

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

Revision date 17-Aug-2023

Revision Number 1

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

1.1. Product identifier	
Product Code(s)	TRC-F421005-10MG
Product Name	Fluconazole N-Oxide
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)	-
CAS No	1997296-62-4
Chemical name	Fluconazole N-Oxide
Pure substance/mixture	Substance
Formula	$C_{13}H_{12}F_2N_6O_2$
Molecular weight	322.27
1.2 Polovant identified uses of the s	substance or mixture and

### 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**

LGC Limited Queens Road Teddington Middlesex TW11 0LY UNITED KINGDOM :+44 (0) 20 8943 7000 Fax :+44 (0) 20 8943 2767 eMail : gb@lgcstandards.com

Web : www.lgcstandards.com

For further information, please contact



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E-mail address sds-request@lgcgroup.com

#### 1.4. Emergency telephone number

Emergency Telephone

For Hazardous Materials or Dangerous Goods Incident Spill, Leak, Fire Exposure, or Accident Call CHEMTREC: USA & Canada 1-800-424-9300 Rest of the world +1 703-741-5970

Emergency Telephone - §45 - (EC)1272/2008		
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)



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Effects on or via lactation	Yes - (H362)
Specific target organ toxicity — repeated exposure	Category 2 - (H373)
Chronic aquatic toxicity	Category 3 - (H412)

#### 2.2. Label elements

Contains Fluconazole N-Oxide



#### 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 N-Oxide	-	-



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# **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 N-Oxide 1997296-62-4	100	-	-	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 No information 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. 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 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.



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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 effects, both acute and delayed		
Symptoms	May cause redness and tearing of the eyes. Burning sensation.	
4.3. Indication of any immediate medical attention and special treatment needed		
Note to doctors	Treat symptomatically.	

SECTION 5: Firefighting measures		
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 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. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.
Other information	Refer to protective measures listed in Sections 7 and 8.
For emergency responders	Use personal protection recommended in Section 8.



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6.2. Environmental precautions	
Environmental precautions	Prevent further leakage or spillage if safe to do so.
6.3. Methods and material for conta	inment 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	Wash hands before breaks and immediately after handling the product. 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.	
7.2. Conditions for safe storage, including any incompatibilities		
Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. 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.	

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**



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#### 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 Concentration	No information available.
(PNEC)	

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	Wear suitable gloves. The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Impervious gloves.

Gloves			
Duration of contact	PPE - Glove material	Glove thickness	Break through time
	Wear protective butyl		
	rubber gloves		
Skin and body protection	Wear suitable protective clothin	ng. Long sleeved clothing.	
Respiratory protection	No protective equipment is nee exceeded or irritation is experie		
General hygiene considerations	Wash hands before breaks and immediately after handling the product. 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.		
Environmental exposure controls	Do not allow into any sewer, or	n the ground or into any body o	of water.

## **SECTION 9: Physical and chemical properties**



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### TRC-F421005-10MG - Fluconazole N-Oxide

Physical state	Solid
Appearance	Solid
Colour	Off white
Odour	No information available.
Odour threshold	No information available
Property	Values

9.1. Information on basic physical and chemical properties

Property_	Values_	Remarks • Method
Melting point / freezing point	No data available	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	> 110 °C	None known
рН	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)	DMSO (Slightly), Methanol (Slightly)	
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		
Molocular weight	300 07	

Molecular weight Molecular formula

322.27 C 13H12F 2N6O 2

9.2.1. Information with regards to physical hazard classes Not applicable > 110  $^\circ C$  > 110  $^\circ C$ 

9.2.2. Other safety characteristics No information available



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SECTION 10: Stability and reactivity		
No information available.		
Stable under normal conditions.		
None. None.		
10.3. Possibility of hazardous reactions		
None under normal processing.		
None known based on information supplied.		
Strong acids. Strong bases. Strong oxidising agents.		
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).



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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	
Delayed and immediate effects as v	vell 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.
STOT - single exposure	No information available.

May cause damage to organs through prolonged or repeated exposure.

STOT - repeated exposure



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Aspiration hazard	No information available.	
11.2. Information on other hazards	<u>8                                    </u>	
11.2.1. Endocrine disrupting prop	erties	
Endocrine disrupting properties	No information available.	
11.2.2. Other information		
Other adverse effects	No information available.	
SECTION 12: Ecological ir	nformation	
12.1. Toxicity		
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		
Endocrine disrupting properties	No information available.	



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#### 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**

|--|

<ul> <li>14.1 UN number or ID number</li> <li>14.2 UN proper shipping name</li> <li>14.3 Transport hazard class(es)</li> <li>14.4 Packing group</li> <li>14.5 Environmental hazards</li> <li>14.6 Special precautions for user</li> </ul>	Not regulated Not regulated Not regulated Not regulated Not applicable
Special Provisions	None
IMDG14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Marine pollutant14.6Special precautions for user Special Provisions14.7Maritime transport in bulk according to IMO instruments	Not regulated Not regulated Not regulated Not regulated Not applicable None No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable None



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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

Water hazard class (WGK)	strongly hazardous to water (WGK 3)
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 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 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,



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#### 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 **EINECS/ELINCS** Contact supplier for inventory compliance status Contact supplier for inventory compliance status

Legend:

ENCS **IECSC** 

KECL PICCS

AIIC

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 and Evaluated Chemical Substances **PICCS** - Philippines Inventory of Chemicals and Chemical Substances AICS - Australian Inventory of Chemical Substances



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### 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	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	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
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method



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Ozone	Calculation method	
Key literature references an Agency for Toxic Substances U.S. Environmental Protection European Food Safety Author EPA (Environmental Protection Acute Exposure Guideline Lee U.S. Environmental Protection Food Research Journal Hazardous Substance Databa International Uniform Chemica Japan GHS Classification Australian National Industrial NIOSH (National Institute for National Library of Medicine's National Library of Medicine's National Toxicology Program New Zealand's Chemical Class Organisation for Economic Co	d sources for data used to compile the SDS and Disease Registry (ATSDR) n Agency ChemView Database rity (EFSA) on Agency) vel(s) (AEGL(s)) n Agency Federal Insecticide, Fungicide, and Rodenticide Act n Agency High Production Volume Chemicals ase al Information Database (IUCLID) Chemicals Notification and Assessment Scheme (NICNAS) Occupational Safety and Health) ChemID Plus (NLM CIP) PubMed database (NLM PUBMED)	
Revision date	17-Aug-2023	
This material safety data sh Disclaimer	eet complies with the requirements of Regulation (EC) No. 1907/2006	

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

End of Safety Data Sheet