERIAL SAFETY DATA SHEET**

**Section I - IDENTITY**

**Common/Trade Name:** Bumetanide Injection, USP 0.5mg/2ml  
 1.0mg/4ml  
 2.5mg/10ml

**Chemical Names:** 3-(butylamino)-4-phenoxy-5-sulfamoylbenzoic acid

**Synonyms:** Bumex® Injection, Burine, Burinex, Segures, PF 1593, Fontego

**Manufacturer's Name:** BEN VENUE LABORATORIES, INC.

**Address:** 300 NORTHFIELD ROAD  
 BEDFORD, OH 44146

**Emergency Telephone Number:** Chemtrec: 1(800)424-9300

**Telephone Number for Info.:** (440)232-3320 or (800)562-4797

**Medical Emergency:** Professional Services 1(800)521-5169

**Date Prepared:** June 29, 1995

**Date Revised:** August 2, 2001

**Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION**

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Bumetanide	0.025	28395-03-1	NONE	NONE	NONE
Sodium Chloride	0.85	7647-14-5	10mg/m <sup>3</sup> total dust; 5mg/m <sup>3</sup> respirable dust		
Ammonium Acetate	0.4	631-61-8	NONE	NONE	NONE
Edetate Disodium	0.01	6381-92-6	NONE	NONE	NONE
Benzyl Alcohol	1.0	100516	NONE	NONE	NONE
Water for Injection	97.715	7732-18-5	NONE	NONE	NONE
Sodium Hydroxide for pH adjustment					

Bumetanide is a sterile injectable liquid drug provided in a vial.

**Section III - HEALTH HAZARD DATA**

**Route(s) of Entry:** Primary exposure routes are via inhalation and skin absorption.

**Health Hazard (Acute & Chronic):** Bumetanide is a drug used for the treatment of edema from congestive heart failure. Bumetanide affects the digestive and circulatory systems. May cause allergic reactions in persons hypersensitive to sulfonamides.

**Carcinogenicity:** NTP? NO IARC Monographs? None

OSHA Regulated? NO

**Signs & Symptoms of Exposure:** Possible irritation to eyes, skin, or respiratory tract or allergic reaction in persons sensitive to sulfonamides. Effects include dryness of mouth, increased thirst, irregular heartbeat, muscle cramps, nausea, vomiting, unusual tiredness, weakness or weak pulse.

**Medical Conditions Generally Aggravated by Exposure:** Kidney ailments or conditions may be aggravated.

**BVL Hazard Category:** 2

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#### **Section IV - FIRST AID MEASURES**

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**Eye Exposure:** Flush eyes with large volumes of water for 15 or more minutes.

**Skin Exposure:** Wash skin with cool soapy water for 15 minutes.

**Ingestion:** If ingestion occurs, flush mouth with water and seek medical attention immediately.

If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

**Inhalation:** If difficulty breathing, administer oxygen. Seek attention of a physician immediately.

If necessary, provide artificial respiration.

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#### **Section V - FIRE AND EXPLOSION HAZARD DATA**

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**Flash Point (Method Used):** Not applicable    **LEL:** Not Applicable    **UEL:** Not Applicable

**Flammable Limits:** Bumetanide Injection is not a flammable liquid.

**Extinguishing Media:** Use water or a type ABC multi-purpose extinguisher.

**Special Fire Fighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

**Unusual Fire/Explosion Hazards:** NONE

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#### **Section VI - ACCIDENTAL RELEASE INFORMATION**

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**Release to Land:** Absorb Bumetanide with sorbent materials and dispose of according to local, state and federal regulations.

**Release to Air:** If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation.

**Release to Water:** Refer to local water authority. Drain disposal is not recommended; however, refer to local, state, and federal disposal guidelines.

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#### **Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE**

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**Steps to be taken in case material is released or spilled:** See Section VI above. Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

**Waste Disposal Method:** Incineration in approved incinerator is recommended. Refer to local, state, and federal rules.

**Precautions to be taken in handling and storing:** Store vials at 59°- 86°F (15-° 30°C).

**Other Precautions:** None

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#### **Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT**

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**Respiratory Protection:** Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Ventilation:** Handle product in a well-ventilated area.

**Protective Gloves:** Latex or nitrile

**Eye Protection:** Safety glasses

**Other Protective Clothing or Equipment:** Lab Coat

**Work/Hygienic Practices:** Wash hands following use. No eating, drinking, or smoking while handling this product.

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## Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

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**Physical State:** Liquid

**Appearance and Odor:** Clear aqueous solution  
with no odor

**Boiling Point:** Not Available

**Vapor Pressure:** Not Available

**Vapor Density:** Not Available

**Specific Gravity:** Not Available

**Melting Point:** Not Applicable

**Evaporation Rate:** Not Available

**Solubility in Water:** Soluble

**pH:** 7

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## Section X - STABILITY AND REACTIVITY DATA

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**Stability:** Stable

**Incompatibility (Materials to Avoid):** Strong oxidizers and water reactive materials.

**Hazardous Decomposition or Byproducts:** May emit toxic fumes of sulfur dioxides and nitrogen dioxides when burned. As with any burning material, carbon monoxide, carbon dioxide and other toxic gases may be generated.

**Hazardous Polymerization:** Not known to occur

**Conditions to Avoid:** Storage with oxidizers and water reactive materials.

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## Section XI - TOXICOLOGICAL INFORMATION

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For active ingredient Bumetanide:

LD<sub>50</sub> oral mouse: 4624 mg/kg

LD<sub>50</sub> intraperitoneal mouse: 519 mg/kg

LD<sub>50</sub> intravenous mammal: 6.2 mg/kg

LD<sub>50</sub> oral, rat = >6 gm/kg

LD<sub>50</sub> intraperitoneal, rat = 891 mg/kg

LD<sub>50</sub> intravenous, rat = >200 mg/kg

LD<sub>50</sub> intramuscular, rat = >5 gm/kg

LD<sub>50</sub> subcutaneous, mouse = 1660 mg/kg

LD<sub>50</sub> intramuscular, mouse = >25 mg/kg

LD<sub>50</sub> subcutaneous, rat = >2 gm/kg

Additional toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

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## Section XII - ENVIRONMENTAL IMPACT INFORMATION

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Information is currently not available on the environmental impact of Bumetanide. Handle in a manner to prevent spills or releases to the environment.

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## Section XIII - DISPOSAL INFORMATION

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Dispose of by incineration at an approved/permitted incinerator.

Review local, state, and federal regulations for your regulatory area.

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**Section XIV - TRANSPORTATION INFORMATION**

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Bumetanide Injection is not a DOT Hazardous Material.  
Bumetanide is not a Marine Pollutant

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**Section XV - REGULATORY INFORMATION**

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SARA 313 listed?: NO  
CERCLA listed?: NO  
RCRA listed?: NO

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**Section XVI - OTHER DATA**

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1. Use of this product should be through or under the direction of a physician.  
This MSDS does not address the therapeutic use of this material.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.