

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

NIFUROXAZIDUM

EN

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

1.1 Product identifier

Product name: Nifuroxazide
Nifuroxazidum
Nifuroxazide
Nifuroxazide
Nifuroxazid

N° CAS: 965-52-6

N° EC: 213-522-0

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

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV
Oostmalsebaan 1c (unit 5)
2960 Sint-Lenaarts
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

Not classified.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable.

Signal word(s): Not applicable.

Hazard statements: Not applicable.

Precautionary statements: Not applicable.

Additional applicable label elements:



2.3 Other hazards

Dust may form explosive mixture in air.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Nifuroxazide
IUPAC name:	4-Hydroxybenzoic acid [(5-nitro-2-furanyl)methylene]hydrazide
Synonyms:	Dicoferin Diarlidan
N° CAS:	965-52-6
N° EC:	213-522-0
Molecular Formula:	C ₁₂ H ₉ N ₃ O ₅
Content:	98.5 per cent to 101.5 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
After inhalation:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
After skin contact:	Wash with plenty of soap and water. Wash contaminated clothing before reuse. Get medical advice/attention. If skin irritation occurs: Wash with plenty of soap and water.
After eye contact:	Rinse cautiously with water for several minutes. If eye irritation persists: If eye irritation persists: Get medical advice/attention. Get medical advice/attention.
After ingestion:	Rinse mouth. Do not induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects:	Not expected to present a significant hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice. May cause drowsiness or dizziness.
Symptoms/effects after inhalation:	May cause respiratory irritation.
Symptoms/effects after skin contact:	May cause moderate irritation.
Symptoms/effects after eye contact:	May cause slight irritation.
Symptoms/effects after ingestion:	May cause drowsiness or dizziness.

4.3 Indication of any immediate medical attention and special treatment needed

Never give anything by mouth to an unconscious person.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

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

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5.2 Special hazards arising from the substance/mixture

Hazardous decomposition products in case of fire: Thermal decomposition generates: Carbon monoxide. fume. Carbon dioxide. Toxic fumes may be released.

5.3 Advice for firefighters

Surrounding fires:	Stop leak if safe to do so. Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment. Exercise caution when fighting any chemical fire.
Protection against fire:	Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

General measures: No open flames. No smoking. No flames, no sparks. Eliminate all sources of ignition.

Protective equipment: Breathing equipment.

Emergency procedures: Evacuate unnecessary personnel. Avoid breathing dust, spray, mist.

Measures in case of dust release : Dust formation: dust mask.

For emergency responders

General measures: No open flames. No smoking. No flames, no sparks. Eliminate all sources of ignition.

Protective equipment: Equip clean-up crew with proper protection.

Emergency procedures: Shovel or sweep up and put in a closed container for disposal. Stop leak if safe to do so.

Ventilate confined spaces before entering.

6.2 Environmental precautions

Notify authorities if liquid enters sewers or public waters. Prevent entry to sewers and public waters. Avoid release to the environment.

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. This material and its container must be disposed of in a safe way, and as per local legislation.

Other information: Dispose of materials or solid residues at an authorized site.

6.4 Reference to other sections

See section 8: Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Ensure good ventilation of the work station. Avoid dust formation. Provide good ventilation in process area to prevent formation of vapour. Do not eat, drink or smoke when using this product. Do not breathe dust. Avoid contact with skin, eyes and clothing. Wash hands and other exposed areas
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	with mild soap and water before eating, drinking or smoking and when leaving work. Additional hazards when processed: Keep away from strong acids, strong bases and oxidation agents, heat and ignition sources. No smoking.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Hygiene measures: Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Keep container closed when not in use. Keep only in original container. Protect from sunlight. Store in a well-ventilated place. Store at room temperature. No smoking. Incompatible products: Strong acids. Strong bases. Incompatible materials: Sources of ignition. Direct sunlight.
Storage – away from:	Store protected from light. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Additional information: MOEHS occupational exposure band: 2 (0.1 - 1 mg/m³)

8.2 Exposure controls

Appropriate engineering control

Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Avoid all unnecessary exposure. Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

Individual protection measures

Eye/face protection:	Chemical goggles or safety glasses.
Type:	Safety glasses
Use:	Fine dust, dust
Characteristics:	Clear
Standard:	EN 166
Skin protection:	Wear suitable protective clothing.
Hand protection:	Protective gloves.
Type:	Disposable gloves
Material:	Butyl rubber

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Respiratory protection:	Standard: EN 374 Wear appropriate mask. Device: Dust mask Filter type: Type P3 Condition: Protection for solid particles, dust protection Standard: EN 143
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:	Bright yellow, crystalline powder.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	≈ 297 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Dust could form explosive mixtures with air.
Upper/lower flammability or explosive limits:	Explosive limits: > 30 g/m ³
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Log Pow: 1.82 Predicted ACDLabs/ALOGPS
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	May form combustible dust concentrations in air.
Oxidising properties:	Not available.

9.2 Other information

Molecular mass: 275.2 g/mol
Density: ≈ 1.49 g/cm ³

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Minimum ignition energy: ≤ 1 mJ
Dust Cloud minimum Flammability Temperature: 420 °C
Layer Minimum flammability Temperature: 300 °C
Explosion Class: St3
Explosion Severity Factor K_{max} (bar.m/s): 364
Explosivity P_{max}: 9.8 bar.m/s

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under use and storage conditions as recommended in section 7. Dust may form explosive mixture in air.

10.2 Chemical stability

Stable in use and storage conditions as recommended in item 7.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures. No flames, no sparks. Eliminate all sources of ignition. Avoid dust formation. Avoid contact with hot surfaces.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Fume. Thermal decomposition generates: Carbon monoxide. Nitrogen oxides. Carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute toxicity (oral):	Not classified.
	Acute toxicity (dermal):	Not classified.
	Acute toxicity (inhalation):	Not classified.
	LD50, acute, intraperitoneal, mouse:	100 mg/kg
Skin corrosion/irritation:	Not classified (Based on available data, the classification criteria are not met).	
Serious eye damage/irritation:	Not classified (Based on available data, the classification criteria are not met).	
Respiratory/skin sensitisation:	Not classified (Based on available data, the classification criteria are not met).	
Germ cell mutagenicity:	Not classified (Based on available data, the classification criteria are not met).	
Carcinogenicity:	Not classified (Lack of data).	
Reproductive toxicity:	Not classified (Based on available data, the classification criteria are not met).	
Summary of evaluation of the CMR properties:	Not available.	
STOT-single exposure:	Not classified (Based on available data, the classification criteria are not met).	
STOT-repeated exposure:	Not classified (Based on available data, the classification criteria are not met).	
Aspiration Hazard:	Not classified (Based on available data, the classification criteria are not met).	

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Other: Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Not available.

Skin contact: Not available.

Inhalation: Not available.

Ingestion: Not available.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Acute aquatic toxicity: Not classified.

Chronic aquatic toxicity: Not classified.

12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

Bioconcentration factor (BCF REACH): 14.28 Bioaccumulation Predicted ACDLabs at pH 5.5

Log Pow: 1.82 Predicted ACDLabs/ALOGPS

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Regional legislation (waste): Disposal must be done according to official regulations.

Product/Packaging disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials: Avoid release to the environment.

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 applicable.

14.2 UN proper shipping name

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

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14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Dangerous for the environment: No.
Marine pollutant: No.

14.6 Special precautions for user

Not available.

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

Not applicable.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.
Risk phrases: Not applicable.
Safety phrases: Not applicable.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

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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