

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: Nitrofurantoin Oral Suspension, USP 25 mg/5 mL

1.2. Intended Use of the Product

Use of the substance/mixture: Pharmaceutical: Treatment of urinary tract infections (UTI)

1.3. Name, Address, and Telephone of the Responsible Party

GAVIS Pharmaceuticals, LLC
400 Campus Drive
Somerset NJ 08873
908-603-6080

1.4. Emergency Telephone Number:

In case of emergency call: **911**
US Poison Control Center: **1-800-222-1222**

SECTION 2: HAZARDS IDENTIFICATION

Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Emergency Overview

May cause eye, skin and respiratory tract irritation.

Potential Health Effects: Eyes

May cause eye irritation.

Potential Health Effects: Skin

May cause skin irritation.

Potential Health Effects: Ingestion

Not considered a likely route of exposure under normal industrial use. May cause adverse effects as described in product insert when ingested.

Potential Health Effects: Inhalation

May cause respiratory tract irritation.

HMIS Ratings: Health: 1 Fire: 0 HMIS Reactivity 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

GHS-US Labeling

Hazard Statements (GHS-US)

: H317: May cause an allergic skin reaction
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements (GHS-US)

: General
P101: If medical advice is needed, have product container or label at hand.
P102: Keep out of reach of children.
P103: Read label before use.

Prevention

P261: Avoid breathing vapors, spray, mist
P272: Contaminated work clothing should not be allowed out of the workplace
P273: Avoid release to the environment.
P280: Wear protective clothing, protective gloves, eye protection

Response

P314: Get Medical advice/attention if you feel unwell.
P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P302+P352: IF ON SKIN: Wash with plenty of soap and water
P305: IF IN EYES: Flush eye(s) immediately with plenty of water. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

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P362+P364: Take off contaminated clothing and wash it before reuse

Storage

No known hazards due to product exposure to high temperatures.

For safety, the glass containers should not be exposed to extreme hot or cold temperatures.

For product quality, product is stable when stored between 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Avoid exposure to strong light which may darken the drug.

Disposal

P501: Dispose of contents/container according to local, regional, national, and international regulations

2.3. Other Hazards

Other Hazards: Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier (CAS No.)
Water	7732-18-5
Sorbital Solution	50-70-4
Glycerin	56-81-5
Carboxymethyl cellulose Sodium	9004-32-4
Citrate, sodium, dihydrate	6132-04-3
Nitrofurantoin Monohydrate	17140-81-7
Methylparaben	99-76-3
Propylparaben	94-13-3
Anhydrous Citric Acid	77-92-9
Saccharin Sodium	128-44-9
Magnesium Aluminum Silicate	1327-43-1
Anise Liquer Flavor	Not Available

SECTION 4: FIRST AID MEASURES

4.1. Description of Most important symptoms and effects, both acute and delayed, and First Aid Measures

General Symptoms/Injuries: Please refer to the package insert for more detailed information.

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Symptoms/Injuries After Inhalation: May cause respiratory tract irritation.

First-aid Measures After Inhalation: Remove the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms appear.

Symptoms/Injuries After Skin Contact: May cause skin irritation.

First-aid Measures After Skin Contact: Rinse immediately with plenty of water for at least 15 minutes.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

First-aid Measures After Eye Contact: Flush eye(s) immediately with plenty of water. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Symptoms/Injuries After Ingestion: May cause adverse effects as described in product insert when ingested.

First-aid Measures After Ingestion: Acute overdosage should be followed by immediate gastric lavage or emesis followed by supportive and symptomatic therapy. Contact a physician.

Chronic Symptoms: None expected under normal conditions of use.

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SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: N/A

5.2. Special Hazards Arising From the Substance or Mixture

General Fire Hazards

See Section 9 for Flammability Properties.

None anticipated.

Hazardous Combustion Products

Not Determined

5.3. Advice for Firefighters

Firefighting Instructions: Exercise caution when fighting any chemical fire.

Protection During Firefighting: Firefighters should wear full protective gear.

NFPA Ratings: Health: 1 Fire: 0 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all eye and skin contact and do not breathe vapor and mist.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Isolate area. Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

6.2. Methods and Material for Containment and Cleaning Up

Containment Procedures: Stop the flow of material, if this is without risk.

Methods for Cleaning Up: Wipe up spills and rinse area with water. Dispose of these materials in accordance with federal, state, and local regulations.

6.3. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Avoid breathing vapor, mist, spray. Avoid all unnecessary exposure. No special handling procedures needed.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store at controlled temperatures. Keep tightly closed and out of reach of children.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Component Exposure Limits (known)

Glycerin (56-81-5)

ACGIH: 10 mg/m³ TWA (mist)

OSHA: 10 mg/m³ TWA (mist, total particulate); 5 mg/m³ TWA (mist, respirable fraction)

8.2. Exposure Controls

Appropriate Engineering Controls : Ensure adequate ventilation, especially in confined areas.

Personal Protective Equipment

Hand Protection : Use impervious gloves.

Eye Protection : Safety glasses with side-shields

Skin and Body Protection : Wash contaminated clothing before reuse.

Respiratory Protection : Breathing apparatus only if aerosol or dust is formed.

Other Information : Eye wash fountain is recommended.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

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Appearance	: Yellow colored suspension
Odor	: Anise
Odor Threshold	: No data available
pH	: 4.5 - 6.5
Relative Evaporation Rate (butylacetate=1)	: No data available
Melting Point	: N/A
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: In water
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2 Chemical Stability:** This is a stable material.
- 10.3 Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4 Conditions to Avoid:** Not determined.
- 10.5 Incompatible Materials:** Not determined.
- 10.6 Hazardous Decomposition Products:** None.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Acute Dose Effects

General Product Information: No information available for the product.

Component Analysis – LD50/LC50

Water (7732-18-5)	
LD50 Oral Rat	>90 mL/kg
Glycerin (56-81-5)	
LD50 Oral Rat	12600 mg/kg
LD50 Dermal Rat	>21900 mg/kg
Sodium carboxymethyl cellulose (9004-32-4)	
LD50 Inhalation Rat	>5800 mg/m ³ 4 h
LD50 Oral Rat	27000 mg/kg
LD50 Dermal Rabbit	>2 g/kg
Citric acid (77-92-9)	
LD50 Oral Rat	3000 mg/kg
Methylparaben (99-76-3)	
LD50 Oral Rat	2100 mg/kg
Propylparaben (94-13-3)	
LD50 Oral Mouse	6332 mg/kg

11.2 Carcinogenicity

General Product Information: No information available for the product.

Component Carcinogenicity

Nitrofurantoin Monohydrate (17140-81-7)
IARC: Monograph 50 [1990] (listed under Nitrofurantoin) (Group 3 (not classifiable))

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Glycerin (56-81-5)	
96 Hr LC50 Oncorhynchus mykiss	51 - 57 mL/L [static]
24 Hr EC50 Daphnia magna	>500 mg/L
Citric acid (77-92-9)	
96 Hr LC50 Lepomis macrochirus	1516 mg/L [static]
72 Hr EC50 Daphnia magna	120 mg/L

12.2. Persistence and Degradability

Nitrofurantoin Oral Suspension, USP 25 mg/5 mL	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Nitrofurantoin Oral Suspension, USP 25 mg/5 mL	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations. See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1 In Accordance with DOT Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

15.2 US State Regulations

The following components appear on one or more of the following state hazardous substances lists:

Component	CAS	CA	MA	MN	NJ	PA	RI
Glycerin	56-81-5	No	Yes	Yes	Yes	Yes	Yes

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision date : 05/06/2015

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)