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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 : GP0380
Product name : Tadalafil
CAS number : 171596-29-5
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.

Details of the supplier of the safety data sheet

Company name : Glentham Life Sciences Ltd Telephone : +44 (0) 1225 667 798

Unit 5 Leafield Way Fax : +44 (0) 2033 978 909
Corsham SN13 9SW Email : info@glentham.com
United Kingdom Web : www.glentham.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

1.3

2. Hazards identification

2.1 Classification of the substance or mixture

Classification under CLP according to (EC) 1272/2008

 H315
 Skin Irr. 2

 H319
 Eye Irr. 2A

 H335
 STOT SE 3

 H336
 STOT SE 3

2.2 Label elements

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

Pictograms



Signal words Warning

Hazard statements

H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation
H336 May cause drowsiness or dizziness

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and

easy to do - continue rinsing.

P264 Do not breathe fume.

2.3 Other hazards

PBT

This substance is not identified as a PBT substance.

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3.0 Composition/information on ingredients

3.1 Substances

Name	ldentifier	%	Classification
Tadalafil	CAS: 171596-29-5 EC: REACH: Not applicable	98%	H315, Skin Irr. 2 H319, Eye Irr. 2A H335, STOT SE 3 H336, STOT SE 3

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. Wash immediately with plenty of soap and water.
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. Remove casualty from exposure ensuring one's own safety whilst doing so. Transfer to hospital as soon as possible. Consult a doctor.

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 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 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. Exposure may cause coughing or wheezing. 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. Eye bathing equipment should be available on the premises.

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

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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. 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

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. 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. 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	Ensure eye bath is to hand. Safety glasses with side-shields. 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.

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GP0380 v2.0



Safety Data Sheet

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Melting point/Freezing point

Boiling point/initial boiling point/boiling range

Flammability

Lower/Upper explosion limit

Flash Point

Auto-ignition temperature Decomposition temperature

pН

Kinematic viscosity

Solubility

Partition coefficient n-octanol/water

Vapour pressure Density/relative density Relative vapour pressure Particle characteristics No data available.

301-303 °C @ Solvent: Dichloromethane, Hexane No data available.

No data available. No data available. No data available. No data available.

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

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

Skin corrosion/irritation (Category 2)

c) Serious eye damage/irritation

Serious eye damage/eye irritation (Category 2A)

d) Respiratory or skin sensitisation

No data available.

e) Germ cell mutagenicity

No data available.

f) Carcinogenicity

No data available.

g) Reproductive toxicity

No data available.

h) STOT-single exposure

Specific target organ toxicity, single exposure; Respiratory tract irritation (Category 3)

i) STOT-repeated exposure

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No data available.

j) Aspiration hazard

No data available.

11.2 Symptoms / routes of exposure

Other information	No data available.
Delayed / immediate effects	Convulsions may occur. Immediate effects can be expected after short-term exposure. There may be loss of consciousness.
Inhalation	Absorption through the lungs can occur causing symptoms similar to those of ingestion. Convulsions may occur. Exposure may cause coughing or wheezing. 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.
Ingestion	Convulsions may occur. There may be loss of consciousness. There may be soreness and redness of the mouth and throat. There may be vomiting.
Eye contact	The eyes may water profusely. There may be irritation and redness. There may be severe pain.
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 redness or whiteness of the skin in the area of exposure.

12. Ecological information

12.1 Toxicity

No data available.

12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

No 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.

NΒ

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

14. Transport information

This product does not require a classification for transport.

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) 2020/787.

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Authorisations/Restrictions

Regulation (EC) 1907/2006, REACH, Annex XIV list of substances subject to

No data available.

authorisation:

Regulation (EC) 1907/2006, REACH, Annex XVII restrictions on the manufacture, placing No data available.

on the market and use of certain dangerous substances:

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

No data available.

2019/1021:

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

H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation
H336 May cause drowsiness or dizziness

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

FC Number Furguean Community Number

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
VOC Volatile Organic Compounds

vPvB Very Persistent and Very Bioaccumulative

WEL Workplace Exposure Limits

This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/787.

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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