

Material Name: BUMEX(R) Tablets (0.5 mg)
Material Code: 72901
MSDS Number .: m-009613.asc

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Approved: 05/26/95

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MATERIAL SAFETY DATA SHEET

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Material Name: BUMEX(R) Tablets (0.5 mg)
Inventory Code: 72901
TSCA Status: FDA Exemption - Not on Inventory.
Therapeutic Category: Diuretic

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name	CAS Number	Concentration %
Starch	9005-25-8	42 Aprox.
Talc	14807-96-6	3 Aprox.
Cellulose, microcrystalline NF	9004-34-6	27 Aprox.
Bumetanide	28395-03-1	0.3-0.6

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Physical State: Tablets/Capsules.
Color: Light green (0.5 mg), yellow (1 mg), peach (2 mg)
Odor: Odorless

POTENTIAL HEALTH EFFECTS

Relevant Routes of
Exposure: Ingestion.
Target Organs: Hematopoietic/ Blood System, Renal System.

Acute Effects

General: May cause headaches. May cause renal (kidney) system effects such as urine retention, increase or decrease in urine production, painful urination, and presence of blood in urine. May cause blood system changes. May cause respiratory effects such as difficulty in breathing, coughing, wheezing, irritation (inflammation) and respiratory arrest.
Eye: May cause eye irritation.

Chronic Effects

General: May decrease blood pressure. May cause muscle weakness and pain.

Carcinogenicity: Not listed by NTP, IARC, or OSHA.

SECTION 3. HAZARDS IDENTIFICATION (Continued. . .)

Conditions

Aggravated: Hypersensitivity to this material and other materials in its chemical class. Liver conditions and/or impaired liver function. Kidney conditions and/or impaired renal function. Respiratory system conditions.

Additional Health

Hazard Information .: Individuals taking beta-adrenergic blocking medication (antihypertensives) should avoid exposure to this material.

SECTION 4. FIRST AID MEASURES

Inhalation: Remove to fresh air. If discomfort occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and shoes. Wash skin with soap and plenty of water. If irritation occurs or persists, get medical attention. Wash clothing and shoes before reuse.

Eye Contact: Immediately flush eyes with plenty of water. If irritation occurs or persists, get medical attention.

Ingestion: If large quantities of this material are swallowed, get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 5. FIRE FIGHTING MEASURES

Flash Point: Not Applicable

Extinguishing Media : Water, Carbon Dioxide, Dry Chemical, Foam.

Unusual Fire and

Explosion Hazards ..: Toxic emissions may be given off in a fire.

Fire Fighting

Instructions: Wear NIOSH/MSHA approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire. Use water to keep fire exposed containers cool.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Spill Clean Up

Procedures: Use proper personal protective equipment and clothing specified in Section 8-Exposure Controls/Personal Protection. Shut off the source of the spill or leak if it is safe to do so. Scoop or shovel spilled material into a suitable labeled open head drum. Secure the drum cover and move the container to a safe holding area. Wash spill area thoroughly with soapy water.

SECTION 6. ACCIDENTAL RELEASE MEASURES (Continued. . .)

Treatment and Disposal: Decontaminate equipment. Dispose of protective clothing with the spilled material. Dispose of in accordance with recommendations in Section 13 Disposal Considerations.

Reporting Requirements: The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials. State and local regulations vary and may impose additional reporting requirements.

SECTION 7. HANDLING AND STORAGE

Storage Temperature (min/max): 15-30 C

Handling & Storage

Precautions: Avoid contact with eyes.
Avoid breathing dust.
Use with adequate ventilation.
When handling, use proper personal protective equipment specified in section 8.
Wash thoroughly after handling.
Keep container tightly closed when not in use.
Store in a dry area at room temperature.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS

Ventilation: General room ventilation is adequate unless the process generates airborne dust or fume.

PERSONAL PROTECTION

Respirator Type(s) ..: None Recommended.

Conditions for Use ..: Under normal conditions of use, respiratory protection is not expected to be necessary. OSHA considers effective engineering controls to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. Whenever respiratory protection is used, a complete respirator program should be developed in accordance with OSHA Subpart I (29CFR1910.134) requirements.

Glove Materials: Any plastic or rubber glove.

Conditions for Use ..: Gloves are required if there is a potential for skin contact.

Skin Protection: None required under normal and foreseeable conditions of use. Consult the protective clothing manufacturer, supplier and/or industrial hygienist.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION (Continued. . .)

Eye Protection: Safety Glasses Required, Safety Goggles Recommended.

OTHER CONTROL MEASURES

Additional

Protective Measures : Work clothing should be removed in a changeroom on site and laundered professionally. Employees should shower and change into street clothes before leaving the facility. Provide safety showers and eyewash stations in the work area. Prevent the accumulation of dust in the work area by thorough periodic cleaning of the area.

EXPOSURE LIMITS

Starch

ACGIH TLV: 10.0 mg/m3 Time Weighted Average.
OSHA PEL: 5.00 mg/m3 Time Weighted Average, Respirable Fraction.
OSHA PEL: 15.0 mg/m3 Time Weighted Average, Total Dust.
NIOSH REL: 5.00 mg/m3 Time Weighted Average, Respirable Fraction.
NIOSH REL: 10.0 mg/m3 Time Weighted Average, Total Dust.

Talc

ACGIH TLV: 2.00 mg/m3 Time Weighted Average, Respirable Fraction.
OSHA PEL: 2.00 mg/m3 Time Weighted Average, Respirable Fraction.
NIOSH REL: 2.00 mg/m3 Time Weighted Average, Respirable Fraction.

Cellulose, microcrystalline NF

NIOSH REL: 5.00 mg/m3 Time Weighted Average, Respirable Fraction.
NIOSH REL: 10.0 mg/m3 Time Weighted Average, Total Dust.
OSHA PEL: 5.00 mg/m3 Time Weighted Average, Respirable Fraction.
OSHA PEL: 15.0 mg/m3 Time Weighted Average, Total Dust.
ACGIH TLV: 10.0 mg/m3 Time Weighted Average.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablets/Capsules.
Color: Light green (0.5 mg), yellow (1 mg), peach (2 mg)
Odor: Odorless
Pure/Mixture: Mixture.

SECTION 10. STABILITY AND REACTIVITY

Stability: Normally stable even under fire exposure conditions and not water reactive

Incompatibility -
Materials to Avoid .: Unknown.
Polymerization: No
Conditions of
Polymerization: Will not occur.

SECTION 11. TOXICOLOGICAL INFORMATION

Bumetanide

Irritation Eye, Rabbit

Summary: An eye irritation study with New Zealand white rabbits produced scores of 14.2, 4.7, 1.0 and 0.0 at 1, 2, 3 and 7 days post-instillation, respectively, indicating that this material was mildly irritating to rabbit eyes under the study conditions utilized.

Irritation Skin, Rabbit

Summary: A primary skin irritation score of 0.0 for the intact and abraded skin indicates that this material was non-irritating to rabbit skin under the study conditions utilized.

Carcinogenicity Oral, Rat

Summary: An eighteen month study showed an increase in mammary adenomas of questionable significance in female rats receiving oral doses of 60 mg/kg/day under the study conditions utilized. However, this finding could not be duplicated in a repeat study.

Reproductive Oral, Rat

Summary: Reproduction studies were performed to evaluate general reproductive performance and fertility in rats at oral dose levels of 10, 30, 60, or 100 mg/kg/day. Except for a slight decrease in pregnancy rate in treated animals, no other adverse effects were evident; however, the differences were small and not statistically significant. In a peri- and postnatal study, no evidence of adverse effects was observed in rats dosed orally at 10, 30, and 60 mg/kg/day under the study conditions utilized.

Teratogenicity Oral, Hamster

Summary: No evidence of teratogenicity was observed in hamsters when administered oral doses during gestation up to 0.5 mg/kg/day, under the study conditions utilized.

Teratogenicity Oral, Mouse

Summary: No evidence of teratogenicity was observed in mice when administered oral doses during gestation up to 100 mg/kg/day, under the study conditions utilized.

Teratogenicity Oral, Rat

Summary: No evidence of teratogenicity was observed in rats when administered oral doses during gestation up to 100 mg/kg/day, under the study conditions utilized.

Teratogenicity Oral, Rabbit

Summary: No evidence of teratogenicity was observed in rabbits when administered oral doses during gestation up to 0.3 mg/kg/day, under the study conditions utilized.

Mutagenicity

Summary: No evidence of mutagenicity was observed in the Ames assay with or without metabolic activation under the study conditions utilized.

SECTION 12. ECOLOGICAL INFORMATION

Cellulose, microcrystalline NF
Aerobic Biodegradation (soil)
Summary: This material is inherently biodegradable under the study conditions utilized.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal
Recommendations : This material is suitable for incineration. These recommendations are based on the product as shipped. Use, processing, alteration or contamination may affect these disposal recommendations. State, local or site restrictions affecting the available proper disposal options may vary.
RCRA Waste # : Not regulated under RCRA
Empty Containers . . . : Empty containers must be triple rinsed prior to disposal, recycling, or reuse.

SECTION 14. TRANSPORTATION INFORMATION

Enforcement Agency .: US Dept. of Transportation
Country/Community .: USA
Proper Ship. Name .: Non-regulated

Enforcement Agency .: International Air Transport Association
Country/Community .: International
Proper Ship. Name .: Non-regulated

SECTION 15. REGULATORY INFORMATION

Law/Regulation : Hazardous Chemical Reporting: Community Right-To-Know
40CFR370
Common Name : SARA Title III Section 312 - Hazardous Chemical
Inventory
Enforcement Agency .: Environmental Protection Agency (EPA)
Governing Authority : USA
Criteria Met : Acute

SECTION 16. OTHER INFORMATION

Additional
Information : NFPA RATING: These ratings are based on NFPA Code 704 and are intended for use by emergency personnel to determine the immediate hazards of a material.
 Health 1
 Fire 0
 Reactivity 0

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SECTION 16. OTHER INFORMATION (Continued. . .)

APPROVAL INFORMATION

Preparer: Hesham M. Soliman
Approver: Corporate Environmental & Safety Affairs
Approval Date: 05/26/95
Reason For Issue: New

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