

Ketoconazole

Version number: GHS 1.0

Date of compilation: 2020-06-10

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

1.1 Product identifier

Identification of the substance	Ketoconazole
Registration number (REACH)	this information is not available
CAS number	65277-42-1
Alternative name(s)	1-[4-[4-[[[(2SR, 4RS)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone
Article number	A0005790

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

Relevant identified uses	General use
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1.3 Details of the supplier of the safety data sheet

Chemos GmbH & Co. KG
Sonnenring 7
84032 Altdorf
Germany

Telephone: +49 871-966346-0
Telefax: +49 871-966346-13
e-mail: chemos@chemos.de
Website: <http://www.chemos.de/>

e-mail (competent person) chemos@chemos.de

1.4 Emergency telephone number

Emergency information service +49 89 1 92 40

Poison centre				
Country	Name	Postal code/ city	Telephone	Telefax
United Kingdom	National Poison Information Centre Medical Toxicology Unit	SE14 5ER London	+44 171 635 91 91	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Category	Hazard class and category	Hazard statement
3.10	acute toxicity (oral)	3	Acute Tox. 3	H301
3.7	reproductive toxicity	1B	Repr. 1B	H360F
3.9	specific target organ toxicity - repeated exposure	2	STOT RE 2	H373
4.1A	hazardous to the aquatic environment - acute hazard	1	Aquatic Acute 1	H400
4.1C	hazardous to the aquatic environment - chronic hazard	1	Aquatic Chronic 1	H410

For full text of abbreviations: see SECTION 16.

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The most important adverse physicochemical, human health and environmental effects

Delayed or immediate effects can be expected after short or long-term exposure. Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

- Signal word danger

- Pictograms

GHS06, GHS08, GHS09



- Hazard statements

- | | |
|-------|--|
| H301 | Toxic if swallowed. |
| H360F | May damage fertility. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H410 | Very toxic to aquatic life with long lasting effects. |

- Precautionary statements

- | | |
|-----------|--|
| P260 | Do not breathe dust/fume/gas/mist/vapours/spray. |
| 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. |
| P308+P313 | IF exposed or concerned: Get medical advice/attention. |
| P314 | Get medical advice/attention if you feel unwell. |
| P391 | Collect spillage. |
| P501 | Dispose of contents/container to industrial combustion plant. |

2.3 Other hazards

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance	ketoconazole
Identifiers	
CAS No	65277-42-1
EC No	265-667-4
Index No	613-283-00-6

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

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Following skin contact

Brush off loose particles from skin. Rinse skin with water/shower.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media

Water, Foam, ABC-powder

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

Deposited combustible dust has considerable explosion potential.

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO₂), Hydrogen chloride (HCl)**5.3 Advice for firefighters**

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains, Take up mechanically

Advice on how to clean up a spill

Take up mechanically.

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Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Take precautionary measures against static discharge. Use only in well-ventilated areas. Ground/bond container and receiving equipment.

- Specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- Explosive atmospheres

Removal of dust deposits.

- Ventilation requirements

Use local and general ventilation.

- Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)											
Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Ceiling-C [ppm]	Ceiling-C [mg/m³]	Notation	Source
GB	dust		WEL		10					i	EH40/2005
GB	dust		WEL		4					r	EH40/2005

Notation

Ceiling-C

i

r

STEL

ceiling value is a limit value above which exposure should not occur

inhalable fraction

respirable fraction

short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

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Notation

TWA

time-weighted average (long-term exposure limit); measured or calculated in relation to a reference period of 8 hours
time-weighted average (unless otherwise specified)

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

In the case of wanting to use the gloves again, clean them before taking off and air them well.

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.
Wash hands thoroughly after handling.

Respiratory protection

Particulate filter device (EN 143).

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state	solid (powder)
Colour	white
Odour	characteristic

Other safety parameters

pH (value)	not applicable
Melting point/freezing point	146 °C
Initial boiling point and boiling range	not determined
Flash point	not applicable
Evaporation rate	not determined
Flammability (solid, gas)	this material is combustible, but will not ignite readily
Explosion limits of dust clouds	not determined
Vapour pressure	not determined

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Density	not determined
Vapour density	this information is not available
Relative density	information on this property is not available
Solubility(ies)	not determined

Partition coefficient

- n-octanol/water (log KOW)	this information is not available
Auto-ignition temperature	not determined
Viscosity	not relevant (solid matter)
Explosive properties	none
Oxidising properties	none

9.2 Other information

Solid content	100 %
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SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

Hints to prevent fire or explosion

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

10.5 Incompatible materials

Oxidisers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Toxic if swallowed.

- Acute toxicity estimate (ATE)

Oral 100 mg/kg

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

May damage fertility.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

SECTION 12: Ecological information

12.1 Toxicity

Very toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Other adverse effects

Data are not available.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

- | | |
|--|--|
| 14.1 UN number | 2811 |
| 14.2 UN proper shipping name | TOXIC SOLID, ORGANIC, N.O.S. |
| Technical name | ketoconazole |
| 14.3 Transport hazard class(es) | |
| Class | 6.1 (toxic substances) (environmentally hazardous) |
| 14.4 Packing group | III (substance presenting low danger) |
| 14.5 Environmental hazards | hazardous to the aquatic environment |
| 14.6 Special precautions for user | |
| Provisions for dangerous goods (ADR) should be complied within the premises. | |
| 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code | |
| The cargo is not intended to be carried in bulk. | |

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN)

UN number	2811
Proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.
Class	6.1
Classification code	T2
Packing group	III
Danger label(s)	6.1, fish and tree



Environmental hazards	yes (hazardous to the aquatic environment)
Special provisions (SP)	274, 614, 802(ADN)
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
Transport category (TC)	2
Tunnel restriction code (TRC)	E

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Hazard identification No	60
Emergency Action Code	2X
International Maritime Dangerous Goods Code (IMDG)	
UN number	2811
Proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.
Class	6.1
Marine pollutant	yes (hazardous to the aquatic environment)
Packing group	III
Danger label(s)	6.1, fish and tree



Special provisions (SP)	223, 274
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
EmS	F-A, S-A
Stowage category	A

International Civil Aviation Organization (ICAO-IATA/DGR)

UN number	2811
Proper shipping name	Toxic solid, organic, n.o.s.
Class	6.1
Environmental hazards	yes (hazardous to the aquatic environment)
Packing group	III
Danger label(s)	6.1



Special provisions (SP)	A3, A5
Excepted quantities (EQ)	E1
Limited quantities (LQ)	10 kg

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Deco-Paint Directive (2004/42/EC)

VOC content	0 %
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Directive on industrial emissions (VOCs, 2010/75/EU)

VOC content	0 %
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National inventories

Country	Inventory	Status
AU	AICS	substance is listed
CA	DSL	substance is listed
EU	ECSI	substance is listed
JP	ISHA-ENCS	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed
TR	CICR	substance is listed
TW	TCSI	substance is listed

Legend

AICS	Australian Inventory of Chemical Substances
CICR	Chemical Inventory and Control Regulation
DSL	Domestic Substances List (DSL)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
INSQ	National Inventory of Chemical Substances
ISHA-ENCS	Inventory of Existing and New Chemical Substances (ISHA-ENCS)
KECI	Korea Existing Chemicals Inventory
NZIoC	New Zealand Inventory of Chemicals
TCSI	Taiwan Chemical Substance Inventory

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule

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Abbr.	Descriptions of used abbreviations
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

List of relevant phrases (code and full text as stated in chapter 2 and 3)

Code	Text
H301	Toxic if swallowed.
H360F	May damage fertility.
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.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.