

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 1/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



## SILDENAFILI CITRAS

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name: Sildenafil citrate  
Sildenafil citras  
Sildenafil citraat  
Sildénafil (citrate de)  
Sildenafilcitrat

N° CAS: 171599-83-0

N° EC: 638-824-3

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

#### 1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV  
Oostmalsebaan 1c (unit 5)  
2960 Sint-Lenaarts  
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
Skin Irrit. 2	H315
Eye Irrit. 2	H319
Eye Irrit. 2B	H320
STOT SE 3	H335
Aquatic Chronic 3	H412

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



## SILDENAFILI CITRAS

### Hazard statements:

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H320	Causes eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long-lasting effects.

### Precautionary statements:

P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351	IF IN EYES: Rinse cautiously with water for several minutes.
P338	Remove contact lenses if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists, get medical advice/attention.
P362	Take off contaminated clothing.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to in accordance with local/regional/national/international regulation.

Additional applicable label elements:	Not applicable.
---------------------------------------	-----------------

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Sildenafil citrate
IUPAC name:	5-[2-ethoxy-5-(4-methylpiperazin-1-yl)sulfonylphenyl]-1-methyl-3-propyl-6H-pyrazolo[4,3-d]pyrimidin-7-one;2-hydroxypropane-1,2,3-tricarboxylic acid
Synonyms:	Revatio Viagra Caverta

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 3/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



## SILDENAFILI CITRAS

N° CAS: 171599-83-0  
N° EC: 638-824-3  
Molecular Formula:  $C_{28}H_{38}N_6O_{11}S$   
Content: 98.0 per cent to 102.0 per cent (anhydrous substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

After skin contact: Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

After eye contact: Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

After ingestion: If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.

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

#### Adverse effects

Adverse effects most commonly reported in clinical use include difficult digestion, nose bleed, headache, flushing, insomnia, abnormal redness of skin, difficulty breathing, muscle pain, fever, gastrointestinal irritation, tingling/itching, transient changes in light perception and colour vision, effects on hearing, and effects on vision.

#### Overdose effects

No overdose of Sildenafil has been reported as of yet. However, any medicine taken in excess can have grave consequences. If you suspect Sildenafil overdose, seek medical attention right away. If you miss a dose of Sildenafil, take it as soon as you can. However, if it is just about time for your next dose, skip the one you forgot and go on with your regular schedule. Never take a double dose of Sildenafil.

#### Acute

Heart, skin, ED (Erectile Dysfunction).

#### Chronic

Effect of chronic Sildenafil citrate is penile endothelial function.

#### Medical conditions aggravated by exposure

Sildenafil side effects include acid indigestion, diarrhoea, flushing, headache, and nasal congestion. Rare Sildenafil side effects may include blindness, heart attack, stroke, high blood pressure, asthma, and sudden death. Heart attack, stroke, sudden rise in blood pressure and sudden death have all been reported usually in men with pre-existing heart problems. Recently, some patients have reported blindness after using Sildenafil (Viagra), though such cases are rare.

#### Cross sensitivity

Sildenafil is prescribed to treat male sexual impotence also known as ED (erectile dysfunction).

#### Target organs

Erectile dysfunction.

#### Symptoms

H320 – Causes eye irritation. P264 – Wash hands thoroughly after handling. P337+P313 – If eye irritation persists: Get medical advice/attention.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## SILDENAFILI CITRAS

EN

FORM-06-14-01 (V00)

Page 4/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



### Effects of exposure

Short term: Active ingredient may be harmful if swallowed. May cause eye irritation (based on components).

Long term: Animal studies indicate that this material may cause adverse effects on the cardiovascular system.

### 4.3 Indication of any immediate medical attention and special treatment needed

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:	Use carbon dioxide, dry chemical, or water spray.
Unsuitable extinguishing media:	Formation of toxic gases is possible during heating or fire.

### 5.2 Special hazards arising from the substance/mixture

Unusual fire and explosion hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build-up of static electricity.

Specific hazards in case of fire: Fine particles (such as dust and mists) may fuel fires/explosions.

### 5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazardous combustion products:	Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Ensuring personal safety, mark out contaminated area with signs and prevent unauthorised access. Turn leaking containers up to prevent further leaks. Evacuate area. Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Sweep up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete.

#### For emergency responders

Ensuring personal safety, mark out contaminated area with signs and prevent unauthorised access. Turn leaking containers up to prevent further leaks. Evacuate area. Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Sweep up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete.

### 6.2 Environmental precautions

Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.

### 6.3 Methods and material for containment and cleaning up

Small spill: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Large spill: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 6.4 Reference to other sections

Not available.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 5/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



## SILDENAFILI CITRAS

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:	Sildenafil citrate is a non-hygroscopic substance at normal conditions of temperature and relative humidity. While handling the material, avoid all contact and inhalation of dust and/or vapours associated with the material. Wash thoroughly after handling.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed. This material should be handled and stored per label instructions to ensure product integrity. Do not store above 25 °C.
Storage – away from:	Store protected from light and moisture.

#### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Exposure limits: Industry: 8- minute OEL: 350 micrograms/m<sup>3</sup>

#### 8.2 Exposure controls

##### Appropriate engineering control

Information on the system design: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Ventilation: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls.

Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals. Do not drink, eat and smoke while working. Avoid contact with the eye and skin. Keep away from food stuffs, feed and beverages.

##### Individual protection measures

Eye/face protection: Splash goggles. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection is preferred. Maintain eyewash facilities in the work area.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 6/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



## SILDENAFILI CITRAS

Skin protection:	Full suit. Boots. Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin.
Hand protection:	Gloves.
Respiratory protection:	Dust respirator. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist before handling this product. NIOSH/MSHA-approved respirator.
Thermal hazards:	Not determined.
<b>Environmental exposure control</b>	
Not available.	

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, slightly hygroscopic, crystalline powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	376.372 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	0 mmHg at 25 °C
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Slightly soluble in methanol, practically insoluble in hexane.
Solubility in water:	Slightly soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Between 185.0 and 195.0 °C with decomposition.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## SILDENAFILI CITRAS

EN

FORM-06-14-01 (V00)

Page 7/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



### SECTION 10: STABILITY AND REACTIVITY

#### 10.1 Reactivity

Not available.

#### 10.2 Chemical stability

Stable under normal conditions of use.

#### 10.3 Possibility of hazardous reactions

Not available.

#### 10.4 Conditions to avoid

Avoid direct sunlight, conditions that might generate heat and sources of ignition.

#### 10.5 Incompatible materials

As a precautionary measure, keep away from strong oxidisers.

#### 10.6 Hazardous decomposition products

This material is combustible.

When heated to decomposition, material emits toxic fumes of SO<sub>x</sub>, NO<sub>x</sub> and HCl. Emits toxic fumes under fire conditions.

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Oral LDmin (rat): 300 – 500 mg/kg Oral LDmin (mouse): 500 – 1 000 mg/kg Dermal LD <sub>50</sub> (rat): > 2 000 mg/kg Summary comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.
Skin corrosion/irritation:	Skin irritation, rabbit: non-irritating.
Serious eye damage/irritation:	Eye irritation, rabbit: moderate.
Respiratory/skin sensitisation:	Skin sensitisation, guinea pig: negative.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

#### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 8/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



## SILDENAFILI CITRAS

Ingestion: Not available.

Aspiration: Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Aquatic toxicity:

*Daphnia Magna* TAD EC50 48 hours 14 mg/l

*Oncorhynchus mykiss* (Rainbow trout) OECD LC50 96hours > 9.5 mg/l

*Pseudokirchneriella subcapitata* (Green alga) OECD EC50 72 hours 20 mg/l

Aquatic toxicity comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC<sub>50</sub>) is not achievable.

#### 12.2 Persistence and degradability

The active ingredient in this formulation is water soluble and is expected to remain primarily in water.

#### 12.3 Bioaccumulative potential

The active ingredient in this formulation has low potential to bioaccumulation and long-term adverse effects to aquatic organisms are not expected.

#### 12.4 Mobility in soil

Solubility: Slightly soluble in water and in methanol.

Volatility: This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.

Adsorption: This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. It may persist in soil or sediment if released directly to the environment.

Partitioning: This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

#### 12.5 Results of PBT and vPvB assessment

Not available.

#### 12.6 Other adverse effects

Environmental overview: In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater.

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Waste disposal/treatment methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release.

Recommendation: It is recommended that waste should be minimised. The best available technology should be utilised to prevent environmental releases. This may include destructive techniques for waste and wastewater.



# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## SILDENAFILI CITRAS

EN

FORM-06-14-01 (V00)

Page 9/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), Not regulated.  
IATA/ICAO (Air) :

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Not regulated.  
IATA/ICAO (Air) :

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), Not regulated.  
IATA/ICAO (Air) :

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), Not regulated.  
IATA/ICAO (Air) :

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not regulated.  
IATA/ICAO (Air) :

##### 14.6 Special precautions for user

Not available.

##### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

##### 14.8 Additional transport information

Not dangerous according to the above specifications.

### SECTION 15: REGULATORY INFORMATION

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Irritant

Risk phrases:

R22 Harmful if swallowed.

R36/37/38 Irritating to eyes, respiratory system and skin.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

S1 Keep locked up.

S7/9 Keep container tightly closed and in a well-ventilated place.

S20/21 When using do not eat, drink or smoke.

S27 Take off immediately all contaminated clothing.

S28 After contact with skin, wash immediately with plenty of soap and water.

S36/373/9 Wear suitable protective clothing, gloves and eye/face protection.

S51 Use only in well-ventilated areas.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 10/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



## SILDENAFILI CITRAS

S61 Avoid release to the environment. Refer to special instructions/safety data sheets.

### 15.2 Chemical safety assessment

Not available.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.

### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.  
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available.

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## SILDENAFILI CITRAS

EN

FORM-06-14-01 (V00)

Page 11/11

Publication: 05/05/2022

Revision: XX/XX/XXXX

Version: 00



This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

### 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be