

# Ketoconazole

## Safety Data Sheet

**1034545**

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU)

2015/830

Issue date: 23/07/2012

Revision date 05/10/2020

Supersedes 27/02/2017

Version: 3.0

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

#### 1.1. Product identifier

Product form : Substance  
 Substance name : Ketoconazole  
 EC Index-No. : 613-283-00-6  
 EC-No. : 265-667-4  
 CAS-No. : 65277-42-1  
 Product code : 1034545  
 Formula : C<sub>26</sub>H<sub>28</sub>Cl<sub>2</sub>N<sub>4</sub>O<sub>4</sub>  
 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 - The Netherlands  
 T +31(0)23-5319093  
[farma@duchefa.nl](mailto:farma@duchefa.nl) - [www.duchefa-farma.com](http://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)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

### 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 3 H301  
 Reproductive toxicity, Category 1A H360

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Specific target organ toxicity — Repeated exposure, Category 2 H373
Hazardous to the aquatic environment — Acute Hazard, H400
Category 1
Hazardous to the aquatic environment — Chronic Hazard, H410
Category 1

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] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP) : [GHS06: Skull and crossbones] [GHS08: Health hazard] [GHS09: Environment]

- Signal word (CLP) : Danger
- Hazard statements (CLP) : H301 - Toxic if swallowed.
H360 - May damage fertility or the unborn child.
H373 - May cause damage to organs through prolonged or repeated exposure.
H410 - Very toxic to aquatic life with long lasting effects.
- Precautionary statements (CLP) : P260 - Do not breathe dust.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor
P330 - Rinse mouth.

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]
Ketoconazole	(CAS-No.) 65277-42-1 (EC-No.) 265-667-4 (EC Index-No.) 613-283-00-6	99 - 101	Acute Tox. 3 (Oral), H301 Repr. 1A, H360 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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	: Remove victim to fresh air If not breathing, give artificial respiration Seek medical advice.
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 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. Never give anything by mouth to an unconscious person Seek medical attention immediately.

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

Symptoms/effects	: Headache Dizziness Exposure may produce an allergic reaction May produce irregular heart beat and nervous symptoms. Gastrointestinal complaints This material or its emissions may induce blood disorders and/or aggravate pre-existing blood disorders. Damage to liver.
Chronic symptoms	: Based on animal experimentation, it is proved that product has shown teratogenic effects May affect: endocrine system.

### 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.
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### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. 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 : 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

#### 6.1.1. For non-emergency personnel

- Emergency procedures : Ensure adequate air ventilation. Avoid raising dust.

#### 6.1.2. For emergency responders

- Protective equipment : Wear proper protective equipment. [In case of inadequate ventilation] wear respiratory protection.

### 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. To clean the floor or objects contaminated by this product, use : Water. Detergent.

### 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.

- Storage temperature : 15 - 25 °C

### 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

#### Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

#### Hand protection:

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

**Eye protection:**

Safety glasses (to European standard EN 166 or equivalent)

**Skin and body protection:**

Protective clothing (with elasticated cuffs and closed neck). Chemical resistant apron

**Respiratory protection:**

Respiratory protection according to European standard EN 14387 or equivalent. Dust production: dust mask with filter type P3

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

Physical state	: Solid
Appearance	: Powder.
Molecular mass	: 531.4 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	: 148 - 152 °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	: Insoluble in water Soluble in ethanol Soluble in dichloromethane.
Log Pow	: 4.35
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

Stable under normal conditions.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None under normal conditions.

### 10.4. Conditions to avoid

High temperature

heat

Light (daylight).

### 10.5. Incompatible materials

Strong oxidizers.

### 10.6. Hazardous decomposition products

Carbon dioxide

Carbon monoxide

Nitrogen oxides

Chlorine.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Toxic if swallowed.

Ketoconazole (65277-42-1)	
LD50 oral rat	166 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 : May damage fertility or the unborn child.

STOT-single exposure : Not classified

STOT-repeated exposure : May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

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**12.2. Persistence and degradability**

No additional information available

**12.3. Bioaccumulative potential**

Ketoconazole (65277-42-1)	
Log Pow	4.35
Bioaccumulative potential	Strong.

**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.

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

**SECTION 14: Transport information**

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

ADR	IATA
<b>14.1. UN number</b>	
2811	2811
<b>14.2. UN proper shipping name</b>	
TOXIC SOLID, ORGANIC, N.O.S.	Not applicable
<b>14.3. Transport hazard class(es)</b>	
6.1	6.1
	
<b>14.4. Packing group</b>	
III	Not applicable
<b>14.5. Environmental hazards</b>	
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) : T2

Special provisions (ADR) : 274, 614

Limited quantities (ADR) : 5kg

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Excepted quantities (ADR) : E1

Vehicle for tank carriage : AT

Transport category (ADR) : 2

Hazard identification number  
(Kemler No.) : 60Orange plates : 

Tunnel restriction code (ADR) : E

EAC code : 2X

**- 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

Ketoconazole is not on the REACH Candidate List

Ketoconazole is not on the REACH Annex XIV List

**15.1.2. National regulations**

No additional information available

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

**SECTION 16: Other information**

Indication of changes:

1			Change of logo
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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



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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. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Repr. 1A	Reproductive toxicity, Category 1A
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H301	Toxic if swallowed.
H360	May damage fertility or the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

SDS EU (REACH Annex II) duchefa nieuwe logo

*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.*