

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078941134

N/A



# SAFETY DATA SHEET

## Nitrofurantoin Macrocrystals Capsules 25 mg, 50 mg, 100 mg

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, Australian WorkSafe, Japanese Industrial Standard JIS Z 7250:2000, and European Directives

### 1. PRODUCT IDENTIFICATION

**1.1 TRADE NAME (AS LABELED):**

**Nitrofurantoin Macrocrystals Capsules 25 mg, 50 mg, 100 mg**

**SYNONYMS:**

Nitrofurantoin macrocrystals

**CAS#:**

Mixture

**1.2 PRODUCT USE:**

Macrocrystals Capsules are for use as a human pharmaceutical.

**1.3 MANUFACTURE:**

**Alvogen, Inc.**

**ADDRESS:**

10 Bloomfield Avenue, Bldg B, Pine Brook, NJ 07058

**BUSINESS PHONE:**

1-844-842-8672

**FAX NUMBER:**

1-973-807-1625

**EMERGENCY PHONE #:**

1-844-842-8672

**COMPANY WEB SITE INFORMATION:**

[www.alvogen.us.com](http://www.alvogen.us.com)

**1.4 PREPARATION INFORMATION:**

**DATE OF CURRENT REVISION:**

November 9, 2017

**DATE OF LAST REVISION:**

New

### 2. HAZARD IDENTIFICATION

**EMERGENCY OVERVIEW:**

**Product Description:** This product is a capsule with no odor.

**Health Hazards:** Intact Macrocrystals capsules are not considered to be a health hazard with normal handling. Accidental excessive ingestion may cause gastrointestinal effects, skin, hypersensitivity reactions, hematological, neurological, liver and pulmonary effects.

**Flammability Hazards:** This product is non-flammable.

**Reactivity Hazards:** None known

**Environmental Hazards:** The Environmental effects of this product have not been investigated. Release of this product is not expected to have significant adverse effects in the aquatic environment.

**US DOT SYMBOLS**

**CANADA (WHMIS) SYMBOLS**

**EUROPEAN and (GHS) Hazard Symbols**  
None

Non-Regulated Material

Complies with WHMIS 2015

Signal Word: **None**

**2.1 GHS CLASSIFICATION OF SUBSTANCE OR MIXTURE IN ACCORDANCE WITH 29 CFR 1200 (OSHA HCS) AND THE EUROPEAN UNION DIRECTIVES:**

This product does not meet the definition of a hazardous substance or preparation as defined by 29 CFR 1910.1200 AND the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

**EU HAZARD CLASSIFICATION OF INGREDIENTS PER DIRECTIVE 1272/2008/EC:**

**EC# 200-646-5 This substance is not classified in the Annex VI of Directive 67/548/EEC**

**Excipients are not listed in Annex VI of Directive 67/548/EEC**

Substances not listed either individually or in group entries must be self classified.

**Component(s) Contributing to Classification(s)**

All ingredients

**2.2 LABEL ELEMENTS:**

**GHS Hazard Classification(s):**

Skin Irritant Category 2

Eye Irritant Category 2

Acute Oral Toxicity Category 4

**Hazard Statement(s):**

Causes skin irritation

Causes eye irritation

May be harmful if swallowed

**Precautionary Statement(s):**

P264: Wash skin after handling.

**2.3 HEALTH HAZARDS OR RISKS FROM EXPOSURE:**

**SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE:** The most significant routes of exposure for this product are by skin contact or eye contact.

**ACUTE:**

**INHALATION:** No health effects are expected due to physical properties of the product.



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**CONTACT WITH SKIN:** No health effects are expected due to physical properties of the product. Prolonged or repeated contact can cause skin irritation.

**EYE CONTACT:** No health effects are expected due to physical properties of the product. Direct contact can cause eye irritation.

**INGESTION:** Single dose oral toxicity is believed to be low. May cause irritation in some individuals.

**CHRONIC:** Accidental excessive ingestion may cause gastrointestinal effects, skin, hypersensitivity reactions, hematological, neurological, liver and pulmonary effects.

**TARGET ORGANS: Acute:** Eyes, Skin

**Chronic:** Gastrointestinal tract

### 3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Ingredients:	WT%	CAS#	EINECS #	GHS Hazard Classification(s)
1-[[[5-Nitro-2-furanyl]methylene]amino]-2,4-imidazolidinedione	12 – 26%	67-20-9	200-646-5	Acute Oral Tox. Cat 4
Excipients: Edible black ink, gelatin, lactose, corn starch, talc, titanium dioxide.	74.0 – 87.2%	Various	Various	Eye Irrit. Cat 2, Skin Irrit. Cat 2
Balance of other ingredients is less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).				

NOTE: This product has been classified in accordance with the hazard criteria of the CFR and the SDS contains all the information required by the CFR, EU Directives and the Japanese Industrial Standard *JIS Z 7250: 2000*.

### 4. FIRST-AID MEASURES

#### 4.1 DESCRIPTION OF FIRST AID MEASURES:

**EYE CONTACT:** If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Seek medical attention if irritation continues or blurred vision occurs.

**SKIN CONTACT:** If product contacts skin, wash skin thoroughly with soap and water after handling. Seek medical attention if irritation develops and persists.

**INHALATION:** If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

**INGESTION:** If product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** None known

#### 4.2 SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Possible skin irritation or eye irritation. Accidental excessive ingestion may cause gastrointestinal effects, skin, hypersensitivity reactions, hematological, neurological, liver and pulmonary effects.

#### 4.3 RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and eliminate overexposure.

### 5. FIRE-FIGHTING MEASURES

#### 5.1 FIRE EXTINGUISHING MATERIALS:

Use fire extinguishing methods below:

Water Spray: Yes

Carbon Dioxide: Yes

Foam: Yes

Dry Chemical: Yes

Halon: Yes

Other: Any "C" Class

#### 5.2 UNUSUAL FIRE AND EXPLOSION HAZARDS:

Explosion Sensitivity to Mechanical Impact: No

Explosion Sensitivity to Static Discharge: No

#### 5.3 SPECIAL FIRE-FIGHTING PROCEDURES:

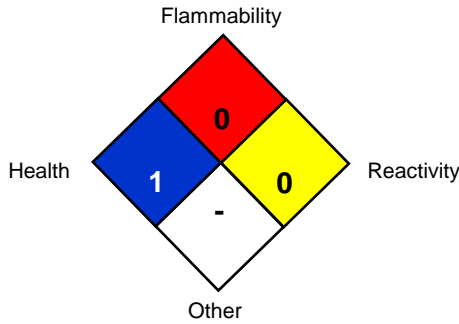
Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.



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## NFPA RATING SYSTEM



## HMIS RATING SYSTEM

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM	
HEALTH HAZARD (BLUE)	1
FLAMMABILITY HAZARD (RED)	0
PHYSICAL HAZARD (YELLOW)	0
PROTECTIVE EQUIPMENT	
EYES	RESPIRATORY
RESPIRATORY	HANDS
HANDS	BODY
	See Sect 8
	See Sect 8
For Routine Industrial Use and Handling Applications	

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

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

See section 8.2 for Exposure Controls.

### 6.2 ENVIRONMENTAL PRECAUTIONS:

None known

### 6.3 SPILL AND LEAK RESPONSE:

Vacuum material with appropriate dust collection filter in place. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

## 7. HANDLING and STORAGE

### 7.1 PRECAUTIONS FOR SAFE HANDLING:

Wash thoroughly after handling.

### 7.2 STORAGE AND HANDLING PRACTICES:

Keep in cool, dry, controlled room temperature between 59°-86°F. Protect containers from physical damage.

### 7.3 SPECIFIC USES:

Pharmaceutical

## 8. EXPOSURE CONTROLS - PERSONAL PROTECTION

### 8.1 EXPOSURE PARAMETERS:

Chemical Name	CAS#	ACGIH TLV	OSHA TWA
1-[[[5-Nitro-2-furanyl]methylene]amino]-2,4-imidazolidinedione	67-20-9	Not Listed	Not Listed
Excipients: Edible black ink, gelatin, lactose, corn starch, talc, titanium dioxide.	Various	10 mg/kg Dust	15 mg/kg Dust

### 8.2 EXPOSURE CONTROLS:

**VENTILATION AND ENGINEERING CONTROLS:** Not Applicable

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standard of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable regulations and standards for relevant details.

**RESPIRATORY PROTECTION:** Not normally required when using this product. If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

**EYE PROTECTION** Not normally required with this product. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.



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## *Nitrofurantoin Macrocrystals Capsules 25 mg, 50 mg, 100 mg*

**SKIN PROTECTION:** Not normally required with this product. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

### 9. PHYSICAL and CHEMICAL PROPERTIES

#### **9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:**

**APPEARANCE (Physical State) and COLOR:** This product is a capsule with no odor.

**ODOR:** None

**ODOR THRESHOLD:** Not Applicable

**pH:** Not Applicable

**MELTING/FREEZING POINT:** 270 - 272°C

**BOILING POINT:** Not Applicable

**FLASH POINT:** Not Applicable

**EVAPORATION RATE (n-BuAc=1):** Not Applicable

**FLAMMABILITY (SOLID, GAS):** Not Applicable

**UPPER/LOWER FLAMMABILITY OR EXPLOSION LIMITS:** Not Applicable

**VAPOR PRESSURE (mm Hg @ 20°C (68°F):** Not Applicable

**VAPOR DENSITY:** Not Applicable

**RELATIVE DENSITY:** Not Applicable

**DENSITY:** Not Applicable

**SPECIFIC GRAVITY:** Not Available

**SOLUBILITY IN WATER:** <0.1 mg/ml at 19°C

**WEIGHT PER GALLON:** Not Applicable

**PARTITION COEFFICIENT (n-octanol/water):** Not Applicable

**AUTO-IGNITION TEMPERATURE:** Not Applicable

**DECOMPOSITION TEMPERATURE:** Not Applicable

**VISCOSITY:** Not Applicable

**VOC g/l / Lb/gal:** Not Applicable

#### **9.2 OTHER INFORMATION:**

No additional information available.

### 10. STABILITY and REACTIVITY

#### **10.1 REACTIVITY:**

This product is not reactive.

#### **10.2 STABILITY:**

Stable under conditions of normal storage and use.

#### **10.3 POSSIBILITY OF HAZARDOUS REACTIONS:**

Will not occur

#### **10.4 CONDITIONS TO AVOID:**

Incompatible materials

#### **10.5 MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:**

Strong Oxidizing agents

#### **10.6 HAZARDOUS DECOMPOSITION PRODUCTS:**

Emits carbon oxides and nitrogen oxides.

### 11. TOXICOLOGICAL INFORMATION

#### **11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:**

##### **TOXICITY DATA:**

No LD 50 Data Available

**SUSPECTED CANCER AGENT:** None of the ingredients within this product are found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, or CAL/OSHA and therefore are considered to be, or suspected to be, cancer-causing agents by these agencies.

**IRRITANCY OF PRODUCT:** This product may be irritating to skin and eyes.

**SENSITIZATION TO THE PRODUCT:** This product is not considered a respiratory system or skin sensitizer.

**REPRODUCTIVE TOXICITY INFORMATION:** None of the ingredients of this product may have adverse effects on the human reproductive system.



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## *Nitrofurantoin Macrocrystals Capsules 25 mg, 50 mg, 100 mg*

**SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:** Skin and eyes irritant.

**SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:** Accidental excessive ingestion may cause gastrointestinal effects, skin, hypersensitivity reactions, hematological, neurological, liver and pulmonary effects.

**ASPIRATION HAZARD:** None

## 12. ECOLOGICAL INFORMATION

### 12.1 TOXICITY:

No toxicity data available.

### 12.2 PERSISTENCE AND DEGRADABILITY:

No specific data available on this product.

### 12.3 BIOACCUMULATIVE POTENTIAL:

No specific data available on this product.

### 12.4 MOBILITY IN SOIL:

No specific data available on this product.

### 12.5 RESULTS OF PBT ANDvPvB ASSESSMENT:

No specific data available on this product.

### 12.6 OTHER ADVERSE EFFECTS:

No specific data available on this product.

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

### 12.7 WATER ENDANGERMENT CLASS:

Water endangering in accordance with EU Guideline 91/155-EWG. Not determined

## 13. DISPOSAL CONSIDERATIONS

### 13.1 WASTE TREATMENT METHODS:

Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Canada, Australia, EU Member States and Japan.

### 13.2 EU Waste Code:

Not determined

## 14. TRANSPORTATION INFORMATION

US DOT, IATA, IMO, ADR:

**U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS:** This product is classified (per 49 CFR 172.101) by the U.S. Department of Transportation, as follows.

**14.1 PROPER SHIPPING NAME:** Non-Regulated Material

**14.2 HAZARD CLASS NUMBER and DESCRIPTION:** None

**14.3 UN IDENTIFICATION NUMBER:** None

**14.4 PACKING GROUP:** None

**14.5 DOT LABEL(S) REQUIRED:** None

**NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER:** None

**RQ QUANTITY:** None

**14.6 MARINE POLLUTANT:** None of the components of this product are designated by the Department of Transportation to be Marine Pollutants (49 CFR 172.101, Appendix B).

### 14.7 SPECIAL PRECAUTIONS FOR USER:

Avoid exposure

### 14.8 INTERNATIONAL TRANSPORTION:

**INTERNATIONAL AIR TRANSPORT ASSOCIATION SHIPPING INFORMATION (IATA):** This product is not considered as dangerous goods.

**INTERNATIONAL MARITIME ORGANIZATION SHIPPING INFORMATION (IMO):** This product is not considered as dangerous goods.

### 14.9 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND IBC CODE:

**EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR):** This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.



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## 15. REGULATORY INFORMATION

### 15.1 UNITED STATES REGULATIONS:

**U.S. SARA REPORTING REQUIREMENTS:** One of the components of this product are subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

**SARA 313 Reporting:** None

**U.S. SARA THRESHOLD PLANNING QUANTITY:** There are no specific Threshold Planning Quantities for the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lbs (4,540 kg) therefore applies, per 40 CFR 370.20.

**U.S. CERCLA REPORTABLE QUANTITY (RQ):** None

**U.S. TSCA INVENTORY STATUS:** The components of this product are listed on the TSCA Inventory or are exempted from listing. Commercial use of this material is regulated by the FDA.

**OTHER U.S. FEDERAL REGULATIONS:** None

**CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65):** Ingredients within this product are not on the Proposition 65 Lists.

### 15.2 CANADIAN REGULATIONS:

**CANADIAN DSL/NDSL INVENTORY STATUS:** The components of this product are on the DSL Inventory, or are exempted from listing.

**OTHER CANADIAN REGULATIONS:** Not applicable.

**CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS:**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.

**CANADIAN WHMIS CLASSIFICATION and SYMBOLS:** Complies with WHMIS 2015

### 15.3 EUROPEAN ECONOMIC COMMUNITY INFORMATION:

This product does meet the definition of a hazardous substance or preparation as defined by the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

See Section 2 for full Details.

### 15.4 AUSTRALIAN INFORMATION FOR PRODUCT:

The components of this product are listed on the International Chemical Inventory list.

### 15.5 JAPANESE INFORMATION FOR PRODUCT:

**JAPANESE MINISTER OF INTERNATIONAL TRADE AND INDUSTRY (MITI) STATUS:**

The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

**JAPANESE ENCS INVENTORY:**

The components of this product are on the ENCS Inventory as indicated in the section on International Chemical Inventories, below.

**POISONOUS AND DELETERIOUS SUBSTANCES CONTROL LAW:**

No component of this product is a listed Specified Poisonous Substance under the Poisonous and Deleterious Substances Control Law.

## 16. OTHER INFORMATION

**PREPARED BY:** Paul Eigbrett – (**GHS MSDS Compliance PLUS**)

**DATE OF PRINTING:** November 9, 2017

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of the need that information is current, applicable and suited to the circumstances of use. Alvogen, Inc. assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, Alvogen, Inc. assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed.

**END OF SDS SHEET**