

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Substance
Trade name	: NIFUROXAZIDE
Chemical name	: 4-Hydroxybenzoic acid [(5-nitro-2-furanyl)methylene]hydrazide
IUPAC name	: 4-Hydroxybenzoic acid [(5-nitro-2-furanyl)methylene]hydrazide
EC-No.	: 213-522-0
CAS-No.	: 965-52-6
Product code	: 75970
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C ₁₂ H ₉ N ₃ O ₅
Synonyms	: Benzoic acid p-hydroxy- (5-nitrofurfurylidene)hidrazide ; (5-Nitro-2-furfurylidene)(4-hydroxybenzoyl)hydrazine ; 1-(p-Hydroxybenzoyl)-2-(5-nitrofurfurylidene)hydrazine
Other means of identification	: SMILE: O=C(C1=CC=C(O)C=C1)N/N=C/C2=CC=C([N+](O-)=O)O2

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category	: API,Industrial use,Professional use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use
Use of the substance/mixture	: Oral nitrofurantoin-based antibiotic used to treat colitis and diarrhea
Function or use category	: Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet**Head office**

MOEHS IBÉRICA, S.L.
Roma, 8 - P.I. Cova Solera
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

Manufacturer

COPRIMA S.L.
Pablo Picasso, 15
08213 Polinya
SPAIN
T +34 93 713 19 56 - F +34 93 713 15 28
hse@moehs.es - www.moehs.com

Manufacturer

MOEHS CATALANA, S.L.
Cesar Martinell i Brunet, 12 A P.I. Rubi Sud
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

1.4. Emergency telephone number

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
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SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2. Label elements

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

No labelling applicable

2.3. Other hazards

Other hazards which do not result in classification : Dust may form explosive mixture in air.

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
NIFUROXAZIDE	CAS-No.: 965-52-6 EC-No.: 213-522-0	100

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	: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
First-aid measures after skin contact	: Wash with plenty of water/.... Wash contaminated clothing before reuse. Get medical advice/attention. If skin irritation occurs: Wash with plenty of water/....
First-aid measures 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.
First-aid measures 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.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Thermal decomposition generates : Carbon monoxide. fume. Carbon dioxide. Nitrogen oxides.
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5.3. Advice for firefighters

Precautionary measures fire	: Stop leak if safe to do so.
Firefighting instructions	: 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 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 : No open flames. No smoking. No flames, no sparks. Eliminate all sources of ignition.

6.1.1. For non-emergency personnel

Protective equipment	: Breathing equipment.
Emergency procedures	: Evacuate unnecessary personnel. Avoid breathing dust, spray, mist.
Measures in case of dust release	: Dust formation: dust mask.

6.1.2. For emergency responders

Protective equipment	: Equip cleanup 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. Minimise 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

Additional hazards when processed	: Keep away from Strong acids, strong bases and oxidation agents, Heat and ignition sources. No smoking.
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 with mild soap and water before eating, drinking or smoking and when leaving work.
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 conditions	: 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. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Incompatible products	: Strong acids. Strong bases.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage area	: Store away from heat. Store in a well-ventilated place.

7.3. Specific end use(s)

API. Pharmaceuticals. Active Ingredient for Medicinal/Pharmaceutical Use.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 2 (0.1 - 1 mg/m3)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

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.

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. Safety glasses. Dust/aerosol mask with filter type P3.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

Eye protection			
Type	Field of application	Characteristics	Standard
Safety glasses	Fine dust, Dust	clear	EN 166

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

Hand protection		
Type	Material	Standard
Disposable gloves	Butyl rubber	EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

Wear appropriate mask

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Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type P3	Protection for Solid particles, Dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Yellow.
Appearance	: Dust.
Molecular mass	: 275.2 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: ≈ 297 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Dust could form explosive mixtures with air
Explosive properties	: May form combustible dust concentrations in air.
Oxidising properties	: No data available.
Explosive limits	: > 30 g/m ³
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 1.82 Predicted ACDLabs/ALOGPS
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: ≈ 1.49 g/cm ³
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosion limits : > 30 g/m³

9.2.2. Other safety characteristics

Minimum ignition energy : ≤ 1 mJ

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Additional information : Minimum ignition energy : $\leq 1\text{mJ}$.
Dust Cloud minimum Flammability Temperature 420 °C.
Layer Minimum flammability Temperature 300 °C.
Explosivity Pmax 9.8 bar.m/s.
Explosion Severity Factor Kmax (bar.m/s) 364.
Explosion Class St3

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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

LD50, acute, intraperitoneal, mouse	1000 mg/kg [ChemIDplus]
LDLO, oral, mouse	6000 mg/kg [ChemIDplus]

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 or 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)
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)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

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11.2.2. Other information

Potential adverse human health effects and symptoms : No data available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

NIFUROXAZIDE (965-52-6)

Persistence and degradability	Not readily biodegradable.
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12.3. Bioaccumulative potential

NIFUROXAZIDE (965-52-6)

Bioconcentration factor (BCF REACH)	14.28 Bioaccumulation Predicted ACDLabs at pH 5.5
Partition coefficient n-octanol/water (Log Pow)	1.82 Predicted ACDLabs/ALOGPS

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : 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

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

14.1. UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

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14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

14.3. Transport hazard class(es)

ADR
Transport hazard class(es) (ADR) : Not applicable

IMDG
Transport hazard class(es) (IMDG) : Not applicable

IATA
Transport hazard class(es) (IATA) : Not applicable

ADN
Transport hazard class(es) (ADN) : Not applicable

RID
Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable
Packing group (ADN)	: Not applicable
Packing group (RID)	: Not applicable

14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

14.6. Special precautions for user

Overland transport
Transport regulations (ADR) : Not subject

Transport by sea
Transport regulations (IMDG) : Not subject

Air transport
Transport regulations (IATA) : Not subject

Inland waterway transport
Transport regulations (ADN) : Not subject

Rail transport
Transport regulations (RID) : Not subject

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen –

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Switzerland

Storage class (LK) : NG - Non-hazardous

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

	non-classified PBT substance
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
SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail

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Abbreviations and acronyms:	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
PNEC	Predicted No-Effect Concentration
PBT	Persistent Bioaccumulative Toxic
OECD	Organisation for Economic Co-operation and Development
NOEC	No-Observed Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
vPvB	Very Persistent and Very Bioaccumulative
LOAEL	Lowest Observed Adverse Effect Level
LD50	Median lethal dose
LC50	Median lethal concentration
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
EC50	Median effective concentration
DSD	Dangerous Substances Directive 67/548/EEC
DPD	Dangerous Preparations Directive 1999/45/EC
DNEL	Derived-No Effect Level
DMEL	Derived Minimal Effect level
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
IARC	International Agency for Research on Cancer
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor

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.

Safety Data Sheet (SDS), EU

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.