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Medicines & Healthcare products Regulatory Agency

British Pharmacopoeia

Quality standards

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 16-Jun-2023

Revision Number 1

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

1.1. Product identifier	
Product Code(s)	CAT 1174
Product Name	Fluconazole
Form	Not applicable

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

EC No (EU Index No)	627-806-0
CAS No	86386-73-4
Chemical name	Fluconazole
Pure substance/mixture	Substance
Formula	C13 H12 F2 N6 O
Molecular weight	306.27
1.2. Relevant identified uses of the	substance or mixture and uses advised against
Recommended use	Laboratory use

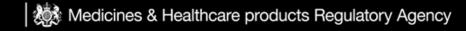
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

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





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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

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)

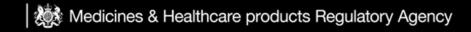
Emergency Telephone - §45 - (EC)1	272/2008
Europe	112
Austria	No information available
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 4 - (H302)
Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Reproductive toxicity	Category 1B - (H360)
Effects on or via lactation	Yes - (H362)
Specific target organ toxicity — repeated exposure	Category 2 - (H373)





SAFETY DATA SHEET

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Revision date 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

2.2. Label elements

Contains Fluconazole



Signal word Danger

Hazard statements

- H302 Harmful if swallowed
- H315 Causes skin irritation
- H319 Causes serious eye irritation
- H360 May damage fertility or the unborn child
- H362 May cause harm to breast-fed children
- H373 May cause damage to organs through prolonged or repeated exposure
- H412 Harmful to aquatic life with long lasting effects

Precautionary Statements - EU (§28, 1272/2008)

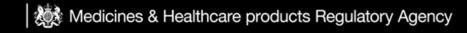
- P201 Obtain special instructions before use
- P260 Do not breathe dust/fume/gas/mist/vapours/spray
- P263 Avoid contact during pregnancy and while nursing
- P264 Wash face, hands and any exposed skin thoroughly after handling
- P280 Wear protective gloves/protective clothing/eye protection/face protection
- P308 + P313 IF exposed or concerned: Get medical advice/attention

2.3. Other hazards

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) - Endocrine
	- Candidate List of Substances of Very	Disruptor Assessment List of
	High Concern (SVHC) for Authorisation	Substances
Fluconazole	-	-





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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Weight-%	REACH registration number		Classification according to Regulation (EC) No. 1272/2008 [CLP]	•	M-Factor	M-Factor (long-term)
Fluconazole 86386-73-4	90 - 100%	-	691-089-0	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Repr. 1B (H360) Lact. (H362) STOT RE 2 (H373) Aquatic Chronic 3 (H412)			

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

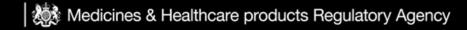
Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Fluconazole	1271	No data available	No data available	No data available	No data available
86386-73-4					

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. Get medical attention immediately if symptoms occur.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and





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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

	persists.
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).
4.2. Most important symptoms and	d effects, both acute and delayed
Symptoms	May cause redness and tearing of the eyes. Burning sensation.
4.3. Indication of any immediate m	edical attention and special treatment needed
Note to doctors	Treat symptomatically.

SECTION 5: Firefighting measures	
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5.1. Extinguishing media

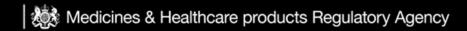
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
5.2. Special hazards arising from the	e substance or mixture
Specific hazards arising from the chemical	No information available.
5.3. Advice for firefighters	
Special protective equipment and	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

precautions for fire-fighters Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.





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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

Other information	Refer to protective measures listed in Sections 7 and 8.		
For emergency responders	Use personal protection recommended in Section 8.		
6.2. Environmental precautions			
Environmental precautions Prevent further leakage or spillage if safe to do so.			
6.3. Methods and material for containment and cleaning up			
Methods for containment	Prevent further leakage or spillage if safe to do so.		
Methods for cleaning up	Take 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.		

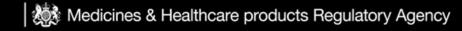
SECTION 7: Handling and storage

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. Ensure adequate ventilation. Take off 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.		

7.3. Specific end use(s)

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





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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

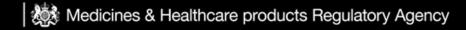
This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL)No information available.Predicted No Effect ConcentrationNo information available.(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). If splashes are likely to occur, wear safety glasses with side-shields.	
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 protective Viton™ gloves. Wear protective butyl rubber gloves. Wear suitable gloves. Impervious gloves.	
Skin and body protection	Wear suitable protective clothing. Long sleeved 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/face protection. Wash hands before breaks and immediately after handling the product.	
Environmental exposure controls	Do not allow into any sewer, on the ground or into any body of water.	





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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

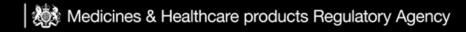
SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

9.1. Information on basic physical a		
Physical state	Solid	
Appearance	Solid	
Colour	white	
Odour	Odourless.	
Odour threshold	No information available	
Property_	Values	Remarks • Method
Melting point / freezing point	135 - 139 °C	None known
Initial boiling point and boiling rang	eNo data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No 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 weight	306.27	
Molecular formula	C13 H12 F2 N6 O	

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available





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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

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 impac Sensitivity to static discharge	t None. None.	
10.3. Possibility of hazardous react	ions	
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 materials	Strong acids. Strong bases. Strong oxidising agents.	
Hazardous decomposition products None known based on information supplied.		

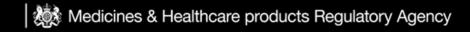
SECTION 11: Toxicological information

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

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).





SAFETY DATA SHEET

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Revision date 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity

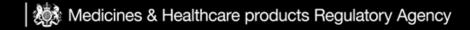
Acute toxicity

Component Information

	Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Γ	Fluconazole	= 1271 mg/kg (Rat)		

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

Skin corrosion/irritation	Classification based on data available for ingredients. Causes skin irritation. May cause skin irritation.	
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.	
Respiratory or skin sensitisation	No information available.	
Germ cell mutagenicity	No information available.	
Carcinogenicity	No information available.	
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child. May cause harm to breast-fed children.	





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 Number 1

Revision date 16-Jun-2023

CAT 1174 - Fluconazole			
STOT - single exposure	OT - single exposure No information available.		
STOT - repeated exposure	May cause damage to organs through prolonged or repeated exposure.		
Aspiration hazard	No information available.		
11.2. Information on other hazards	_		
11.2.1. Endocrine disrupting prope	erties		
Endocrine disrupting properties	rupting properties No information available.		
11.2.2. Other information			
Other adverse effects	No information available.		
SECTION 12: Ecological information			
<u>12.1. Toxicity</u>			
Ecotoxicity	Harmful to aquatic life with long lasting effects.		
12.2. Persistence and degradability			
Persistence and degradability	No information available.		

12.3. Bioaccumulative potential

Bioaccumulation No information available.

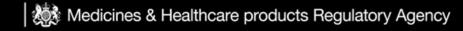
12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties





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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

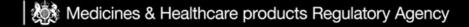
13.1. Waste treatment methods

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 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group 14.5 Environmental hazards 14.6 Special precautions for user 	Not regulated Not regulated Not regulated Not applicable None
Special Provisions	None
IMDG	
14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Marine pollutant	Not applicable
14.6 Special precautions for user	
Special Provisions	None No information available
14.7 Maritime transport in bulk	No information available
according to IMO instruments	
RID	
14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable





SAFETY DATA SHEET

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Revision date 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

14.6 Special precautions for user Special Provisions	None
ADR	
14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

SECTION 15: Regulatory information

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

non-hazardous to water (nwg)

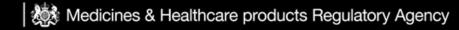
National regulations

Germany

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Water hazard class (WGK)
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Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650) . Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of





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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

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 does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

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

Not applicable

Persistent Organic Pollutants

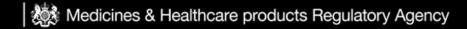
Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories TSCA Complies under research and development exemption or is regulated by a different government agency. DSL/NDSL Contact supplier for inventory compliance status Contact supplier for inventory compliance status **EINECS/ELINCS** Contact supplier for inventory compliance status ENCS **IECSC** Contact supplier for inventory compliance status Contact supplier for inventory compliance status KECL PICCS Contact supplier for inventory compliance status Contact supplier for inventory compliance status AIIC

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





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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

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

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

Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H360 - May damage fertility or the unborn child

H362 - May cause harm to breast-fed children

H373 - May cause damage to organs through prolonged or repeated exposure

H412 - Harmful to aquatic life with long lasting effects

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL
Ceiling	Maximum limit value	*

STEL (Short Term Exposure Limit) Skin 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



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 16-Jun-2023

Revision Number 1

CAT 1174 - Fluconazole

STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (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) Japan GHS Classification 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) 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** 16-Jun-2023

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

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End of Safety Data Sheet