

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200)

SECTION1. Identification

Product Name Nitrofurantoin Capsule USP, 100mg

Cat No. : AC229380000; AC 229380100; AC229380250; AC229381000

CAS No 67-20-9
Synonyms No information available

Recommended Use Laboratory chemicals.
Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company Creekwood Pharmaceuticals LLC 11130, Route 46 W, Suite 21
Parsippany, New Jersey 07045

SECTION2. Hazard(s) identification

Classification

This chemical is considered hazardous according to [US] OSHA (29 CFR 1910.1200, 2024)

Acute oral toxicity	Category 4
Respiratory Sensitization	Category 1
Skin Sensitization	Category 1
Specific target organ toxicity - (repeated exposure)	Category 2

Label Elements

Signal Word
Danger

Hazard Statements
Harmful if swallowed

May cause an allergic skin reaction
 May cause allergy or asthma symptoms or breathing difficulties if inhaled
 May cause damage to organs through prolonged or repeated exposure



Precautionary Statements

Prevention

Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product
 In case of inadequate ventilation wear respiratory protection
 Contaminated work clothing should not be allowed out of the workplace
 Wear protective gloves
 Do not breathe dust/fume/gas/mist/vapors/spray

Response

Get medical attention/advice if you feel unwell

Inhalation

If experiencing respiratory symptoms: Call a POISON CENTER or doctor
 IF INHALED: Remove person to fresh air and keep comfortable for breathing

Skin

IF ON SKIN: Wash with plenty of soap and water
 If skin irritation or rash occurs: Get medical advice/attention
 Take off contaminated clothing and wash before reuse

Ingestion

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 Rinse mouth

Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

No information available

WARNING. Reproductive Harm - <https://www.p65warnings.ca.gov/>.

3. Composition/information on Ingredients

Component	CAS No	Weight %
Nitrofurantoin	67-20-9	<=100

4. First-aid measures

General Advice	If symptoms persist, call a physician.
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
Most important symptoms and effects	None reasonably foreseeable. . May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause allergic skin reaction. Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing
Notes to Physician	Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media	Water spray, carbon dioxide (CO ₂), dry chemical, alcohol-resistant foam.
Unsuitable Extinguishing Media	No information available
Flash Point	No information available
Method -	No information available
Autoignition Temperature	No information available
Explosion Limits	
Upper	No data available
Lower	No data available
Sensitivity to Mechanical Impact	No information available
Sensitivity to Static Discharge	No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrogen oxides (NO_x).

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.

NFPA

Health	Flammability	Instability	Physical hazards
2	1	0	N/A

6. Accidental release measures

Personal Precautions	Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.
Environmental Precautions	Should not be released into the environment.
Methods for Containment and Clean Up	Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

7. Handling and Storage

Handling	Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid dust formation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation.
Storage.	Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible Materials. Strong oxidizing agents. Strong acids. Strong bases.

8. Exposure controls / personal protection

Exposure Guidelines	This product does not contain any hazardous materials with occupational exposure limit established by the region specific regulatory bodies.
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Engineering Measures Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Recommended Filter type: Particulates filter conforming to EN 143.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

Physical State Solid
Color Yellow
Odor No information available
Odor Threshold No information available
Property Values
Melting Point/Range 263 - 265 °C / 505.4 - 509 °F
Softening Point No data available
Boiling Point/Range No information available
Flash Point No information available
Flammability (liquid) Not applicable
Flammability (solid,gas) No information available
Explosion Limits No data available

Remarks • Method

Method - No information available
 Solid

Autoignition Temperature No data available
Decomposition Temperature No data available
pH No information available
Viscosity Not applicable
Water Solubility No information available
Solubility in other solvents No information available
Partition Coefficient (n-octanol/water)
Vapor Pressure No data available
Density / Specific Gravity No data available
Bulk Density No data available
Vapor Density Not applicable
Particle characteristics No data available

Solid

Solid

Other Information

Molecular Formula C8 H6 N4 O5
Molecular Weight 238.16
Evaporation Rate Not applicable - Solid

10. Stability and reactivity

Reactive Hazard	None known, based on information available
Stability	Stable under normal conditions.
Conditions to Avoid	Avoid dust formation. Incompatible products. Excess heat.
Incompatible Materials	Strong oxidizing agents, Strong acids, Strong bases
Hazardous Decomposition Products	Carbon monoxide (CO), Carbon dioxide (CO ₂), Nitrogen oxides (NO _x)
Hazardous Polymerization	Hazardous polymerization does not occur.
Hazardous Reactions	None under normal processing.

11. Toxicological information

Information on expected route of exposure

Inhalation	May be harmful if inhaled. May cause irritation of respiratory tract.
Ingestion	Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Eyes	May cause irritation.
Skin	May be harmful in contact with skin. May cause irritation.

Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Nitrofurantoin	604 mg/kg (Rat) 360 mg/kg (Mouse)	-	-

Toxicologically Synergistic Products	No information available
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(b) skin corrosion/irritation;	No data available
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(c) serious eye damage/irritation;	No data available
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(d) respiratory or skin sensitization;

Respiratory	Category 1
Skin	Category 1
	May cause sensitization by skin contact

(e) germ cell mutagenicity;	No data available
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(f) carcinogenicity;

The table below indicates whether each agency has listed any ingredient as a carcinogen

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Nitrofurantoin	67-20-9	Not listed	Not listed	Not listed	Not listed	Not listed

(g) reproductive toxicity;	No data available
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(h) STOT-single exposure;	No data available
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(i) STOT-repeated exposure; No data available

Target Organs No information available.

(j) aspiration hazard; Not applicable
Solid

Symptoms / effects, both acute and delayed Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing.

Other Adverse Effects The toxicological properties have not been fully investigated.

Endocrine Disrupting Properties This product does not contain any known or suspected endocrine disruptors.

12. Ecological information

Ecotoxicity

Persistence and Degradability No information available

Bioaccumulation/ Accumulation No information available.

Mobility No information available.

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOT Not regulated
TDG Not regulated
IATA Not regulated
IMDG/IMO Not regulated

15. Regulatory Information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Nitrofurantoin	67-20-9	X	ACTIVE	-

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA - Per 40 CFR 751, Regulation of Certain Chemical Substances & Mixtures, Under TSCA Section 6(h) (PBT) Not applicable

TSCA 12(b) - Notices of Export Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Nitrofurantoin	67-20-9	X	-	200-646-5	-	-		-	-	-

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

U.S. Federal Regulations

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

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and Health Administration Not applicable

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.

California Proposition 65 This product contains the following Proposition 65 chemicals.

Component	CAS No	California Prop. 65	Prop 65 NSRL	Category
Nitrofurantoin	67-20-9	Male Reproductive	-	

U.S. State Right-to-Know Regulations Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): N

DOT Marine Pollutant N

DOT Severe Marine Pollutant N

U.S. Department of Homeland Security This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Nitrofurantoin	67-20-9		Use restricted. See entry 75. (see link for restriction details)	

REACH links

<https://echa.europa.eu/substances-restricted-under-reach>

Safety, health and environmental regulations/legislation specific for the substance or mixture

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Nitrofurantoin	67-20-9	Not applicable	Not applicable	Not applicable	Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)?

Not applicable

Other International Regulations

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Nitrofurantoin	67-20-9	Not applicable	Not applicable	Not applicable	Not applicable

16. Other Information

Prepared By Creekwood Pharmaceuticals LLC.
 (Regulatory affairs)

Disclaimer

The information provided in this 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