

Safety Data Sheet

NITROFURANTOIN ORAL SUSPENSION, USP 25 mg/5 mL

Section 1. Identification

Product information

Product Name	Nitrofurantoin Oral Suspension, USP 25 mg/5 mL
Use	Nitrofurantoin oral suspension is indicated in adults and pediatric patients 1 month of age and older for the treatment of urinary tract infections due to susceptible strains of <i>Escherichia coli</i> , <i>Enterococcus</i> species, <i>Staphylococcus aureus</i> , <i>Klebsiella</i> species and <i>Enterobacter</i> species.
Manufacturer	Suven Pharmaceuticals Ltd. 202, A-Wing, Galaxy Towers, Plot No-1, Hyderabad Knowledge City, TSIC, Raidurg, Serilingampally, Rangareddy District, Hyderabad - 500081
Emergency (In India)	+91-40-23549414

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

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.

Other hazards

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

Section 3. Composition and Information on Ingredients

Name	CAS #
Nitrofurantoin Monohydrate EP, USP-NF	17140-81-7
Glycerin USP-NF (Moon K Glycerin)	56-81-5
Methyl Paraben USP-NF	99-76-3
Propyl Paraben USP-NF	94-13-3
Carboxy Methyl Cellulose Sodium USP	9004-32-4
Magnesium Aluminum Silicate USP-NF	12199-37-0
Sorbitol Solution (Neosorb® 70/20B) USP-NF	50-70-4
Anhydrous Citric acid USP -NF	77-92-9
Sodium citrate Dihydrate USP-NF	6132-04-3
Saccharin Sodium USP- NF (40-80 mesh M311 15%)	128-44-9
Sodium Hydroxide Pellets USP-NF	1310-73-2
Hydrochloric acid USP-NF	7647-01-0
Tutti Fruti (Bubble gum flavour)	5392-40-5 & 119-84-6

Section 4. First Aid Measures

General Symptoms/Injuries:	Please refer to the package insert for more detailed information. No hazards which require special first aid measures
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Safety Data Sheet

NITROFURANTOIN ORAL SUSPENSION, USP 25 mg/5 mL

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
Section 5. Fire Fighting Measures	
Suitable extinguishing media	Use extinguishing media appropriate for surrounding fire
Unsuitable extinguishing media	Not Applicable
Hazardous Combustion Products	Not Determined
General Fire Hazards	None anticipated
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
Section 6. Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Avoid all eye and skin contact and do not breathe vapor and mist.
Methods and materials 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
Section 7. Handling and Storage	
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

Safety Data Sheet

NITROFURANTOIN ORAL SUSPENSION, USP 25 mg/5 mL

	should not be allowed out of the workplace. Wash contaminated clothing before reuse.
Recommended storage temperature	Store between 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature]. Avoid exposure to strong light which may darken the drug. Protect from freezing.
Section 8. Exposure Controls/Personal Protection	
Exposure Controls	Ensure adequate ventilation, especially in confined areas.
Personal Protection equipment	
Eye	Safety goggles, Face-shield.
Body	Lab coat.
Respiratory	Breathing apparatus only if aerosol or dust is formed..
Hands	Gloves
Feet	Suit Boots
Personal Protection in Case of a Large Spill	Splash goggles, Full suit boots and Gloves
Other Information	Eye wash fountain is recommended.
Section 9. Physical and Chemical Properties	
Appearance	Yellow to dark yellow coloured suspension with tutti frutti flavour (bubble gum flavour)
Colour	Yellow to dark yellow coloured
pH	4.5 – 6.0
Density	1.047 to 1.113 g/mL at 25°C
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Explosive properties	No statements available
Oxidizing properties	No data available
Impact sensitivity	No data available
Minimum ignition energy	No data available
Section 10. Stability and Reactivity	
Reactivity	Hazardous reactions will not occur under normal conditions.
Chemical stability	This is a stable material
Possibility of hazardous reactions	Hazardous polymerization will not occur
Conditions to avoid	Not determined.
Incompatible materials	Not determined.
Hazardous decomposition products	None
Section 11. Toxicological Information	
Acute Effects	No data available
Chronic effects on Humans	No data available
Other Toxic effects on Humans	No data available
Special Remarks on Toxicity to Animals	No data available
Special Remarks on Chronic Effects on Humans	No data available
Special Remarks on other Toxic Effects on Humans	No data available

Safety Data Sheet

NITROFURANTOIN ORAL SUSPENSION, USP 25 mg/5 mL

Section 12. Ecological Information

No Data available

Section 13. Disposal Considerations

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

International Regulations

IATA-DGR	Not regulated as a dangerous good
IMDG-Code	Not regulated as a dangerous good
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable for product as supplied.

National Regulations

49 CFR	Not regulated as a dangerous good
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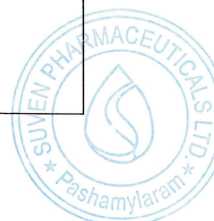
Section 15. Regulatory Information (Contd.)

No information available

Section 16. Additional Information

No additional remark

Prepared by: Signature	6/4 07/11/2024	Verified by: Signature:	07/11/24
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