

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 30-Sep-2025 Revision Number 2

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

1.1. Product identifier

Product Code(s) CAT 1169

Product Name ketoconazole

Form Not applicable

REACH registration number

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

Substance Name Ketoconazole

EC No. (Index No.) 265-667-4

CAS No. 65277-42-1

Pure substance/mixture Substance

Formula C26H28Cl2N4O4

Molecular weight 531.48

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

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

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Supplier

British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom

Tel: +44 (0)20 3080 6561 eMail: bpcrs@mhra.gov.uk

For further information, please contact

E-mail address bpcrs@mhra.gov.uk

1.4. Emergency telephone number

Emergency Telephone +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

Emergency Telephone - §45 - (EC)1272/2008				
	112			
Austria	No information available			
Bulgaria				
Croatia				
Cyprus				
Czech Republic				
Denmark				
France				
Hungary				
Ireland				
Italy				
Lithuania				
Luxembourg				
Netherlands				
Norway				
Portugal				
Romania				
Slovakia				
Slovenia				
Spain				

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Sweden	
Switzerland	

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 1B - (H360F)
Specific target organ toxicity (repeated exposure)	Category 2 - (H373)
Endocrine disruption for human health	Category 1
Hazardous to the aquatic environment - acute	Category 1 - (H400)
Hazardous to the aquatic environment - chronic	Category 1 - (H410)
Endocrine disruption for the environment	Category 1

2.2. Label elements

265-667-4

Contains Ketoconazole



Signal word

Danger

Hazard statements

EUH380 - May cause endocrine disruption in humans.

EUH430 - May cause endocrine disruption in the environment.

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 - EU (§28, 1272/2008)

P201 - Obtain special instructions before use

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P260 - Do not breathe dust, fume, gas, mist, vapors and spray

P273 - Avoid release to the environment

P280 - Wear protective gloves, protective clothing, eye protection and face protection

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P321 - Specific treatment (see supplemental first aid instructions on this label)

P391 - Collect spillage

2.3. Other hazards

No information available.

Fudasina Diamentas Information

PBT & vPvB

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information	This product does not contain any known or suspected endocrine disruptors.	
Chemical name	EU - REACH (1907/2006) - Article 59(1) EU - REACH (1907/2006) - E	ndocrine
	- Candidate List of Substances of Very Disruptor Assessment Lis	st of
	High Concern (SVHC) for Authorisation Substances	
Ketoconazole	-	

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No. (Index No.)		Specific concentration limit (SCL)	M-Factor	M-Factor (long-ter m)	Notes
Ketoconazole 65277-42-1	100	-	(613-283-00-6) 265-667-4	Acute Tox. 3 (H301) Repr. 1B (H360F) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) EUH380 EUH430	-	•		1

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Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Ketoconazole 65277-42-1	166	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air.

Eye contactRinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a doctor.

Skin contactWash skin with soap and water. In the case of skin irritation or allergic reactions see a

doctor.

Ingestion Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious

person. Get medical attention.

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

Symptoms No information available.

Effects of Exposure May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility.

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May cause damage to organs through prolonged or repeated exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Note to doctorsTreat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing mediaDo not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

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Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning upTake up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove

contaminated clothing and shoes.

General hygiene considerations Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Please refer to the manufacturer's certificate for specific storage and transport temperature

conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

of children. Store locked up.

Storage class (TRGS 510) LGK 6.1C.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Biological occupational exposure

limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) - Workers No information available

Derived No Effect Level (DNEL) - General Public No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

Hand protection The protective gloves to be used must comply with the specifications of EC Directive

89/686/EEC and the related standard EN374. Wear suitable gloves.

Gloves					
Duration of contact	Glove thickness	Break through time	PPE - Glove material Wear protective Viton™ gloves		
	0.11 mm	480 minutes	Wear protective nitrile rubber gloves		
Skin and body protection	Wear suitable protective clothing.				
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.				
General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/fa protection. Wash hands before breaks and immediately after handling the product.				
Environmental exposure controls	re controls Do not allow into any sewer, on the ground or into any body of water.				

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None known

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

AppearanceSolidPhysical stateSolid

Colourwhite, to, off-whiteOdourNo information availableOdour thresholdNo information available

Property Values Remarks • Method

Melting point / freezing point146 - 147 °CNone knownInitial boiling point and boiling rangeNo data availableNone knownFlammabilityNo data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits Flash point

Autoignition temperature

Decomposition temperature

SADT (°C)

No data available

No data available

None known

No data available

None known

No data available

None known

None known

None known

None known

No data available

pHNo data availableNone knownpH (as aqueous solution)No data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone knownWater solubilityNone known

Solubility(ies) Chloroform Methanol slightly soluble

 Partition coefficient
 4.34
 None known

 Vapour pressure
 No data available
 None known

Vapour pressureNo data availableNone knownRelative densityNo data availableNone knownBulk densityNo data available

Liquid Density

No data available

Relative vapour density

No data available

None known

Particle characteristics

Particle Size No information available Particle Size Distribution No information available

9.2. Other information

Molecular formula C26H28Cl2N4O4

Molecular weight 531.48

9.2.1. Information with regards to physical hazard classes

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No information available

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materialsNone known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 Information on likely routes of exposure

Inhalation Specific test data for the substance or mixture is not available.

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Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Acute toxicity Toxic if swallowed.

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Ketoconazole	= 166 mg/kg (Rat)	-	-

Skin corrosion/irritationBased on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicityBased on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicityContains a known or suspected reproductive toxin. Classification based on data available

for ingredients. May damage fertility or the unborn child.

The table below indicates ingredients above the cut-off threshold considered as relevant which are listed as reproductive toxins.

Chemical name	European Union

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Ketoconazole Repr. 1B

STOT - single exposure Based on available data, the classification criteria are not met.

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

Aspiration hazard Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors. May cause

endocrine disruption in humans.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Very toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Chemical name	Partition coefficient	
Ketoconazole	4.34	

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessmentBased on available data, the classification criteria are not met.

12.6. Endocrine disrupting properties

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Endocrine disrupting properties May cause endocrine disruption in the environment.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

<u>IATA</u>

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Ketoconazole)

14.3 Transport hazard class(es)14.4 Packing group6.1

Description UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III

14.5 Environmental hazards Yes

14.6 Special precautions for user

Special Provisions A3, A5 ERG Code 6L

IMDG

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Ketoconazole)

14.3 Transport hazard class(es)14.4 Packing group

Description UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III, Marine pollutant

14.5 Environmental hazards Yes

14.6 Special precautions for user

Special Provisions 223, 274 EmS-No. F-A, S-A

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14.7 Maritime transport in bulk according to IMO instruments

No information available

RID

14.1 UN number or ID number

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Ketoconazole)

UN2811

14.3 Transport hazard class(es) 6.1

14.4 Packing group

Description UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III, Environmentally Hazardous

14.5 Environmental hazards Ye

14.6 Special precautions for user

Special Provisions 274, 614 **Classification code** T2

ADR

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Ketoconazole)

14.3 Transport hazard class(es) 6.1

14.4 Packing group

Description UN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III, (E), Environmentally

Hazardous

14.5 Environmental hazards Yes

14.6 Special precautions for user

Special Provisions274, 614Classification codeT2Tunnel restriction code(E)

ADN

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Ketoconazole)

14.3 Transport hazard class(es)14.4 Packing group

DescriptionUN2811, Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III, Environmentally Hazardous

14.5 Environmental hazard Yes

14.6 Special precautions for user

Special Provisions 274, 614, 802
Classification code T2
Equipment Requirements PP, EP

SECTION 15: Regulatory information

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

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National regulations

Germany

Water hazard class (WGK)

Chemical Prohibition Ordinance

strongly hazardous to water (WGK 3)

This product is subject to requirements and restrictions regarding handling and delivery

TRGS 905 Not applicable

Netherlands

(ChemVerbotsV)

Carcinogenic, mutagenic and reproductive toxic effects

Chemical name	Netherlands - List of	Netherlands - List of Mutagens	Netherlands - List of
	Carcinogens		Reproductive Toxins
Ketoconazole - 65277-42-1	-	-	Fertility Category 1B

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018

Not applicable SC 6.1

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

Major Accidents Ordinance SR 814.012

Class A

Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name		Restricted substance per REACH	Substance subject to authorisation per
		Annex XVII	REACH Annex XIV
	Ketoconazole - 65277-42-1	30	
		75	

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

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Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

Ozone-depleting substances (ODS) regulation (EC) 2024/590

Not applicable

International Inventories

TSCA U.S. INVENTORY (TSCA): Not listed on inventory. For purposes of 40 CFR 720.36, this

product is for Research and Development (R&D) Use Only

DSL/NDSL
Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

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Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

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

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P321 - Specific treatment (see supplemental first aid instructions on this label)

P330 - Rinse mouth

P201 - Obtain special instructions before use

P273 - Avoid release to the environment

P202 - Do not handle until all safety precautions have been read and understood

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

P391 - Collect spillage

P280 - Wear protective gloves, protective clothing, eye protection and face protection

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P405 - Store locked up

P263 - Avoid contact during pregnancy and while nursing

P260 - Do not breathe dust, fume, gas, mist, vapors and spray

P314 - Get medical advice/attention if you feel unwell

Legend

Legena		
ACGIH	American Conference of Governmental Industrial Hygienists	
AIDII	Italian Association of Industrial Hygienists	
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterway (Europe)	
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)	
AIIC	Australian Inventory of Industrial Chemicals	
ATE	Acute Toxicity Estimate	
ASTM	American Society for the Testing of Materials	
bar	Biological Reference Values for Chemical Compounds in the Work Area	
BAT	Biological tolerance values for occupational exposure	
BEL	Biological exposure limits	
bw	Body weight	
Ceiling	Maximum limit value	
CLP	Classification, Labelling and Packaging Regulation; Regulation (EC) No 1272/2008	
CMR	Carcinogen, Mutagen or Reproductive Toxicant	
DFG	German Research Foundation	

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DOT	Department of Transportation (United States)	
DSL	Domestic Substances List (Canada)	
ECHA	European Chemicals Agency	
EC Number	European Community number	
EmS	Emergency Schedule	
ENCS	Existing and New Chemical Substances (Japan)	
EPA	Environmental Protection Agency	
EWC	European Waste Codes	
GHS	Globally Harmonized System	
IARC	International Agency for Research on Cancer	
IATA	International Air Transport Association	
IBC	International Code for the Construction and Equipment of Ships carrying Dangerous	
	Chemicals in Bulk	
ICAO	International Civil Aviation Organisation	
IECSC	Inventory of Existing Chemical Substances in China	
IMDG	International Maritime Dangerous Goods	
IMO	International Maritime Organization	
ISO	International Organisation for Standardisation	
KECI	Korean Existing Chemicals Inventory	
LC50	Lethal Concentration to 50% of a test population	
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)	
MAL	Measuring Technical Hygienic Air Needs	
MARPOL	International Convention for the Prevention of Pollution from Ships	
MDLPS	Ministry of Labour and Social Policy	
n.o.s.	Not Otherwise Specified	
NOAEC	No Observed Adverse Effect Concentration	
NOAEL	No Observed Adverse Effect Level	
NOELR	No Observable Effect Loading Rate	
NZIoC	New Zealand Inventory of Chemicals	
OECD	Organization for Economic Cooperation and Development	
OEL	Occupational exposure limits	
PBT	Persistent, Bioaccumulative and Toxic substance	
PICCS	Philippines Inventory of Chemicals and Chemical Substances	
PMT	Persistent, Mobile and Toxic	
PPE	Personal protective equipment	
QSAR	Quantitative Structure Activity Relationship	
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation (EC 1907/2006)	
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)	
SADT	Self-Accelerating Decomposition Temperature	
SAR	Structure-activity relationship	

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SDS	Safety Data Sheet	
SL	Surface Limit	
STEL	Short Term Exposure Limit	
STOT RE	Specific target organ toxicity - Repeated exposure	
STOT SE	Specific target organ toxicity - Single exposure	
SVHC	Substance of very high concern	
TCSI	Taiwan Chemical Substance Inventory	
TDG	Transport of Dangerous Goods (Canada)	
TRGS	Technical Rule for Hazardous Substances	
TSCA	Toxic Substances Control Act (United States)	
TWA	Time-Weighted Average	
UN	United Nations	
VOC	Volatile organic compounds	
vPvB	Very Persistent and Very Bioaccumulative	
vPvM	Very Persistent and Very Mobile	
Sen+	Sensitiser	
Sk*	Skin designation	
**	Hazard Designation	

Classification procedure			
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used		
Acute oral toxicity	Calculation method		
Acute dermal toxicity	Calculation method		
Acute inhalation toxicity - gas	Calculation method		
Acute inhalation toxicity - vapour	Calculation method		
Acute inhalation toxicity - dust/mist	Calculation method		
Skin corrosion/irritation	Calculation method		
Serious eye damage/eye irritation	Calculation method		
Respiratory sensitisation	Calculation method		
Skin sensitisation	Calculation method		
Mutagenicity	Calculation method		
Carcinogenicity	Calculation method		
Reproductive toxicity	Calculation method		
STOT - single exposure	Calculation method		
STOT - repeated exposure	Calculation method		
Chronic aquatic toxicity	Calculation method		
Acute aquatic toxicity	Calculation method		
Aspiration hazard	Calculation method		
Ozone	Calculation method		

Key literature references and sources for data used to compile the SDS

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SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 30-Sep-2025 Revision Number 2

CAT 1169 - ketoconazole

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)

European Chemicals Agency (ECHA) (ECHA_API)

Environmental Protection Agency

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

National Institute of Technology and Evaluation (NITE)

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

U.S. National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 30-Sep-2025

Reason for revision Endocrine Disruptor Information Physical and chemical properties Chemical Safety Report

Gloves Material Classification

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

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End of Safety Data Sheet

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