



# SAFETY DATA SHEET

Revision Date 01-Feb-2019

Version 1

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

**Product Name** Monurol Sachet

### Other means of identification

**Product Code** FG00201

**Synonyms** Fosfomycin tromethamine Sachet

### Recommended use of the chemical and restrictions on use

**Recommended Use** Used to target bacteria responsible for urinary tract infections

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

### Details of the supplier of the safety data sheet

#### **Manufacturer**

Allergan plc  
5 Giralda Farms  
Madison, NJ USA 07940  
+1-800-272-5525

**E-mail address** SDS@Allergan.com

### Emergency telephone number

**Emergency Telephone** Call CHEMTREC Day or Night  
Within USA or Canada: 1-800-424-9300  
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

## 2. HAZARDS IDENTIFICATION

### Classification

#### **OSHA Regulatory Status**

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

### Label elements

#### **Emergency Overview**

The product contains no substances which at their given concentration, are considered to be hazardous to health

**Appearance** granules **Physical state** Solid **Odor** No information available

**Chemical Name** Fosfomycin tromethamine **Symptoms** Diarrhea, nausea, vaginitis, headache, dizziness, asthenia, dyspepsia

**Chemical Name** Fosfomycin tromethamine **Medical Conditions Aggravated by Exposure** Contraindicated in patients with known hypersensitivity to the drug

**Other Information**

Unknown Acute Toxicity 29.45% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
Fosfomycin tromethamine	78964-85-9	279-018-8	60 - 100*
Sucrose Palmitate	26446-38-8	247-706-7	10 - 30*
Mandarin & Orange Flavoring	RM101080	N/A	1 - 5*
Saccharin	81-07-2	201-321-0	0.1 - 1*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. FIRST AID MEASURES

**First aid measures**

<b>Eye contact</b>	Rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	Consult a physician if necessary.

**Chemical Name**  
Fosfomycin tromethamine

**Note to physicians**

overexposure may result in serious illness or death. Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including MONUROL, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile. In acute toxicology studies, oral administration of high doses of MONUROL up to 5 gm/kg were well-tolerated in mice and rats, produced transient and minor incidences of watery stool in rabbits, and produced diarrhea with anorexia in dogs occurring 2-3days after single dose administration. These doses represent 50-125 times the human therapeutic dose. The following events have been observed in patients who have taken Monurol in overdose: vestibular loss, impaired hearing, metallic taste, and general decline in taste perception. In the event of overdosage, treatment should be symptomatic and supportive. Do not use more than one single dose of MONUROL to treat a single episode of acute cystitis. Repeated daily doses of MONUROL did not improve the clinical success or microbiological eradication rates compared to single dose therapy, but did increase the incidence of adverse events. Urine specimens for culture and susceptibility testing should be obtained.

### 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable extinguishing media**

None known.

**Specific hazards arising from the chemical**

Fire may produce irritating, corrosive and/or toxic gases.

**Explosion data****Sensitivity to Mechanical Impact**

Not impact sensitive.

**Sensitivity to Static Discharge**

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

**Protective equipment and precautions for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**6. ACCIDENTAL RELEASE MEASURES****Personal precautions**

Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

**Environmental precautions**

See Section 12 for additional ecological information.

**Methods for containment**

Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up**

Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

**7. HANDLING AND STORAGE****Advice on safe handling**

Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

**Storage Conditions**

Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

**Incompatible materials**

None known based on information supplied.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Control parameters****Exposure Guidelines**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**Appropriate engineering controls****Engineering Controls**

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation 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 as low as reasonably achievable.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

<b>Skin and body protection</b>	During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).
<b>Respiratory protection</b>	Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

<b>Physical state</b>	Solid	<b>Appearance</b>	granules
<b>Color</b>	No information available	<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available		

<u>Property</u>	<u>Values</u>
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

**Other Information**

<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Density</b>	No information available
<b>Bulk density</b>	No information available

**10. STABILITY AND REACTIVITY**

**Reactivity**  
Not defined As Reactive substance

**Chemical stability**  
Stable under normal conditions.

**Possibility of Hazardous Reactions**  
None under normal processing.

**Conditions to avoid**  
Aerosol formation.

**Incompatible materials**  
None known based on information supplied.

**Hazardous Decomposition Products**

None known based on information supplied.

**11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure****Acute toxicity**

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Fosfomycin tromethamine	Inhalation may cause allergy or asthma symptoms or breathing difficulties, Inhalation may cause irritation of the lungs and respiratory system, Harmful by inhalation, May be harmful if inhaled. Causes respiratory tract irritation.	Eye contact may result in redness, pain or severe eye damage, Causes serious eye irritation.	Skin contact may result in inflammation characterized by itching, scaling, reddening, blistering, pain or dryness.	May be harmful if swallowed.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Fosfomycin tromethamine	>5000 mg/kg rat	N/A	N/A
Saccharin	= 14200 mg/kg ( Rat )	N/A	N/A

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Fosfomycin tromethamine	MONUROL was not mutagenic or genotoxic in the in vitro Ames' bacterial reversion test, in cultured human lymphocytes, in Chinese hamster V79 cells, and the in vivo mouse micronucleus assay.	Long term carcinogenicity studies in rodents have not been conducted because MONUROL is intended for single dose treatment in humans.	MONUROL did not affect fertility or reproductive performance in male and female rats. When administered to pregnant female rabbits at dosages as high as 1000mg/kg/day (approximately 9 and 2.7 times the human dose based on body weight and mg/m <sup>2</sup> , respectively), fetotoxicities were observed. However, these toxicities were seen at maternally toxic doses and were considered to be due to the sensitivity of the rabbit to changes in the intestinal microflora resulting from the antibiotic administration. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.	No information available

**Target Organ Effects**

Gastrointestinal tract (GI).

**Numerical measures of toxicity - Product Information****Unknown Acute Toxicity**

29.45% of the mixture consists of ingredient(s) of unknown toxicity

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

99.85% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Saccharin 81-07-2	N/A	18300: 96 h Pimephales promelas mg/L LC50	N/A

**Other adverse effects** No information available

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse container. Dispose of contents/containers in accordance with local regulations.

**14. TRANSPORT INFORMATION**

**DOT** Not regulated

**TDG** Not regulated

**ICAO (air)** Not regulated

**IATA** Not regulated

**IMDG** Not regulated

**ADR** Not regulated

**ADN** Not regulated

**15. REGULATORY INFORMATION**

**International Inventories**

**TSCA** Not Listed  
**DSL/NDSL** Not Listed  
**EINECS/ELINCS** Not Listed

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**US Federal Regulations**

**Carcinogenicity** The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

Chemical Name	ACGIH	IARC	NTP	OSHA
Saccharin 81-07-2	-	Group 3	-	-

*IARC (International Agency for Research on Cancer)  
 Not classifiable as a human carcinogen*

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

**SARA 311/312 Hazard Categories**

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

**US State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals

**U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Saccharin 81-07-2	X	X	X

**16. OTHER INFORMATION**

Revision Date 01-Feb-2019  
 Revision Note No information available

**Disclaimer**

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**