



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.03.2021

Version number 1

Revision: 17.03.2021

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

· 1.1 Product identifier

· **Product name:** Sildenafil

· **Part number:** DRE-C16946490

· **CAS Number:**
139755-83-2

· **EC number:**
604-158-7

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Reference material for laboratory use only

· 1.3 Details of the supplier of the safety data sheet

· **Manufacturer/Supplier:**

LGC Limited
Queens Road
Teddington
Middlesex TW11 0LY
UNITED KINGDOM

Tel : +44 (0) 20 8943 7000
Fax : +44 (0) 20 8943 2767
eMail : gb@lgcstandards.com
Web : www.lgcstandards.com

· Further information obtainable from:

Product safety department
eMail : sds-request@lgcgroup.com

· 1.4 Emergency telephone number:

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

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

· **Classification according to Regulation (EC) No 1272/2008**



Acute Tox. 4	H302 Harmful if swallowed.
Acute Tox. 4	H332 Harmful if inhaled.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.
STOT SE 3	H336 May cause drowsiness or dizziness.
Lact.	H362 May cause harm to breast-fed children.
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects.

(Contd. on page 2)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.03.2021

Version number 1

Revision: 17.03.2021

Product name: Sildenafil

(Contd. from page 1)

· 2.2 Label elements**· Labelling according to Regulation (EC) No 1272/2008**

The substance is classified and labelled according to the CLP regulation.

· Hazard pictograms

GHS07

· Signal word Warning**· Hazard statements**

H302+H332 Harmful if swallowed or if inhaled.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H362 May cause harm to breast-fed children.

H336 May cause drowsiness or dizziness.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P260 Do not breathe dusts or mists.

P263 Avoid contact during pregnancy and while nursing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards**· Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· 3.1 Chemical characterisation: Substances**· CAS No. Description**

139755-83-2 Sildenafil

· Identification number(s) None**· EC number:** 604-158-7**· RTECS:** TL4256300

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

GB

(Contd. on page 3)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.03.2021

Version number 1

Revision: 17.03.2021

Product name: Sildenafil

(Contd. from page 2)

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**
Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.
- **After inhalation:**
Supply fresh air and call a doctor.
In case of unconsciousness place patient in recovery position for transport.
Seek medical treatment.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
Rinse mouth. Do not induce vomiting.
Seek medical treatment.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable for surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
- **Protective equipment:**
Mouth respiratory protective device.
Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Avoid formation of dust.
- **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose of contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.

(Contd. on page 4)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.03.2021

Version number 1

Revision: 17.03.2021

Product name: Sildenafil

(Contd. from page 3)

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Store in cool, dry place in tightly closed receptacles.

Ensure good ventilation/extraction at the workplace.

Remove dust thoroughly.

· Information about fire - and explosion protection: No special measures required.**· 7.2 Conditions for safe storage, including any incompatibilities****· Storage:****· Requirements to be met by storerooms and receptacles:**

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 container in a well-ventilated place. Keep away from sources of ignition and heat.

· Information about storage in one common storage facility: Store away from foodstuffs.**· Further information about storage conditions:** Keep container tightly sealed.**· 7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters**· Additional information about design of technical facilities:** No further data; see item 7.**· Ingredients with limit values that require monitoring at the workplace:** Not required.**· Additional information:** Lists used were valid at the time of SDS preparation.**· 8.2 Exposure controls****· Personal protective equipment:****· General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

(Contd. on page 5)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.03.2021

Version number 1

Revision: 17.03.2021

Product name: Sildenafil

(Contd. from page 4)

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

*Protective gloves*

- **Material of gloves** Butyl rubber, BR
- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**

*Tightly sealed goggles*

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Solid
Colour:	White
Odour:	Odourless
Odour threshold:	Not determined.

· **pH-value:** Not applicable.

· Change in condition

Melting point/freezing point:	188-190 °C
Initial boiling point and boiling range:	Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not determined.

· **Ignition temperature:** Not determined

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Not determined.

· **Explosive properties:** Not determined.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· **Vapour pressure:** Not applicable.

(Contd. on page 6)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.03.2021

Version number 1

Revision: 17.03.2021

Product name: Sildenafil

(Contd. from page 5)

· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	DMSO (Slightly), Methanol (Slightly) Not determined.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity**
Stable under normal conditions.
No further relevant information available.
- **10.2 Chemical stability** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:**
Formation of toxic gases is possible during heating or in case of fire.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** Heat.
- **10.5 Incompatible materials:** Strong oxidizing agents.
- **10.6 Hazardous decomposition products:**
Formation of toxic gases is possible during heating or in case of fire.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
Harmful if swallowed or if inhaled.

LD/LC50 values relevant for classification:

TD L0 (Intraperitoneal) 10 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.

(Contd. on page 7)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.03.2021

Version number 1

Revision: 17.03.2021

Product name: Sildenafil

(Contd. from page 6)

· Additional toxicological information:**· CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

Oral	Reproductive	1 mg/kg (rat)
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Lact.

- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
May cause harm to breast-fed children.
- **STOT-single exposure**
May cause drowsiness or dizziness.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Harmful to aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.

GB

(Contd. on page 8)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.03.2021

Version number 1

Revision: 17.03.2021

Product name: Sildenafil

(Contd. from page 7)

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-Number | |
| · ADR, IMDG, IATA | Not applicable |
| · ADR, IMDG, IATA | Not applicable |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Not applicable |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Not applicable |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Not applicable |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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.

· Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent

(Contd. on page 9)



Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 17.03.2021

Version number 1

Revision: 17.03.2021

Product name: Sildenafil

(Contd. from page 8)

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Lact.: Reproductive toxicity – effects on or via lactation

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

• **Sources**

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

- **Data compared to the previous version altered.** All sections have been updated.

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