

Trade name: Sildenafil citras

Substance number: 067618

Version: 1 / CH

Date revised: 30.09.13

Replaces Version: - / CH

Date of printing: 30.09.13

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

1.1. Product identifier

Sildenafil citras

Item-No. 06761800

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

Use of the substance/preparation

Active pharmaceutical substance

1.3. Details of the supplier of the safety data sheet

Address

Hänseler AG

Industriestrasse 35

9101 Herisau

Telephone no. 0041 (0)71 353 58 58

E-mail address of sdb@haenseler.ch

person responsible
for this SDS

1.4. Emergency telephone number

Switzerland :145 / Abroad +41 (0)44 251 51 51

2. Hazards identification

2.1. Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008)

Skin Irrit. 2 H315

Eye Irrit. 2 H319

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms



Signal word

Warning

Hazard statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Precautionary statements

P281	Use personal protective equipment as required.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Labelling in accordance with EC directives 1999/45/EC and 67/548/EEC

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Hazard symbols

irritant

R phrases

36/37/38

Irritating to eyes, respiratory system and skin.

3. Composition/information on ingredients**3.1. Substances****Substance / product identification**

CAS-Nr. 171599-83-0

Molecular weight

Value 666.70 g/mol

4. First aid measures**4.1. Description of first aid measures****General information**

Take affected person to fresh air. Never give anything by mouth to an unconscious person. Seek medical advice immediately.

After inhalation

Remove the casualty into fresh air and keep him calm. Irregular breathing/no breathing: artificial respiration. If necessary, give oxygen. Take medical treatment.

After skin contact

Remove contaminated, soaked clothing immediately and dispose of safely. Wash off immediately with soap and water and rinse well. Take for medical treatment.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Begin with medical treatment.

After ingestion

If swallowed, rinse mouth with water (only if the person is conscious). Take medical treatment.

4.2. Most important symptoms and effects, both acute and delayed

Headache, Nausea, Vomiting, Disturbance of vision

4.3. Indication of any immediate medical attention and special treatment needed**Hints for the physician / treatment**

If necessary, give oxygen

5. Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Water spray jet, Carbon dioxide, Dry powder, Foam

5.2. Special hazards arising from the substance or mixture

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In case of combustion evolution of dangerous gases possible. Carbon dioxide (CO₂); Carbon monoxide (CO); Nitrogen oxides (NO_x)

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Use self-contained breathing apparatus. Wear protective clothing.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing. Do not inhale dust.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

6.3. Methods and material for containment and cleaning up

Take up mechanically and collect in suitable container for disposal.

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Observe the usual precautions for handling chemicals. Do not inhale dust. Avoid contact with skin, eyes and clothing. Avoid longer or repeated exposition. Provide good ventilation of working area (local exhaust ventilation if necessary). Keep away sources of ignition. Smoking, eating and drinking should be prohibited in application area.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep in original packaging, tightly closed. Store away from sources of ignition and heat.

Hints on storage assembly

Do not store with oxidizing agents.

Further information on storage conditions

Protect from light. Protect from atmospheric moisture and water.

7.3. Specific end use(s)

Active pharmaceutical substance

8. Exposure controls/personal protection

8.2. Exposure controls

General protective and hygiene measures

General industrial hygiene practice. Hold eye wash fountain available. Wash hands before breaks and after work. At work do not eat, drink, smoke or take drugs. Store work clothing separately.

Respiratory protection

Full mask

Hand protection

Chemical resistant gloves

Eye protection

Tightly fitting safety glasses

Body protection

Protective clothing

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9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form	Crystalline powder			
Colour	white			
Melting point				
Value	185	to	195	°C
Boiling point				
Value	672.4			°C
Pressure	1.013	bar		
Flash point				
Value	376.4	to	383.6	°C
Solubility in water				
Remarks	completely soluble			
Octanol/water partition coefficient (log Pow)				
log Pow	0.93			

10. Stability and reactivity

10.1. Reactivity

No hazardous reactions when stored and handled according to prescribed instructions.

10.2. Chemical stability

Stable under recommended storage and handling conditions (see section 7).

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

Keep away from sources of heat and ignition. Protect from light.

10.5. Incompatible materials

Strong oxidising agents

10.6. Hazardous decomposition products

Toxic gases/vapours, Carbon monoxide and carbon dioxide, nitrous oxides (NOx)

11. Toxicological information

11.1. Information on toxicological effects

Acute oral toxicity

Species	rat			
LD	300	to	500	mg/kg
Species	mouse			
LD	500	to	1000	mg/kg

Acute dermal toxicity

Species	rat			
LD50	> 2000			mg/kg

Skin corrosion/irritation

Species	rabbit			
Remarks	No effect of irritation known.			

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Serious eye damage/irritation

Species rabbit eye
 Remarks slightly irritating (Eye)

Sensitization

Species guinea pig
 Remarks negative

Reproduction toxicity

Remarks negative on animals

Carcinogenicity

Remarks No evidence available on carcinogenicity.

12. Ecological information**12.1. Toxicity****Fish toxicity**

Species rainbow trout (*Oncorhynchus mykiss*)
 LC50 > 9.5 mg/l
 Duration of exposure 96 h

Daphnia toxicity

Species *Daphnia magna*
 EC50 14 mg/l
 Duration of exposure 48 h

Algae toxicity

Species *Pseudokirchneriella subcapitata*
 EC50 20 mg/l
 Duration of exposure 72 h

Bacteria toxicity

Species activated sludge
 EC50 > 1000 mg/l
 Duration of exposure 3 h

12.3. Bioaccumulative potential**Octanol/water partition coefficient (log Pow)**

log Pow 0.93

Bioconcentration factor (BCF)

Remarks Due to the distribution coefficient n-octanol/water, accumulation in organisms is possible.

13. Disposal considerations**13.1. Waste treatment methods****Disposal recommendations for the product**

EWC waste code No not dispose with rubbish.
 EWC waste code Should not be released into the sanitary sewer system.
 Disposal in compliance with local and national regulations.

Disposal recommendations for packaging

Dispose of as unused product.

14. Transport information

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Land transport ADR/RID

Non-dangerous goods

Marine transport IMDG/GGVSee

The product does not constitute a hazardous substance in sea transport.

Air transport ICAO/IATA

The product does not constitute a hazardous substance in air transport.

15. Regulatory information

16. Other information

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***

This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.