

Miconazole nitrate

Safety Data Sheet

according to Regulation (EU) 2015/830

Date of issue: 18/09/2012 Revision date 16/03/2018

M0132

Version: 2.0

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

1.1. Product identifier

Product form : Substance
 Trade 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 : M0132
 Formula : C₁₈H₁₄Cl₄N₂O · HNO₃
 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 : Professional use
 Industrial/Professional use spec : For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.
 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 Biochemie B.V.
 A. Hofmanweg 71
 2031 BH Haarlem - The Netherlands
 T +31(0)23-5319093 - F +31(0)23-5318027
info@duchefa.nl

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)

Organisation/Company	Address	Comment
World Health Organization world directory of poison centres	http://apps.who.int/poisoncentres/	Consult website for a local poison centre

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

Full text of 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/doctor if you feel unwell.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%
Miconazole nitrate	(CAS-No.) 22832-87-7 (EC-No.) 245-256-6	> 99

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/effects : 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: Firefighting 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. [In case of inadequate ventilation] 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.

Store at ambient temperature.

Maximum storage period : 5 year

7.3. Specific end use(s)

For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

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	: Soluble in : Propylene glycol Ethanol. 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
Other information	: See actual entry in RTECS for complete information: NI4771000.

SECTION 12: Ecological information

12.1. Toxicity

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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.

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

Additional information : Very toxic to aquatic life with long lasting effects.. Avoid release to the environment.. Prevent entry to sewers and public waters

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.

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

Additional information : Very toxic to aquatic life with long lasting effects.

SECTION 14: Transport information

In accordance with ADR / IATA / IMDG

ADR	IMDG	IATA
14.1. UN number		
3077	3077	3077
14.2. UN proper shipping name		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Miconazole nitrate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Miconazole nitrate)	Environmentally hazardous substance, solid, n.o.s. (contains Miconazole nitrate)
Transport document description		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Miconazole nitrate), 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Miconazole nitrate), 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s. (contains Miconazole nitrate), 9, III
14.3. Transport hazard class(es)		
9	9	9

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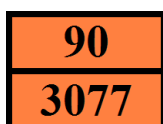
according to Regulation (EU) 2015/830

ADR	IMDG	IATA
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment : Yes	Dangerous for the environment : Yes Marine pollutant : Yes	Dangerous for the environment : Yes
No supplementary information available		

14.6. Special precautions for user

. Overland transport

Classification code (ADR) : M7
Special provisions (ADR) : 274, 335, 375, 601
Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1
Transport category (ADR) : 3
Hazard identification number (Kemler No.) : 90
Orange plates :



Tunnel restriction code (ADR) : -
EAC code : 2Z

- Transport by sea

Special provisions (IMDG) : 274, 335, 966, 967, 969
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-F
Stowage category (IMDG) : A
Stowage and handling (IMDG) : SW23

- Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y956
PCA limited quantity max net quantity (IATA) : 30kgG
PCA packing instructions (IATA) : 956
PCA max net quantity (IATA) : 400kg
CAO packing instructions (IATA) : 956
CAO max net quantity (IATA) : 400kg
Special provisions (IATA) : A97, A158, A179, A197
ERG code (IATA) : 9L

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**Germany**

12th Ordinance Implementing the Federal Immission Control Act -
12.BImSchV

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

Netherlands

SZW-lijst van kankerverwekkende stoffen

: The substance is not listed

SZW-lijst van mutagene stoffen

: The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding

: The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen –
Vruchtbaarheid

: The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling

: The substance is not listed

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:

ATE	Acute Toxicity Estimate
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

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

SDS Biochemicals version 2018

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