

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078792528

N/A

## MATERIAL SAFETY DATA SHEET

**Product Name: FUROSEMIDE ORAL SOLUTION 10mg/mL**

NDC Product(s) Code(s): 60432-613-60  
60432-613-04

Prep. Date: 05/15/04 Rev.

### 1. Manufacturer:

Morton Grove Pharmaceuticals, Inc.  
6451 W. Main Street  
Morton Grove, IL 60053

Emergency Telephone: (847) 967-5600  
(800) 346-6854

### 2. Product Identification:

Product Name:	FUROSEMIDE ORAL SOLUTION 10mg/mL
Product NDC Code:	60432- 613-60, 60432-613-04
Chemical Family:	Liquid/Mixture
Synonym(s):	Lasix Oral Solution
Product Category:	Antihypertensive, diuretic

### 3. Composition/ Ingredient Information:

Each 5mL contains:

**Actives:** Furosemide, USP 10mg

Other Ingredients: Purified Water; Sodium Hydroxide; Sorbitol Solution; Glycerin; Hydrochloric Acid; Dehydrated Alcohol; Methylparaben; Propylparaben; D&C yellow #10; F,D&C yellow#6; Natural and Artificial Orange Juice Flavor.

### 4. Physical and Chemical Properties:

Appearance:	Yellow
Odor:	Orange
pH Range:	8.0-9.0
Specific Gravity:	1.11
Boiling Point:	Not Determined
Evaporation Rate:	Slower than Ether
Clarity:	Clear

Vapor Density: Heavier than air

## 5. Stability and Reactivity:

Stability:	Stable
Physical conditions to avoid:	Excessive Heat
Incompatibility with other materials:	None
Hazardous Decomposition Products:	None
Hazardous Polymerization:	Will not occur

## 6. Hazards Identification:

Primary Route(s) of Exposure:	Ingestion
Effects of Over Exposure:	Dehydration; hypertension; dry mouth; thirst; lethargy; weakness; muscle cramping; nausea; vomiting; drowsiness; stupor; coma.

## 7. Side Effects:

May include any of the following:

Lightheadedness; skin rash; hives; drug fever; reduced appetite; indigestion; nausea; vomiting; diarrhea; headache; dizziness; yellow vision; numbness; metabolic alkalosis.

### Possible Adverse Effects:

Temporary hearing loss; fluid in lungs; weakness; hepatitis with jaundice; fever; sore throat; low blood potassium or magnesium; vitamin B1 deficiency; kidney stones; skin lesions.

### Symptoms of Overdose:

Excessive loss of body water; increased viscosity of blood; increased tendency for the blood to clot; heart attack; thrombophlebitis.

## 8. Emergency and First-Aid Measures:

**Skin Contact:** Remove any contaminated clothing immediately. Wash affected areas with soap and large amounts of water.

**Eye Contact:** Immediately flush eyes with water and continue flushing for several minutes. Seek medical attention.

**Inhalation:** Remove to fresh air; get medical attention for any breathing difficulty.

**Excess Ingestion:** See section 7 under “Symptoms of Overdose.” Contact a doctor or poison control.

## 9. Fire Fighting Measures:

Flammability Classification:	Flammable
Flash Point:	Not Determined
Lower Explosion Limit:	Not Determined
Upper Explosion Limit:	Not Determined
Extinguishing Media:	Foam, chemical, water may spread fire.
Fire Fighting Measures:	Normal
Unusual Fire or Explosion Hazards:	None

## 10. Toxicological Information:

**CAUTION:** Furosemide oral solution must be discarded 60 days after opening the bottle for the first time if not contents are used. Take the exact dose prescribed by your physician.

**Pregnancy:** Category “C”. Adequate studies in pregnant women are not available. Avoid if possible especially the first three months. Refer to your physician for guidance.

**Nursing Mothers:** Present in breast milk. Avoid drug or refrain from nursing.

**Children:** Significant potassium loss can occur within the first two weeks of drug use.

**Adults/Geriatrics:** Over 60 years of age small starting doses are critical.

## 11. Spill and Leak Procedures:

Steps to be taken if material is spilled:

Provide adequate ventilation to keep vapor levels as low as possible. Use proper personal protective equipment to avoid overexposure. Stop leak if you can do so without risk. Small spills can be absorbed with proper material, e.g., rags, paper towels, etc. Large spills should be contained and vacuumed and placed in a suitable container.

Contains Furosemide. Flush to sanitary system with copious amounts of water following local and federal requirements for disposal.

## 12. Waste Disposal Method:

Dispose of this material in accordance with applicable international, national, state, and local waste regulations.

### **13. Storage and Handling Precautions:**

As with any drug/medicine, keep out of the reach of children. Store at a controlled room temperature, 15 °C - 30°C (59°F - 86°F). Dispense in tight, light resistant container. Store away from heat and direct light.

Always follow the advice of your physician while using this drug. Make sure your healthcare professional is aware of any allergies or any other medical problems that you may have.

### **14. Process Handling Precautions:**

A system of local exhaust is recommended to keep employee exposure below the airborne exposure limits.

Local exhaust is usually preferred because it controls the emission at its source, preventing dispersion of it into the general work area.

As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with this material. Wash thoroughly after handling.

### **15. Personal Protection/ Exposure Controls:**

Respiratory Protection:	Not required
Ventilation:	Local exhaust
Protective Gloves:	Yes
Eye Protection:	Yes

### **16. Shipping Regulations (Ref: 49 CFR § 172.101):**

Proper Shipping Name:	Not regulated
Hazard Class:	None
UN/NA Number:	None Listed
Subsidiary Risk:	None
US DOT Emergency Response Guide:	None
Transportation Label Required:	None

### **17. Disclaimer:**

The contents of this MSDS are believed to be correct but do not purport to be all-inclusive and should only be used as a guide. Morton Grove Pharmaceuticals disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.

## 1. Identification

**Product identifier** Furosemide Oral Solution 10 mg/mL

**Other means of identification**

**SDS number** 101920

**Product code** 60432-613-60, 60432-613-04

**Synonyms** Lasix Oral Solution

**Recommended use** Antihypertensive, diuretic  
Use as a source to lower high blood pressure

**Recommended restrictions** None known.

**Manufacturer/Importer/Supplier/Distributor information**

**Company Name** Morton Grove Pharmaceuticals, Inc.

**Address** 6451 Main Street  
Morton Grove, IL 60053

**Telephone** 1-847-967-5600

**Emergency phone number** 3E Hotline: 1-844-225-0667 (access code 14789)

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Reproductive toxicity Category 1B

**OSHA defined hazards** Not classified.

**Label elements**



**Signal word** Danger

**Hazard statement** May damage fertility or the unborn child.

**Precautionary statement**

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If exposed or concerned: Get medical advice/attention.

**Storage** Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)** None known.

## 3. Composition/information on ingredients

### Mixtures

#### Active Ingredients

Chemical name	CAS number	%
Furosemide, USP	54-31-9	10 mg/5 mL

#### Other Ingredients

Chemical name	CAS number	%
Propylparaben	94-13-3	N/A
Methylparaben	99-76-3	N/A
Glycerin	56-81-5	N/A

## Other Ingredients

Chemical name	CAS number	%
Dehydrated Alcohol	64-17-5	N/A

**Composition comments** The product contains: Purified Water, USP; Sodium Hydroxide; Sorbitol Solution; Hydrochloric Acid; D & C Yellow #10; F,D & C Yellow #6; Natryal and Artificial Orange Juice Flavor  
All concentrations are in percent by weight unless otherwise indicated. Components not listed are either non-hazardous or are below reportable limits.

## 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	Direct contact with eyes may cause temporary irritation. Prolonged skin contact may cause temporary irritation. If used as a drug: Side Effects: Lightheadedness; skin rash; hives; drug fever; reduced appetite; indigestion; nausea; vomiting; diarrhea; headache; dizziness; yellow vision; numbness; metabolic alkalosis. Possible Adverse Effects: Temporary hearing loss; fluid in lungs; weakness; hepatitis with jaundice; fever; sore throat; low blood potassium or magnesium; vitamin B1 deficiency; kidney stones; skin lesions. Effects of Overdose: Excessive loss of body water; increased viscosity of blood; increased tendency for the blood to clot; heart attack; thrombophlebitis.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
<b>General information</b>	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapor. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent product from entering drains. Following product recovery, flush area with water.  Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.  Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Contains Furosemide. Flush to sanitary system with copious amounts of water following local and federal requirements for disposal.
<b>Environmental precautions</b>	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

## 7. Handling and storage

### Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Provide adequate ventilation. Do not breathe mist or vapor. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

### Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store away from excessive heat and direct light at room temperature 15 - 30°C (59 - 68°F). Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Other Ingredients	Type	Value	Form
Dehydrated Alcohol (CAS 64-17-5)	PEL	1900 mg/m3	
		1000 ppm	
Glycerin (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

#### US. ACGIH Threshold Limit Values

Other Ingredients	Type	Value
Dehydrated Alcohol (CAS 64-17-5)	STEL	1000 ppm

#### US. NIOSH: Pocket Guide to Chemical Hazards

Other Ingredients	Type	Value
Dehydrated Alcohol (CAS 64-17-5)	TWA	1900 mg/m3
		1000 ppm

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields (or goggles).

#### Skin protection

##### Hand protection

Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.

##### Other

Wear suitable protective clothing.

#### Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

### Appearance

#### Physical state

Liquid.

#### Form

Clear liquid.

#### Color

Yellow.

#### Odor

Orange.

#### Odor threshold

Not available.

#### pH

8 - 9

#### Melting point/freezing point

Not available.



<b>Initial boiling point and boiling range</b>	Not determined.
<b>Flash point</b>	Not determined.
<b>Evaporation rate</b>	Slower than ether.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not determined.
<b>Flammability limit - upper (%)</b>	Not determined.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Heavier than air.
<b>Relative density</b>	1.11 (H2O=1)
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Thermal decomposition may produce CO, CO <sub>2</sub> , oxides of nitrogen and other potentially toxic gases.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	No adverse effects due to inhalation are expected.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation.
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Expected to be a low ingestion hazard.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	<p>Direct contact with eyes may cause temporary irritation. Prolonged skin contact may cause temporary irritation.</p> <p>If used as a drug: Side Effects: Lightheadedness; skin rash; hives; drug fever; reduced appetite; indigestion; nausea; vomiting; diarrhea; headache; dizziness; yellow vision; numbness; metabolic alkalosis.</p> <p>Possible Adverse Effects: Temporary hearing loss; fluid in lungs; weakness; hepatitis with jaundice; fever; sore throat; low blood potassium or magnesium; vitamin B1 deficiency; kidney stones; skin lesions.</p> <p>Effects of Overdose: Excessive loss of body water; increased viscosity of blood; increased tendency for the blood to clot; heart attack; thrombophlebitis.</p>
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### Information on toxicological effects

<b>Acute toxicity</b>	Not expected to be acutely toxic.
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**Toxicological data**

Other Ingredients	Species	Test Results
Dehydrated Alcohol (CAS 64-17-5)		
Acute		
Inhalation		
LC50	Mouse	39 g/m3, 4 Hours
Oral		
LD50	Rat	7000 - 11000 mg/kg
Glycerin (CAS 56-81-5)		
Acute		
Dermal		
LD50	Guinea pig	45 ml/kg, Days
Inhalation		
LC50	Rat	4655 mg.min/l, 7 Hours
Oral		
LD50	Rat	27 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Furosemide, USP (CAS 54-31-9)	3 Not classifiable as to carcinogenicity to humans.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
Reproductive toxicity	May damage fertility or the unborn child.	
Specific target organ toxicity - single exposure	Not classified.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not an aspiration hazard.	
Further information	CAUTION: Furosemide oral solution must be discarded 60 days after opening the bottle for the first time if not entire content is used. Take the exact dose prescribed by your physician. Pregnancy: Category "C". Adequate studies in pregnant women are not available. Avoid if possible especially the first three months. Refer to your physician for guidance. Nursing Mothers: Present in breast milk. Avoid drug or refrain from nursing. Children: Significant potassium loss can occur within the first two weeks of drug use. Adults/Geriatrics: Over 60 years of age small starting doses are critical.	

**12. Ecological information**

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Other Ingredients		Species	Test Results
Dehydrated Alcohol (CAS 64-17-5)			
Aquatic			
Crustacea	LC50	Ceriodaphnia dubia	5012 mg/l, 48 hours
		Daphnia magna	454 mg/l, 11 days
	NOEC	Ceriodaphnia dubia	9.6 mg/l
Fish	LC50	Pimephales promelas	13480 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.		

<b>Bioaccumulative potential</b>	No data available on bioaccumulation.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

### 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

### 14. Transport information

#### DOT

Not regulated as dangerous goods.

#### IATA

Not regulated as dangerous goods.

#### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

### 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.  
This product is exempt from the TSCA Inventory. It is regulated by the FDA.

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

#### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** Yes

#### SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

##### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

##### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

<b>Safe Drinking Water Act (SDWA)</b>	Not regulated.
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## US state regulations

## US. Massachusetts RTK - Substance List

Dehydrated Alcohol (CAS 64-17-5)

Glycerin (CAS 56-81-5)

## US. New Jersey Worker and Community Right-to-Know Act

Dehydrated Alcohol (CAS 64-17-5)

Glycerin (CAS 56-81-5)

## US. Pennsylvania Worker and Community Right-to-Know Law

Dehydrated Alcohol (CAS 64-17-5)

Glycerin (CAS 56-81-5)

### US, Rhode Island RTK

Not regulated.

## US, California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

**16. Other information, including date of preparation or last revision**

**Issue date** 08-July-2015

**Revision date** 08-July-2015

Version # 02

### NFPA ratings



## Disclaimer

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