

According to REACH Regulations (EC) 1907/2006 and (EU) 2020/878

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product code : GA6740
Product name : Ketoconazole
CAS number : 65277-42-1
EINECS : 265-667-4
Physical form : solid, substance
REACH : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

PC21: Laboratory chemicals.

1.3 Details of the supplier of the safety data sheet

Company name	: Glenthams Life Sciences Ltd	Telephone	: +44 (0) 1225 667 798
	Unit 5 Leafield Way	Fax	: +44 (0) 2033 978 909
	Corsham SN13 9SW	Email	: info@glenthams.com
	United Kingdom	Web	: www.glenthams.com

1.4 Emergency telephone number

Emergency telephone : NHS Direct 111 (UK, 24 hours), 112 (EU, 24 Hours), +44 (0) 1225 667 798 (09.00 – 17.00 GMT) number

2. Hazards identification

2.1 Classification of the substance or mixture

Classification under CLP according to (EC) 1272/2008

H301	Acute Tox. 3
H360	Repr. 1B
H373	STOT RE 2
H400	Aquatic Acute 1
H410	Aquatic Chronic 1

2.2 Label elements

Label elements under CLP according to (EC) 1272/2008

Pictograms



GHS06 GHS08 GHS09

Signal words

Danger

Hazard statements

H301	Toxic if swallowed
H360	May damage fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Precautionary statements

P273	Avoid release to the environment.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/...
P308+P313	IF exposed or concerned: Get medical advice/attention.
P264	Do not breathe fume.
P260	Do not breathe dust.

2.3 Other hazards

PBT

This substance is not identified as a PBT substance.

3.0 Composition/information on ingredients

3.1 Substances

Name	Identifier	%	Classification
Ketoconazole	CAS: 65277-42-1 EC: 265-667-4 REACH: Not applicable	99.0%	H301, Acute Tox. 3 H360, Repr. 1B H373, STOT RE 2 H400, Aquatic Acute 1 H410, Aquatic Chronic 1

4. First aid measures

4.1 Description of first aid measures

Skin contact	Consult a doctor. Drench the affected skin with running water for 10 minutes or longer if substance is still on skin. Remove all contaminated clothes and footwear immediately unless stuck to skin. Transfer to hospital if there are burns or symptoms of poisoning.
Eye contact	Consult a doctor. Transfer to hospital for specialist examination. Bathe the eye with running water for 15 minutes.
Ingestion	Consult a doctor. Do not induce vomiting. If conscious, give half a litre of water to drink immediately. If unconscious and breathing is OK, place in the recovery position. If unconscious, check for breathing and apply artificial respiration if necessary. Transfer to hospital as soon as possible. Wash out mouth with water.
Inhalation	If breathing becomes bubbly, have the casualty sit and provide oxygen if available. If conscious, ensure the casualty sits or lies down. If unconscious and breathing is OK, place in the recovery position. If unconscious, check for breathing and apply artificial respiration if necessary. Transfer to hospital as soon as possible. Consult a doctor. Remove casualty from exposure ensuring one's own safety whilst doing so.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact	Absorption through the skin may be fatal. Irritation or pain may occur at the site of contact. There may be irritation and redness at the site of contact. There may be mild irritation at the site of contact. There may be redness or whiteness of the skin in the area of exposure.
Eye contact	The eyes may water profusely. There may be irritation and redness. There may be severe pain.
Ingestion	Convulsions may occur. Nausea and stomach pain may occur. There may be irritation of the throat. There may be loss of consciousness. There may be soreness and redness of the mouth and throat. There may be vomiting.
Inhalation	Absorption through the lungs can occur causing symptoms similar to those of ingestion. Convulsions may occur. Nausea and stomach pain may occur. There may be irritation of the throat with a feeling of tightness in the chest. There may be loss of consciousness. There may be shortness of breath with a burning sensation in the throat. There may be vomiting.
Delayed / immediate effects	Convulsions may occur. Delayed effects can be expected after long-term exposure. Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur. There may be loss of consciousness.

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment

Do not induce vomiting. Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

5.2 Special hazards arising from the substance or mixture

Exposure hazards

In combustion emits toxic fumes. Toxic.

5.3 Advice for fire-fighters

Wear protective clothing to prevent contact with skin and eyes. Wear self-contained breathing apparatus.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

Do not attempt to take action without suitable protective clothing - see section 8 of SDS. Do not create dust. Evacuate the area immediately. If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Notify the police and fire brigade immediately. Refer to section 8 of SDS for personal protection details.

6.2 Environmental precautions

Alert the neighbourhood to the presence of fumes or gas. Do not discharge into drains or rivers.

6.3 Methods and material for containment and cleaning up

Clean-up procedures

Clean-up should be dealt with only by qualified personnel familiar with the specific substance. Transfer to a closable, labelled salvage container for disposal by an appropriate method. Absorb into dry earth or sand.

6.4 Reference to other sections

Refer to section 8 of SDS.

7. Handling and storage

7.1 Precautions for safe handling

Handling requirements

Avoid direct contact with the substance. Avoid the formation or spread of dust in the air. Do not handle in a confined space. Ensure there is exhaust ventilation of the area. Ensure there is sufficient ventilation of the area.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Avoid contact with water or humidity. Keep container tightly closed. The floor of the storage room must be impermeable to prevent the escape of liquids. Store in cool, well ventilated area.

7.3 Specific end use(s)

No data available.

8. Exposure controls/personal protection

8.1 Control parameters

Workplace exposure limits

No workplace exposure limit control parameters set

8.2 Exposure controls

Engineering measures	Ensure there is exhaust ventilation of the area. The floor of the storage room must be impermeable to prevent the escape of liquids. Ensure there is sufficient ventilation of the area.
Respiratory protection	Particle filter class P1 (EN143). Respiratory protective device with particle filter. Self-contained breathing apparatus must be available in case of emergency.
Hand protection	Impermeable gloves. Protective gloves.
Eye protection	Safety glasses with side-shields. Ensure eye bath is to hand. Safety glasses.
Skin protection	Protective clothing.
Environmental	The floor of the storage room must be impermeable to prevent the escape of liquids.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Colour	White
Odour	No data available.
Melting point/Freezing point	146 °C
Boiling point/initial boiling point/boiling range	No data available.
Flammability	No data available.
Lower/Upper explosion limit	No data available.
Flash Point	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
pH	No data available.
Kinematic viscosity	No data available.
Solubility	No data available.
Partition coefficient n-octanol/water	No data available.
Vapour pressure	No data available.
Density/relative density	No data available.
Relative vapour pressure	No data available.
Particle characteristics	No data available.

9.2 Other information

No data available.

10. Stability and reactivity

10.1 Reactivity

Stable under recommended transport or storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions

Decomposition may occur on exposure to conditions or materials listed below. Hazardous reactions will not occur under normal transport or storage conditions.

10.4 Conditions to avoid

Flames. Hot surfaces. Heat.

10.5 Incompatible materials

Materials to avoid

Strong acids. Strong oxidising agents.

11. Toxicological information

11.1 Information on toxicological effects

a) Acute toxicity

No data available.

b) Skin corrosion/irritation

No data available.

c) Serious eye damage/irritation

No data available.

d) Respiratory or skin sensitisation

No data available.

e) Germ cell mutagenicity

No data available.

f) Carcinogenicity

No data available.

g) Reproductive toxicity

Reproductive toxicity (Category 1B)

h) STOT-single exposure

No data available.

i) **STOT-repeated exposure**

Specific target organ toxicity, repeated exposure (Category 2)

j) **Aspiration hazard**

No data available.

Symptoms / routes of exposure

Skin contact	Absorption through the skin may be fatal. Irritation or pain may occur at the site of contact. There may be irritation and redness at the site of contact. There may be mild irritation at the site of contact. There may be redness or whiteness of the skin in the area of exposure.
Eye contact	The eyes may water profusely. There may be irritation and redness. There may be severe pain.
Ingestion	Convulsions may occur. Nausea and stomach pain may occur. There may be irritation of the throat. There may be loss of consciousness. There may be soreness and redness of the mouth and throat. There may be vomiting.
Inhalation	Absorption through the lungs can occur causing symptoms similar to those of ingestion. Convulsions may occur. Nausea and stomach pain may occur. There may be irritation of the throat with a feeling of tightness in the chest. There may be loss of consciousness. There may be shortness of breath with a burning sensation in the throat. There may be vomiting.
Delayed / immediate effects	Convulsions may occur. Delayed effects can be expected after long-term exposure. Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur. There may be loss of consciousness.
Other information	No data available.

11.2 **Information on other hazards**

11.2.1 **Endocrine disrupting properties**

This product does not contain known or suspected endocrine disruptors according to REACH or relevant EU Regulations.

11.2.2 **Other information**

No additional information

12. **Ecological information**

12.1 **Toxicity**

No data available.

12.2 **Persistence and degradability**

Not biodegradable.

12.3 **Bioaccumulative potential**

Bioaccumulation potential.

12.4 **Mobility in soil**

Readily absorbed into soil.

12.5 **Results of PBT and vPvB assessment**

This substance is not identified as a PBT substance.

12.6 **Endocrine disrupting properties**

This substance is not identified as having endocrine disrupting properties

12.7 **Other adverse effects**

No data available.

13. **Disposal considerations**

13.1 **Waste treatment methods**






Disposal operations

Transfer to a suitable container and arrange for collection by specialised disposal company.

NB

The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

14. Transport information

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN2811	UN2811	UN2811	UN2811	UN2811
14.2. UN proper shipping name				
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.	TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.
Transport document description				
UN2811 TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE), 6.1, III	UN2811 TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE), 6.1, III	UN2811 Toxic solid, organic, n.o.s. (Ketoconazole), 6.1, III	UN2811 TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE), 6.1, III	UN2811 TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE), 6.1, III
14.3. Transport hazard class(es)				
6.1	6.1	6.1	6.1	6.1
				
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
No	No	No	No	No

15. Regulatory information

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

This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/878.

Authorisations/Restrictions

Regulation (EC) 1907/2006, REACH, Annex XIV list of substances subject to authorisation:	No data available.
Regulation (EC) 1907/2006, REACH, Annex XVII restrictions on the manufacture, placing on the market and use of certain dangerous substances:	No data available.
Regulation (EC) 1005/2009 on substances that deplete the ozone layer:	No data available.
Regulation (EC) 850/2004 on persistent organic pollutants, amended by (EU) No 2019/1021:	No data available.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

16. Other information

H-Statement Full Texts

H301	Toxic if swallowed
H360	May damage fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Abbreviations Full Texts

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ALARP	As low as is reasonably practicable
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging Regulations
COSHH	Control of Substances Hazardous to Health
EC Number	European Community Number
EC50	Effective Concentration 50%
EILINCS	European List of Notified Chemical Substances
EINECS	European Inventory of Existing Commercial Chemical Substances
GHS	Globally Harmonised System
HSE	Health & Safety Executive UK
IATA	International Air Transport Association
IM	Intramuscular
IMDG	The International Maritime Dangerous Goods Code
IP	Intraperitoneal
IV	Intravascular
LD50	Lethal Dose 50%
LOEC	Lowest Observable Effective Concentration
LTEL	Long Term Exposure Limit
NOEC	No Observable Effective Concentration
OECD	Organisation for Economic Cooperations and Development
PBT	Persistent Bioaccumulative Toxic
PPE	Personal Protective Equipment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Regulations Concerning the International Carriage of Dangerous Goods by Rail
SC	Subcutaneous
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
STOT	Specific Target Organ Toxicity
VOC	Volatile Organic Compounds
vPvB	Very Persistent and Very Bioaccumulative
WEL	Workplace Exposure Limits

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Disclaimer: Glentham Life Sciences shall not be held liable for any damage resulting from handling or from contact with the above product. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This document does not guarantee the properties or quality of the product.

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