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

Printing date 30.08.2021 Version number 1.00 Revision: 30.08.2021

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

· **Product identifier**

· **Trade name:** **Sildenafil citrate, micronized, API**

· **Article number:** 4615
· **CAS Number:**
171599-83-0
· **EC number:**
638-824-3
· **Registration number** The substance is exempt from REACH-registration.
· **Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture**
Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.
· **Uses advised against** No relevant information available.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
CAELO
Caesar & Loretz GmbH
Herderstr. 31
D-40721 Hilden
GERMANY

· **Further information obtainable from:**
E-mail: info@caelo.de
Tel.: +49210349940 (during regular opening hours)
· **Emergency telephone number:**
Poison Information Center Bonn
Venusberg-Campus 1, 53127 Bonn
Tel: +49 (0) 228-192400

2 Hazards identification

· **Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
STOT SE 3 H335 May cause respiratory irritation.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.

(Contd. on page 2)

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

Printing date 30.08.2021 Version number 1.00 Revision: 30.08.2021

Trade name: Sildenafil citrate, micronized, API

(Contd. of page 1)

· **Hazard pictograms**

GHS07

· **Signal word** Warning
· **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
· **Precautionary statements**

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves.
P280	Wear eye protection / face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterisation: Substances**
· **CAS No. Description**
171599-83-0 Sildenafil
· **Identification number(s)**
· **EC number:** 638-824-3

4 First aid measures

· **Description of first aid measures**
· **After inhalation:**
Bring the person out of the contaminated area to fresh air.
Call a doctor immediately.
Show product-label or this MSDS.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing:**
Drink plenty of water.

(Contd. on page 3)

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

Printing date 30.08.2021 Version number 1.00 Revision: 30.08.2021

Trade name: Sildenafil citrate, micronized, API

(Contd. of page 2)

Do not induce vomiting; call for medical help immediately.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
All regular extinguishing media can be used.
Use fire extinguishing methods suitable to surrounding conditions.
· **Special hazards arising from the substance or mixture**
Flammable.
Formation of toxic gases is possible during heating or in case of fire.
· **Advice for firefighters**
· **Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.
· **Additional information**
Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Avoid contact with the substance.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Take up dry. Clean up with water.
Dispose contaminated material as waste according to item 13.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling:**
· **Precautions for safe handling** No special precautions are necessary if used correctly.
· **Information about fire - and explosion protection:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
Store in a cool location.
Tightly closed.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** Store in dry conditions.
· **Storage class:** TRHS 510: 11 Combustible solids

(Contd. on page 4)

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

Printing date 30.08.2021 Version number 1.00 Revision: 30.08.2021

Trade name: Sildenafil citrate, micronized, API

(Contd. of page 3)

· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:** Not required.

· **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:** Dust protection mask.
· **Protection of hands:** Protective gloves
· **Material of gloves**
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
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
· **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:** Safety glasses

9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**

Form:	Solid material
Colour:	Whitish
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/freezing point:	185–195 °C
Initial boiling point and boiling range:	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gas):**	Product is not flammable.
· **Decomposition temperature:**	Not determined.
· **Auto-ignition temperature:**	Not determined.

(Contd. on page 5)

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

Printing date 30.08.2021 Version number 1.00 Revision: 30.08.2021

Trade name: Sildenafil citrate, micronized, API

(Contd. of page 4)

· **Explosive properties:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapour pressure:**	Not applicable.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with water:**	Not determined.
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** Strong oxidizing agents
· **Hazardous decomposition products:** Poisonous gases/vapours

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **Primary irritant effect:**
· **Skin corrosion/irritation**
Causes skin irritation.
· **Serious eye damage/irritation**
Causes serious eye irritation.
· **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
· **Additional toxicological information:**
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **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** Based on available data, the classification criteria are not met.
· **STOT-single exposure**
May cause respiratory irritation.

(Contd. on page 6)

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

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Trade name: Sildenafil citrate, micronized, API

(Contd. of page 5)

· **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.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behaviour in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to local regulations.

14 Transport information

· **UN-Number**	Not subject to transport regulations.
· **ADR, IMDG, IATA**	not regulated
· **UN proper shipping name**	
· **ADR, IMDG, IATA**	not regulated
· **Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	not regulated
· **Packing group**	
· **ADR, IMDG, IATA**	not regulated
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.

(Contd. on page 7)

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

Printing date 30.08.2021 Version number 1.00 Revision: 30.08.2021

Trade name: Sildenafil citrate, micronized, API

(Contd. of page 6)

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)** Not listed
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Not listed

· **National regulations:**
· **Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)**
TRHS 510: 11 Combustible solids
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.
· **Reasons for alterations** This version replaces all old versions.
· **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)
MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3