

Nitrofurantoin

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 25/03/2015 Revision date: 24/02/2017

650714

Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
Substance name : Nitrofurantoin
Chemical name : 1-((5-Nitrofurfurylidene)amino)hydantoin
EC No : 200-646-5
CAS No : 67-20-9
Product code : 650714
Formula : C8H6N4O5
Synonyms : N-(5-Nitrofurfurylidene)-1-aminohydantoin / 1-[(5-Nitrofurfurilidene)amino]idantoina
Product group : Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry
Industrial/Professional use spec : Industrial
For professional use only
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4	H302
Sensitisation — Respiratory, Category 1	H334
Sensitisation — Skin, Category 1	H317

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07 GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H302 - Harmful if swallowed
 H317 - May cause an allergic skin reaction
 H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements (CLP) : P261 - Avoid breathing dust, fume, gas, mist, spray, vapours
 P280 - Wear eye protection, face protection, protective clothing, protective gloves
 P342+P311 - If experiencing respiratory symptoms: Call a doctor, a POISON CENTER
 P333+P313 - If skin irritation or rash occurs: Get medical advice/attention

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Nitrofurantoin	(CAS No) 67-20-9 (EC No) 200-646-5	≈ 100	Acute Tox. 4 (Oral), H302 Resp. Sens. 1, H334 Skin Sens. 1, H317

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

- 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).
- First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration. Get medical advice and attention if you feel unwell.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists. Ensure adequate flushing of eyes by separating eyelids with the fingers. Remove contact lenses, if present and easy to do. Continue rinsing.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor/physician if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries after inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
- Symptoms/injuries after ingestion : Swallowing a small quantity of this material will result in serious health hazard.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : On burning: release of harmful/irritant gases/vapours e.g.: carbon monoxide - carbon dioxide.

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid raising dust.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.

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Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

See Heading 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Do not breathe dust.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Keep only in the original container in a cool, well-ventilated place.

Incompatible materials : Moisture. Direct sunlight.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Hand protection:**

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P2

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 238.2 g/mol
Colour	: Yellow.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 257 - 263 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Poorly soluble in water. Water: 79.5 mg/l
Log Pow	: -0.47
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Protect from light. Moisture. Do not allow contact with air.

10.5. Incompatible materials

No additional information available

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10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

Nitrofurantoin (67-20-9)	
LD50 oral rat	604 g/kg
LD50 intravenous (rat)	112, mg/kg
Additional information	TDL0 oral/man 80 mg/kg

Skin corrosion/irritation	: Not classified
Additional information	: Moderate skin and eyes irritant
Serious eye damage/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: TDL0 oral/man: 29 mg/kg/20D-I - increased intracranial pressure; changes in visual field, somnolence TDL0 oral/woman: 42 mg/kg/6W-I - diffuse hepatocellular necrosis TDL0 orale/donna: 365 mg/kg/1Y-I - dispnea, fibrosis interstitial, liver function tests impaired
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Harmful if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Nitrofurantoin (67-20-9)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Nitrofurantoin (67-20-9)	
Log Pow	-0.47
Bioaccumulative potential	Not established.

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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Dispose of contaminated material at an authorized site.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user**- Overland transport**

No data available

- Air transport

No data available

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

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Nitrofurantoin is not on the REACH Candidate List

Nitrofurantoin is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

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15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. REACH Disclaimer:
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number).

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Resp. Sens. 1	Sensitisation — Respiratory, Category 1
Skin Sens. 1	Sensitisation — Skin, Category 1
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

SDS EU (REACH Annex II) Version 2017

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product