

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 : GA1761
Product name : Ketoconazole, EP grade
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, EP grade | 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 | 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. Wash immediately with plenty of soap and water. |
| Eye contact | Transfer to hospital for specialist examination. Bathe the eye with running water for 15 minutes. |
| Ingestion | 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 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. 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. 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. Immediate effects can be expected after short-term exposure. 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.

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. Ensure there is exhaust 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. 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. |
| 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 | Protective gloves. |
| Eye protection | Safety glasses with side-shields. Ensure eye bath is to hand. Safety glasses. |
| Skin protection | Protective clothing. |

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 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. 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. 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. Immediate effects can be expected after short-term exposure. 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, EP GRADE), 6.1, III | UN2811 TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE, EP GRADE), 6.1, III | UN2811 Toxic solid, organic, n.o.s. (Ketoconazole, EP grade), 6.1, III | UN2811 TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE, EP GRADE), 6.1, III | UN2811 TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE, EP GRADE), 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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