SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition UNITED NATIONS New York and Geneva, 2021

Nitrofurantoin capsules USP (25 mg, 50 mg,100 mg)

1. IDENTIFICATION

GHS Product identifier: Nitrofurantoin capsules USP (Macrocrystals), Nitrofurantoin Capsules USP 100 mg (macrocrystals+monohydrate)
Product code: #

Chemical Description: 1-[(E)-(5-nitrofuran-2-yl)methylideneamino]imidazolidine-2,4-dione

Other means of identification:

Recommended use of the chemical: Treatment of acute urinary tract infections or over long term as chronic prophylaxis against recurrent infections.

Restrictions on use: The product should be used only for the above mentioned uses and may not be used for any other purpose than stated above.

Manufactured by:
Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification
Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route
Acute Toxicity	4	Oral
Skin sensitization	1	-
Skin Irritation (only for macrocrystals + monohydrate)	3	-
Respiratory sensitization	1	-

Labeling
Globally Harmonized System, UN (GHS)

Signal Word	**Danger**
Hazard Statements:	H302: Harmful if swallowed H370: Causes damage to organs H317: May cause allergic skin reaction H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled
Precautionary Statements:	P261 Avoid breathing dust. P264 Wash hands thoroughly after handling. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P311: Call a poison centre/physician P391: Collect spillage
Other hazards	Control formation and generating of dusts during use.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Nitrofurantoin macrocrystals

Hazardous ingredients	CAS	Content
Nitrofurantoin Macrocrystals	67-20-9	27.78%
Lactose monohydrate	64044-51-5 (tablettose 80)	-
Corn starch	9005-25-8 (maize starch extra white pharma grade)	-
Talc (Luzenac Pharma M)	14807-96-6	-
Empty hard gelatin capsule	NA	-
This product is a mixture of chemical substances. The specific chemical % for other chemical ingredients of this product is being withheld as it is Propriety information.		

Chemical nature: Mixture containing Nitrofurantoin macrocrystals+monohydrate*

Hazardous ingredients	CAS	Content
Nitrofurantoin Macrocrystals	67-20-9	27.78%
Lactose monohydrate	64044-51-5 (tablettose 80)	-
Nitrofurantoin Monohydrate	17140-81-07	33.33%
Corn starch	9005-25-8 (maize starch extra white pharma grade)	-
Sucrose	57-50-1	
Talc (Luzenac Pharma M)	14807-96-6	-
Magnesium Stearate	557-04-0	
Povidone	9003-39-8	
Carbomer Homopolymer Type B	9003-01-4	
Empty hard gelatin capsule	NA	-
This product is a mixture of chemical substances. The specific chemical % for other chemical ingredients of this product is being withheld as it is Propriety information.		

*** % of drug content including Nitrofurantoin (Macrocrystals and Monohydrate) in Capsules is 31.75%.**

4. FIRST-AID MEASURES

Inhalation

Move the person into fresh air. In case of respiratory symptoms, place the person in a semi-seated position and administer oxygen. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion

Never give anything by mouth to an unconscious person. DO not induce emesis. Rinse mouth with water. Consult a physician.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Fire/explosion hazard

Combustible solid which burns but propagates flame with difficulty. Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

Specific hazards arising from the chemical

Carbon oxides, Nitrogen oxides (NOx)

Personal protection

Self-contained breathing apparatus. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary

Special exposure hazards

Do not release chemically contaminated water into drains, soil or surface water. Dispose of contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Prevent contamination of soil, drains and surface waters.

Spillage procedure

Take up mechanically and collect in suitable container (adequately labelled) for disposal.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Conditions for safe storage

Avoid dust formation and ignition sources. Ensure good local exhaust ventilation.
Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Storage facilities

Store in a cool, dry area with adequate ventilation. Keep tightly closed. Store at 25 °C

Segregation

Store locked up.

Storage conditions

Keep containers closed.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

Contains no substances with occupational exposure limit values

Occupational exposure controls

Appropriate engineering controls

Maintain air concentrations below occupational exposure standards. Prevent dust formation.

General Personal Protection

Goggles, gloves, protective clothing.

Respiratory protection

Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Hand protection

Protective gloves.

Eye protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Opaque capsules with colour coding for different strengths.
Macrocrystals: 25mg - White cap & body, 50mg - Blue cap & white body, 100mg - Blue cap & blue body.
Macrocrystals and Monohydrate - 100mg - grey cap and brown body
Form: Capsules
Odour: Not specific
pH: Not available
Melting point: Not determined
Boiling point: Not applicable
Flash point: Not applicable
Flammability (solid): Product is not flammable
Vapour pressure: < 0.0000001 kPa at 25 °C (nitrofurantoin substance)
Auto-ignition temperature: Not available
Decomposition temperature: Not available
Density: Not available
Solubility in solvents: Very slightly soluble in alcohol and practically insoluble in ether and water.
n-Octanol/Water Partition Coefficient: Not available
Viscosity: Not applicable
Oxidizing properties: Not applicable
Explosivity: Stable under ordinary conditions.

10. STABILITY AND REACTIVITY

Conditions to avoid
Avoid heat and light.

Materials to avoid
Keep away from strong oxidizing agents, strong acids and alkalis.

Hazardous decomposition products
When heated to decomposition it emits toxic fumes of nitroxides.

Possible combustion products are Carbon monoxide, carbon dioxide, nitrogen oxides

11. TOXICOLOGICAL INFORMATION

Acute toxicity
Nitrofuratoin 100% active ingredient has been tested for acute toxicity and belongs to category 4.
Nitrofurantoin capsules also belongs to category 4.

LD_{50} (oral,rat): 604 mg/kg
LD_{50} (oral,mouse): 360 mg/kg

Primary Irritation

Skin: Nitrofurantoin active ingredient not classified for skin or eye irritation.

Mixture containing Nitrofurantoin macrocrystals+monohydrate will fall under category 3 for skin as concentration of magnesium stearate is ≥1%.

GHS Classification is not applicable for the mixture for eye irritation.

Respiratory or Skin sensitization
Nitrofurantoin active ingredient falls under category 1 for skin and respiratory sensitization. Mixture is also classified as category 1 for respiratory and skin sensitization since it contains >1% active ingredient.

CMR consideration:

Germ cell mutagenicity:
- Data not sufficient for classification.

GHS Classification is not possible.

Carcinogenicity

The substance is classified by IARC as Group 3

Not classifiable as human carcinogen. Evidence of carcinogenicity may be inadequate or limited in animal testing. Oral (man) TDLo: 29 mg/kg/20D - I

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

GHS Classification for active ingredient is not possible due to lack of data.

Reproductive toxicity

Based on available data, the classification criteria are not met. Human epidemiological studies have not identified abnormalities caused by therapeutic use of this material during pregnancy.

Specific target organ toxicity single exposure: (STOT SE)

Based on available data, the classification criteria are not met.

Specific target organ toxicity repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:
GHS Classification is not possible.

Additional information: None

12. ECOLOGICAL INFORMATION

Ecotoxicity

Acute/chronic aquatic toxicity data
Not available.

Persistence and degradability
High

Bioaccumulation
Low
Behaviour in treatment plants
Data not available. GHS Classification is not possible.

Additional information
Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal
Product residues should be considered as hazardous waste. Disposal must be done through authorised waste disposal firms in compliance with local regulations. Waste should not be released to sewers.

Contaminated packaging
Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

This substance is not classified as dangerous for transport.
Not regulated for transport of dangerous goods: DOT, IATA, IMDG

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING
Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2021 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2019

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

Prepared on 17/01/23 updated on 17/07/23