

Miconazole nitrate

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 03/11/2011 Revision date: 24/02/2017

631779

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Miconazole nitrate
IUPAC name : 1-[(2RS)-2-[2,4-Dichlorobenzyl)oxy]-2-(2,4-dichlorophenyl)-ethyl]-1H-imidazole nitrate
EC No : 245-256-6
CAS No : 22832-87-7
Product code : 631779
Formula : C₁₈H₁₅Cl₄N₃O₄
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
Function or use category : Raw material

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
Hazardous to the aquatic environment — Chronic Hazard, Category 1 H410

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Hazardous to the aquatic environment — Acute Hazard, Category 1 H400

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

GHS09

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed
H410 - Very toxic to aquatic life with long lasting effects

Precautionary statements (CLP) : P280 - Wear eye protection, face protection, protective clothing, protective gloves
P273 - Avoid release to the environment
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell

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]
Miconazole nitrate	(CAS No) 22832-87-7 (EC No) 245-256-6	99 - 101	Acute Tox. 4 (Oral), H302 Aquatic Chronic 1, H410 Aquatic Acute 1, H400

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 after inhalation : Assure fresh air breathing. Obtain medical attention if breathing difficulty persists.

First-aid measures after skin contact : Wash skin with mild soap and water. Seek medical attention if ill effect or irritation develops.

First-aid measures after eye contact : Rinse immediately with plenty of water. If eye irritation persists, take medical advice.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Seek medical advice.

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

Symptoms/injuries : Ingestion may cause nausea, vomiting and diarrhea. Gastrointestinal complaints. Damage to liver.

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 : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides. Chlorine.

Explosion hazard : Product is not explosive.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Wear proper protective equipment. Wear respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Avoid raising powdered materials into airborne dust. Evacuate area.

6.1.2. For emergency responders

Protective equipment : Wear proper protective equipment.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Protect from sunlight.

Maximum storage period : 5 year

7.3. Specific end use(s)

No additional information available

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:

Dust production: dust mask with filter type P2

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 479.1 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 178 - 184 °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)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Water: < 1 g/100ml
Log Pow	: 4.5
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

Stable under normal conditions. May decompose under the influence of light.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

Light (daylight).

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. Nitrogen oxides. Chlorine.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

Miconazole nitrate (22832-87-7)	
LD50 oral rat	920 mg/kg
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Miconazole nitrate (22832-87-7)	
LC50 fish 1	0.144 mg/l 96 h

12.2. Persistence and degradability

Miconazole nitrate (22832-87-7)	
Persistence and degradability	Not readily biodegradable.

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12.3. Bioaccumulative potential

Miconazole nitrate (22832-87-7)	
Bioconcentration factor (BCF REACH)	1071
Log Pow	4.5
Bioaccumulative potential	highly bioaccumulative.

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

No additional information available

SECTION 13: Disposal considerations



13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment. Notify authorities if product enters sewers or public waters.

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

SECTION 14: Transport information

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

ADR	IATA
14.1. UN number	
3077	3077
14.2. UN proper shipping name	
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
9	9
	
14.4. Packing group	
III	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available	

14.6. Special precautions for user

- Overland transport

Classification code (ADR) : M7

Excepted quantities (ADR) : E1

Hazard identification number (Kemler No.) : 90

Orange plates :



Tunnel restriction code (ADR) : E

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EAC code : 2Z

- 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

Miconazole nitrate is not on the REACH Candidate List

Miconazole nitrate is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

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. Supplier.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
H302	Harmful if swallowed

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H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

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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