

# SAFETY DATA SHEET

Issue Date: 12/14/2023

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## 1. IDENTIFICATION

**Product identifier:** Nitrofurantoin Oral Suspension

**NDC Numbers:** 00121-1996-95

**Distributor Name and Address:** Pharmaceutical Associates, Inc.  
201 Delaware Street  
Greenville, SC 2960

**Telephone number:** (864) 277-7282

**Emergency phone number:** CHEMTREC 800-424-9300

**Recommended use:** Human drug – treatment of urinary tract infections

**Restrictions on use:** Prescription use only.

## 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Not hazardous	Skin Sensitization Category 1 Respiratory Sensitization Category 1

**Label Elements:**  
Danger!



**Hazard statement(s)**

May cause an allergic skin reaction.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Precautionary statement(s)**

Avoid breathing mists.  
Contaminated clothing must not be allowed out of the workplace.  
Wear protective clothing and gloves.

**Precautionary statement(s)**

IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Take off contaminated clothing and wash it before reuse.  
In case of inadequate ventilation, wear respiratory protection.  
IF INHALED: remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor.  
Dispose in accordance with local and national regulations.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Nitrofurantoin	67-20-9	<1%
Glycerin	56-81-5	Proprietary
Magnesium Aluminum Silicate	1327-43-1	Proprietary
Sodium Citrate Dihydrate	6132-04-3	

Carboxymethylcellulose sodium	9004-32-4	
Methylparaben	99-76-3	Proprietary
Propylparaben	94-13-3	
Sorbitol	50-70-4	Proprietary
Sucralose	56038-13-2	Proprietary
Citric Acid	77-92-9	Proprietary
Flavor	Mixture	Proprietary
Water	7732-18-5	Proprietary

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

#### 4. FIRST-AID MEASURES

**Inhalation:** Remove person to fresh air. If irritation occurs, get medical attention.

**Skin contact:** Remove contaminated clothing. Wash skin with soap and water. If irritation or rash develops, get medical attention. Launder clothing before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

**Ingestion:** In the case of unintentional ingestion or overdose, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

**Most important symptoms/effects, acute and delayed:** May cause mild eye and skin irritation. Repeated skin contact may cause an allergic skin reaction. Inhalation of mist may cause an allergic respiratory reaction with asthma symptoms (wheezing and shortness of breath), respiratory irritation and effects similar to ingestion. Swallowing may cause nausea, vomiting, fever, chills, cough, chest pain, shortness of breath and nervous system effects including dizziness, headache, and drowsiness.

**Indication of immediate medical attention and special treatment, if necessary:** Medical attention is recommended for unintended ingestion or overdose.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use any media that is suitable for the surrounding fire.

**Specific hazards arising from the chemical:** Product is not classified as flammable or combustible but will burn in a fire after the water has evaporated.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8. Use caution – spill may be a slip hazard.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

## 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure guidelines:

Nitrofurantoin	None Established
Glycerin	5 mg/m <sup>3</sup> (respirable) 15 mg/m <sup>3</sup> (total particulate) TWA OSHA PEL
Magnesium Aluminum Silicate	5 mg/m <sup>3</sup> (respirable) 15 mg/m <sup>3</sup> (total particulate) TWA OSHA PEL
Sodium Citrate Dihydrate	None Established
Carboxymethylcellulose sodium	None Established
Methylparaben	None Established
Propylparaben	None Established
Sorbitol	None Established
Sucralose	None Established
Citric Acid	None Established
Flavor	None Established
Water	None Established

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

### Individual protection measures:

**Respiratory protection:** None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate/organic vapor respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** None required for normal use. Impervious gloves and clothing recommended for manufacturing operations.

**Eye protection:** None required for normal use. Chemical safety goggles recommended for manufacturing operations.

**Other:** None known.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance (physical state, color, etc.):** Yellow liquid

**Odor:** Fruity

<b>Odor threshold:</b> No data available	<b>pH:</b> 4.8-6.2
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<b>Melting point/freezing point:</b> No data available	<b>Boiling Point:</b> No data available
<b>Flash point:</b> No data available	<b>Evaporation rate:</b> No data available
<b>Flammability (solid, gas):</b> Not applicable	<b>VOC:</b> No data available
<b>Flammable limits: LEL:</b> No data available	<b>UEL:</b> No data available
<b>Vapor pressure:</b> No data available	<b>Relative vapor density:</b> No data available
<b>Relative density:</b> 1.0-1.2	<b>Solubility(ies):</b> Soluble
<b>Partition coefficient: n-octanol/water:</b> No data available	<b>Auto-ignition temperature:</b> No data available
<b>Decomposition temperature:</b> No data available	<b>Dynamic Viscosity:</b> 1500-4500 cps
<b>Particle Characteristics:</b> Not applicable	<b>Kinematic Viscosity:</b> No data available

## 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use.

**Chemical stability:** Stable.

**Possibility of hazardous reactions:** None known.

**Conditions to avoid:** None known.

**Incompatible materials:** Avoid oxidizing agents.

**Hazardous decomposition products:** Thermal decomposition may yield carbon, nitrogen oxides, hydrogen chloride.

## 11. TOXICOLOGICAL INFORMATION

### Acute effects of exposure:

**Inhalation:** Inhalation of mists may cause an allergic respiratory reaction with asthma symptoms (wheezing and shortness of breath), respiratory irritation and effects similar to ingestion.

**Ingestion:** Swallowing may cause nausea, vomiting, fever, chills, cough, chest pain, shortness of breath and nervous system effects including dizziness, headache, and drowsiness.

**Skin contact:** May cause mild irritation. Repeated skin contact may cause an allergic skin reaction.

**Eye contact:** May cause mild irritation with redness and tearing.

**Chronic Effects:** None known.

**Sensitization:** Nitrofurantoin is a skin and respiratory sensitizer.

**Germ Cell Mutagenicity:** Components are not classified as germ cell mutagens. Nitrofurantoin has been shown to induce point mutations in certain strains of *Salmonella typhimurium* and forward mutations on L5178Y mouse lymphoma cells. Nitrofurantoin induced increased numbers of sister chromatid exchanges and chromosomal aberrations in Chinese hamster ovary cells but not in human cells in culture. Results of the sex-linked recessive lethal assay in *Drosophila* were negative after administration of nitrofurantoin by feeding or by injection. Nitrofurantoin did not induce heritable mutation in the rodent models examined.

**Reproductive Toxicity:** The administration of high doses of nitrofurantoin to rats causes temporary spermatogenic arrest; this is reversible on discontinuing the drug. Several reproduction studies have been performed in rabbits and rats at doses up to six times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to nitrofurantoin.

**Carcinogenicity:** Nitrofurantoin was not carcinogenic when fed to female Holtzman rats for 44.5 weeks or to female Sprague-Dawley rats for 75 weeks. Two chronic rodent bioassays utilizing male and female Sprague-Dawley rats and two chronic bioassays in Swiss mice and in BDF<sup>1</sup> mice revealed no evidence of carcinogenicity. Nitrofurantoin presented evidence of carcinogenic activity in female B6C3F1 mice as shown by increased incidences of tubular adenomas, benign mixed tumors, and granulosa cell tumors of the ovary. In male F344/N rats, there were increased incidences of uncommon kidney tubular cell neoplasms, osteosarcomas of the

bone, and neoplasms of the subcutaneous tissue. In one study involving subcutaneous administration of 75 mg/kg nitrofurantoin to pregnant female mice, lung papillary adenomas of unknown significance were observed in the F1 generation. None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

**Acute Toxicity Values:** Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg  
Nitrofurantoin: Oral LD50 604 mg/kg

## 12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

**Ecotoxicity values:** No data available.

**Persistence and degradability:** No data available.

**Bioaccumulative potential:** No data available.

**Mobility in soil:** No data is available.

**Other adverse effects:** None known.

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

## 14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

**Transport in bulk according IMO instruments:** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

## 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Refer to Section 2 for the OSHA hazard classification.

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

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**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

**16. OTHER INFORMATION**

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**SDS Revision History:** N/A

**Disclaimer :** The information provided on this SDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.