

NITROFURANTOINUM

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Nitrofurantoin Nitrofurantoinum Nitrofurantoïne Nitrofurantoïne Nitrofurantoin
N° CAS:	67-20-9
N° EC:	200-646-5

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
Skin Sens. 1	H317
Resp. Sens. 1	H334

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.

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H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements:	
P270	Do not eat, drink or smoke when using this product.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.
P233	Keep container tightly closed.
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P264	Wash hands [and ...] thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P284	[In case of inadequate ventilation] wear respiratory protection.
P301+P317	If swallowed: Get medical help.
P302+P352	If inhaled: Wash with plenty of water
P304+P340	If inhaled: Remove person to fresh air and keep comfortable for breathing.
P321	Specific treatment (see section 4 on this label).
P330	Rinse mouth.
P333+P317	If skin irritation or rash occurs: Get emergency medical help.
P342+P316	If experiencing respiratory symptoms: Get emergency medical help immediately.
P362+P364	Take off contaminated clothing and wash it before reuse.
P403	Store in a well-ventilated place.
P501	Dispose of contents/container to local/regional/national/international regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

None known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Nitrofurantoin
IUPAC name:	1-[(E)-(5-nitrofur-2-yl)methylideneamino]imidazolidine-2,4-dione
Synonyms:	Furadantin Furadonine
N° CAS:	67-20-9
N° EC:	200-646-5
Molecular Formula:	C ₈ H ₆ N ₄ O ₅
Content:	98.0 % to 102.0 % (dried substance)

3.2 Mixtures

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Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove contaminated clothing. If unconscious, lay the person on his side in fresh air in a stable position.
After inhalation:	Move the affected person from the area and allow him to stretch. If breathing is difficult give oxygen. If breathing fails, use mechanical ventilation. Consult a physician if symptoms occur.
After skin contact:	Remove contaminated clothing and wash thoroughly with water. Consult a physician if symptoms occur.
After eye contact:	Wash immediately with plenty of water for at least 15 minutes, taking care to keep eyelids separated. Contact lenses should only be removed by experienced personnel. Consult a physician if symptoms occur.
After ingestion:	Do not induce vomiting unless advised by medical personnel. In case of vomiting, tilt the patient forward or lay on his side with the head down to keep the airways open and prevent aspiration. Do not give anything by mouth to people who show signs of drowsiness or numbness, or who are about to lose consciousness. Consult a physician if symptoms occur.
Self-protection of the first aider:	First aiders should take care of their self-protection first and foremost.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray, foam, dry chemical, carbon dioxide.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

When heated to decomposition or under fire conditions, it could be emitted toxic fumes like carbon monoxide or other typical organic combustion products.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Firefighters should use self-contained breathing apparatus and protective clothing.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

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For non-emergency personnel

Avoid dust formation. Avoid breathing vapours, mist or gas.

For emergency responders

Avoid dust formation. Avoid breathing vapours, mist or gas.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and material for containment and cleaning up

Small spill: Remove any source of ignition. Stop the source of spill. Avoid contact with skin or inhalation. Use personal protective equipment (see section 8). Clean up immediately with adsorbent materials. Collected material should be placed in appropriate container, labeled and sent for final disposal.

Large spill: Immediately report the incident and remove unnecessary personnel from the area. Stop the spread and isolate the spilled material; isolate sewers that discharge to surface waters and/or separate any runoff into catch basins or tanks to facilitate processing or disposal. Personnel involved in containment and cleanup should wear appropriate personal protective equipment to minimize exposure. The area should be thoroughly cleaned with adsorbent materials. Collected material should be placed in the appropriate container, labeled and sent for final disposal.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid contact with eyes, skin and clothing. Remove contaminated clothing and wash thoroughly after handling.
Personal protection:	Not available.
Technical protective measures:	The substance must be handled in ventilated environment or with the appropriate local air extraction. Minimize dust formation and avoid accumulation on surfaces. Use antistatic equipment and clothing and prevent dust contact with possible ignition sources.
Handling:	Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Use a tightly closed and resistant container. Avoid contact with air and light. Properly label containers in case of pouring and clean external container surfaces with proper detergents and/or solvents.
Storage – away from:	Store away from moisture and sunlight.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Control band (o OEL) FIS OEB 2 (10 micrograms/mc < OEB < 500 micrograms/mc as 8-hours TWA)

8.2 Exposure controls

Appropriate engineering control

Laboratory: It is always recommended to use fume cupboard or cabinet. Can be provided additional safety controls according to specific "control band" and the specific Exposure Control Matrix established for the substance.

Individual protection measures

Warning: Substance properties, local substance concentration, quantity handled and conditions of use (hierarchy of controls) determine the type of protective equipment needed.

Eye/face protection: Safety glasses goggles (EN 166), face shield or other full-face protection, if it is required also airways protection.

Skin protection: In production or packaging plants is recommended full-body suite like Tyvek® type, protection against liquid aerosols Type 4 (EN 14605) resistant to penetration by solid particles sprayed Type 5 (EN 13982-1), low intensity sprays Type 6 (EN 13034 and EN 17491) and antistatic (EN 1149).

Hand protection: Use chemical resistant gloves (EN374) with material compatible with solvent in which the substance is dissolved.

The actual permeation time through the gloves and their life can be affected by mode of use, temperature and substance quantities handled.

Respiratory protection: Use protective mask with P2 or P3 type dust filter (EN 143).
If the substance is dissolved in organic solvent and manipulated in an open environment in significant quantities, use an appropriate filter for chemicals (A type for boiling temperature > 65°C or Ax type for boiling temperature < 65°C) or ABEK type if simultaneous presence of other substances like, inorganic vapors, ammonia, etc. (EN 14387).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Crystalline powder, lemon yellow to brown yellow.

Odour: Odourless.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: 257-263 °C

Initial boiling point: Not available.

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Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Soluble in DMF.
Solubility in water:	Slightly soluble in water: 79.5 mg/L (25°C).
Partition coefficient (n-octanol/water):	Log P (octanol-water) -0.47
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	<div>Tcl (°C): 450 / 460 T5mm (°C): 260 Explosion class: St 2</div> <div>Pmax (bar): 11.3 Kst (bar m/s): 237 Resistivity (ohm m): 4.00x10¹¹</div> <div>30 mJ < MIE < 100 mJ</div>
Oxidising properties:	Not available.

9.2 Other information

Smiles notation: C1=C(OC(=C1)[N+][O-])=O)/C=N/N2C(=O)NC(=O)C2.O

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Not available.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

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11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ (rat): 604 mg/kg Intraperitoneal LD ₅₀ (rat): 112 mg/kg Oral TDL ₀ (man): 80 mg/kg
Skin corrosion/irritation:	Moderately irritant.
Serious eye damage/irritation:	Moderately irritant.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Some positive results from various assays invitro (SCE and AMES).
Carcinogenicity:	This product is or contains a component that is not classifiable as to its carcinogenicity based on its IARC, ACGIH, NTP, or EPA classification. ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH. Not classified: Limited evidence on animals; inadequate evidence on man (IARC – group 3)
Reproductive toxicity:	Oral-Man TDL ₀ : 140 mg/kg (14D male): Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	TDL ₀ oral/man: 29 mg/kg/20D-I - increased intracranial pressure; changes in visual field, somnolence. TDL ₀ oral/woman: 42 mg/kg/6W-I - diffuse hepatocellular necrosis. TDL ₀ oral/woman: 365 mg/kg/1Y-I - dyspnea, fibrosis interstitial, liver function tests impaired.
Aspiration Hazard:	Not available.
Other:	Likely routes of exposure: Inhalation, ingestion.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

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Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Avoid material contact with ground or water (do not dispose in sewer systems). Offer surplus and non-recyclable solutions to a licensed disposal company. Containers should be sent to appropriate treatment and final disposal according to local regulations.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not classified.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not classified.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Regulation CE 1272/2008 - Classification Labelling Packaging Regulation (hazards are fully reported in section 2)

Regulation CE 1907/2006 – REACH

Regulation CE 453/2010 – changes to Regulation REACH

Regulation CE 830/2015 – changes to Regulation REACH

EU Directive 67/548/CE

EU Directives: 89/391/CEE, 89/654/CEE, 89/655/CEE, 89/656/CEE, 90/269/CEE, 90/270/CEE, 90/394/CEE, 90/679/CEE, 93/88/CEE, 95/63/CE, 97/42/CE, 98/24/CE, 99/38/CE, 99/92/CE, 2001/45/CE, 2003/10/CE, 2003/18/CE e 2004/40/CE related to the improvement of health and safety for employees at work;

EU Directives: 80/1107/CEE, n. 82/605/CEE, n. 83/477/CEE, n. 86/188/CEE e n. 88/642/CEE protection against biological, chemical and physical risks at work;

EU Directives: 96/61/CE, 2000/60/CE, 91/156/CEE, 91/689/CEE, 94/62/CE, 84/360/CEE, 94/63/CE, 1999/13/CE, 1999/32/CE, 93/12/CEE, 2001/80/CE, 2004/35/CE environmental safety;

ADR;

European Agreement concerning the International Carriage of Dangerous Goods by Rail – RID (UNECE)

IMDG Code (IMO);

IATA Dangerous Goods Regulation.

Hazard symbol:



Risk phrases:

R22 Harmful if swallowed.

Safety phrases:

S20/21 When using do not eat, drink or smoke.

15.2 Chemical safety assessment

Not applicable.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail

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STOT: Specific Target Organ Toxicity
UN (number): United Nations (number)
vPvB: very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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