

MATERIAL SAFETY DATA SHEET

Product: **SILDENAFIL CITRATE (EUR. PH.)**

Product code: 003734

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Emission date: 11/06/2026

Version: 003734_MSDS_ENG_0126



1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: **SILDENAFIL CITRATE (EUR. PH.)**
Product code: 003734
N° CAS: 150-13-0
N° EC: 205-753-0

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

Relevant identified uses: Pharmaceutical active ingredient

1.3. Details of the supplier of the safety data sheet

Company: **METAPHARMACEUTICAL INDUSTRIAL SLU**
JOSEP PLA 163 2º 5ª
08020 BARCELONA
SPAIN
Phone number: (0034) 933 089 976
Contact e-mail: info@metaph.es
Web page: www.metaph.com

1.4. Emergency telephone number

National Institute of Toxicology of Madrid: (0034) 915 620 420

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

The product is classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP).

Skin Irrit. 2, H315

Eye Irrit. 2, H319

STOT SE 3, H335

2.2. Label Elements



Signal word (CLP): 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/vapors/spray
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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2.3. Other hazards

No additional information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Product name:	SILDENAFIL CITRATE
Synonyms:	SILDENAFIL CITRATE, SILDENAFIL CITRATO
IUPAC name:	1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1h-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine citrate
Nº CAS:	171599-83-0
Nº EC:	638-824-3
Molecular formula:	C ₂₂ H ₃₀ N ₆ O ₄ S·C ₆ H ₈ O ₇

3.2. Mixtures

Not applicable.

4. FIRST AID MEASURES

4.1. Description of first aid measures

General advises:	Consult a doctor. Show the safety data sheet to the doctor on duty.
Inhalation:	Take outdoors. If breathing is irregular, call a doctor immediately. Only apply artificial respiration if breathing stops or under medical supervision.
Skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.
Eye contact:	Remove contact lenses and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Ingestion:	If conscious, give victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

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

Symptoms include headache, nausea, vomiting, nasal congestion, facial flushing, and temporary visual disturbances. Serious side effects occur rarely. Increases blood pressure. May cause visual disturbances and dizziness.

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

Special treatment: Observe the victim for delayed symptoms. If breathing is difficult, administer oxygen. Ensure that safety showers and eyewash stations are available in the workplace.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing methods:	Foam, dry chemical powder, carbon dioxide, sand, water spray/mist
Unsuitable extinguishing methods:	Direct water jet.
Neighboring fires (containers exposed to fire):	Water spray or water mist.

5.2. Special hazards arising from the substance or mixture

May emit toxic fumes of carbon dioxide, carbon monoxide, and nitrogen oxides when burned.

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**5.3. Advice for firefighters**

General information: Cool containers with water to prevent product decomposition and development of potential health hazards. Always use full fire protection. Collect the water that should not enter the sewer. Eliminate the contaminated water used to extinguish and the remains of the second current regulations.

Equipment: Helmet with visor, flame retardant clothing (jacket and trousers with braces around the arms, legs and waist, EN 469), gloves (fire and dielectric proof, EN 659), a mask with a full-face mask. operator's face or car (protective car) in the case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

6. ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

For exposure controls and personal protection measures, see Section 8.

Provide cleanup personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

6.2. Environmental precautions

Prevent release into the environment. Avoid entry into sewers and waterways. If the product reaches drains or public watercourses, notify the relevant authorities.

6.3. Methods and material for containment and cleaning up

Store away from other materials. If spilled on the ground, sweep up or collect using a shovel or similar tool and place in suitable containers. Minimize dust generation.

6.4. Reference to other sections

For exposure controls and personal protective measures, see Section 8.

For disposal recommendations, see Section 13.

7. HANDLING AND STORAGE**7.1. Precautions for safe handling**

Avoid breathing dust. Prevent contact with eyes, skin, and clothing. Avoid prolonged or repeated exposure. Ensure adequate ventilation. Protect from ignition sources. Wash hands thoroughly after handling. Do not eat, drink, or smoke in the workplace.

Keep work clothing separate from normal clothing.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed, original, light-resistant containers. Protect from high temperatures and strong oxidizing agents. Take measures to prevent contact with moisture or water.

In storage areas, do not eat, drink, smoke, use open flames, or operate spark-producing equipment.

7.3. Specific end use(s)

No additional information available beyond that provided in Section 1.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Exposure controls/personal protection**

Monitoring procedures for airborne concentrations of hazardous substances and workplace air quality control procedures, where available and justified, should be implemented in accordance with applicable workplace standards using validated measurement methodologies.

8.2. Exposure controls

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation in the workplace by means of effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE marking that certifies compliance with the applicable regulations. Arrange an emergency shower with a visco-elastic tray.

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Eye and face protection:	Protection masks and safety glasses according to EN 165, EN 166, EN 167, EN 168.
Hands protection:	Handle with gloves. The selected protective gloves must comply with the specifications of the EU Directive 89/686/EEC and the standards EN 374-1, EN 374-2, EN 374-3, EN 420 derived from it.
Respiratory protection:	Where risk assessment shows that air purifying respirators are appropriate, use type N95 (USA) or type P1 (EN 149) dust mask. Use respirators and components tested and approved under the appropriate government standards such as NIOSH (USA) or CEN (EU).
Skin protection:	Choose body protection based on the amount and concentration of the dangerous substance in the workplace.
Hygiene measures:	Handle with adequate industrial hygiene precautions, and respect safety practices. Wash your hands before breaks and after finishing the workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aspect:	Solid
Color:	White or almost white
Molecular weight (g·mol ⁻¹):	666.70 g/mol
Density (25°C):	0.302 g/mL
Melting Point (°C):	185 – 195
Flash point (°C):	380 ± 3.6
Boiling point (20°C, 760 mmHg):	672.4
n-Octanol/Water Partition Coefficient (20°C):	0.93

9.2. Other information

Maximum Explosion Pressure (bar):	80 ± 0.4
Maximum Rate of Pressure Rise (bar/s):	751 ± 75
Minimum Ignition Energy (mJ):	< 2.9
Explosion Index (m·bar/s):	204 ± 21
Dust Explosion Class:	St2

10. STABILITY AND REACTIVITY

10.1. Reactivity

No special conditions. Stable under recommended handling and storage conditions (see Section 7).

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No data available.

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**10.4. Conditions to avoid**

Avoid ignition sources, high temperatures, and exposure to sunlight.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

May produce toxic fumes in the event of fire.

11. TOXICOLOGICAL INFORMATION**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Acute oral toxicity (LD50, rat):	2210 mg/Kg
Skin corrosion/irritation:	Causes skin irritation
Serious eye damage/eye irritation:	Causes serious eye irritation
Skin or respiratory sensitization:	No additional information available (Lack of data)
Germ cell mutagenicity:	No additional information available (Lack of data)
Carcinogenicity:	No component present at levels greater than or equal to 0.1% is identified as a probable, possible, or confirmed human carcinogen
Reproductive toxicity:	No additional information available (Lack of data)
STOT – single exposure:	May cause respiratory irritation
STOT – repeated exposure:	No additional information available (Lack of data)
Aspiration Hazard:	No additional information available (Lack of data)

Potential Health Effects

Inhalation:	Harmful if inhaled. May cause respiratory tract irritation
Ingestion:	Harmful if swallowed
Skin:	Harmful if absorbed through the skin. May cause skin irritation
Eyes:	May cause eye irritation
Signs and Symptoms of Exposure:	Symptoms include headache, nausea, vomiting, nasal congestion, facial flushing, and temporary visual disturbances. Serious adverse effects occur rarely. Increases blood pressure. May cause visual disturbances and dizziness. Overdose may cause abnormal and prolonged erection, which in extreme cases may last up to 6 hours. Drug abuse in healthy men may lead to painful erectile dysfunction without sildenafil

11.2. Information on other hazards

Nº RTECS: TL4284390

12. ECOLOGICAL INFORMATION

Use in accordance with good work practices, avoiding dispersing the product in the environment. Notify the competent authorities if the product has reached water courses or if it has contaminated the soil or vegetation.

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

The substance has low bioaccumulation potential.

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12.4. Results of PBT and vPvB assessment

No data available.

12.5. Other adverse effects

This substance/mixture does not contain components considered persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

14. INFORMACIÓN RELATIVA AL TRANSPORTE

The product should not be considered hazardous according to the applicable regulations for the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code), and air (IATA).

14.1. UN Number

Not dangerous for transport.

14.2. UN proper shipping name

Not dangerous for transport.

14.3. Transport hazard class(es)

Not dangerous for transport.

14.4. Packing group

Not dangerous for transport.

14.5. Environmental hazards

Not dangerous for transport.

14.6. Special precautions for user

Not dangerous for transport.

14.7. Maritime transport in bulk according to IMO instruments

No additional information available.

15. REGULATORY INFORMATION

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

The Safety Data Sheet complies with the requirements of Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council is modified, relating to the registration, evaluation, authorization and restriction of chemical substances and mixtures (REACH).

15.2. Chemical safety assessment

No additional information available.

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16. OTHER INFORMATION

Abbreviations and acronyms:

PBT: Persistent, bioaccumulative and toxic

mPmB: Very persistent and very bioaccumulative

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

Data sources used:

Regulation (CE) No. 1272/2008 of the European Parliament and of the Council, of December 16, 2008, on the classification, labeling and packaging of substances and mixtures, and by which Directives 67/548/CEE and 1999 are modified and repealed /45/CE and modifies Regulation (CE) No. 1907/2006.

Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council, regarding registration, evaluation, authorization and the restriction of chemical substances and mixtures (REACH)

Safety Data Sheet according to Annex II of REACH Regulation (EU) 2020/878

Department issuing the Safety Data Sheet:

Technical Department

The information in this Product Safety Data Sheet is based on current knowledge and current EC and national laws, as far as the working conditions of users are beyond our knowledge and control. The product must not be used for purposes other than those specified, without first having a written instruction on its handling. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established in the legislation.