


# Safety Data Sheet



## 1. Identification

<b>Product Identifier</b>	Sildenafil Citrate
<b>Other means of identification</b>	
<b>Internal item number</b>	82393-0303
<b>CAS number</b>	171599-83-0
<b>Chemical name</b>	Piperazine, 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methyl-, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)
<b>Relevant use and restrictions:</b>	No further information available.
<b>Application of substance:</b>	Active pharmaceutical ingredient.
<b>Manufacturer/Supplier information</b>	
<b>Company name</b>	Pharma Source Direct
<b>Address</b>	8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112
<b>Website</b>	www.pharmasd.com
<b>Emergency phone number</b>	Infotrac: 1-800-535-5053

## 2. Hazard(s) Identification

<b>Physical hazards</b>	Not classified	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2A
<b>Environmental hazards</b>	Not classified	
<b>OSHA defined hazards</b>	Not classified	
<b>Label elements</b>		

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<b>Signal word</b>	Warning
<b>Hazard statement</b>	Harmful if swallowed. Causes serious eye irritation
<b>Precautionary statement</b>	
<b>Prevention</b>	Wash thoroughly after handling. Wear eye protection/face protection.
<b>Response</b>	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
<b>Storage</b>	Store locked up.

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**Disposal**

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

**Hazards not otherwise classified (HNOC)**

The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

**Supplemental information**

Pharmacologically active material.

### 3. Composition/Information on Ingredients

**Substance**

Chemical name	Common name and synonyms	CAS number	%
Sildenafil Citrate		171599-83-0	100

### 4. First-aid Measures

**Inhalation**

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

**Skin contact**

Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact**

Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

**Ingestion**

Rinse mouth thoroughly. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

**Most important symptoms/effects, acute and delayed**

Pharmacologically active material. Occupational exposure may cause physiological effects.

**Indication of immediate medical attention and special treatment needed**

Provide general supportive measures and treat symptomatically. Treatment of phosphodiesterase (PDE) 5 inhibitor overdose may include the following: Administer activated charcoal as a slurry. For hypotension, infuse isotonic fluids, dopamine, or norepinephrine. Nitrates are contraindicated due to the possibility of severe hypotensive reaction. Priapism is an emergency requiring immediate consult with a urologist. Hemodialysis or hemoperfusion are unlikely to be of benefit.

**General Information**

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting Measures

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<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO <sub>2</sub> . Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental Release Measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and Storage

<b>Precautions for safe handling</b>	As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure Controls & Personal Protection

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## Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

## Exposure limit values

### ACGIH

Material	Type	Value
Sildenafil Citrate (CAS 171599-83-0)	TWA	0.35mg/m3

## Biological limit values

No biological exposure limits noted for the ingredient(s)

## Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

## Individual protection measures, such as personal protective equipment

### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

### Skin protection

#### Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

#### Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

### Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

## General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Procedures for any use or quantity should be determined after an appropriate assessment. Procedures for any use or quantities should be determined after an appropriate assessment.

## 9. Physical and Chemical Properties

### Appearance

Appearance descriptions are general information and not specific to any lot.

#### Physical state

Solid.

#### Form

Crystalline powder.

#### Color

White.

### Odor

Not available.

### Odor threshold

Not available.

### pH

Not available.

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<b>Melting point/freezing point</b>	392 – 395.6 °F (200 - 202 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Slightly soluble.
<b>Solubility (other)</b>	Dimethylsulfoxide: Soluble. Dimethylformamide: Soluble. Ethanol: Slightly soluble. Methanol: Slightly soluble. Isopropyl alcohol: Slightly soluble. Acetone: Slightly soluble. Hexane: Insoluble. Methylene chloride: Insoluble.
<b>Partition coefficient (n-octanol/water)</b>	2.7
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Methylpiperazine.
<b>Dust explosion properties</b>	
<b>Kst</b>	211 bar.m/s
<b>St class</b>	2 Strong explosion.
<b>Minimum ignition energy (MIE) - dust cloud</b>	3 - 5 mJ
<b>Molecular formula</b>	C <sub>22</sub> H <sub>30</sub> N <sub>6</sub> O <sub>4</sub> S . C <sub>6</sub> H <sub>8</sub> O <sub>7</sub>
<b>Molecular weight</b>	666.7
<b>Potential for dust explosion</b>	Strong explosion hazard.

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<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage, and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Contact with incompatible materials.
<b>Incompatible materials</b>	None known
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx.

## 11. Toxicological Information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Causes serious eye irritation.
<b>Ingestion</b>	Harmful if swallowed.

**Symptoms related to the physical, chemical, and toxicological characteristics** Phosphodiesterase (PDE) 5 inhibitors: Nausea. Headache. Flu-like symptoms. Indigestion. Nasal congestion. Flushing. Dizziness. Vertigo. Visual disturbances. Insomnia. Anxiety. Muscle pain. Back pain. Leg pain. Prolonged or painful erection in men.

### Information on toxicological effects

**Acute toxicity** Harmful if swallowed.

#### Product

#### Species

#### Test Results

Sildenafil Citrate (CAS 171599-83-0)

#### Dermal

LD50

Rat

> 2000mg/kg

#### Oral

LD50

Rat

500 – 1000 mg/kg

**Skin corrosion/irritation**

Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation**

Causes serious eye irritation.

#### Local effects

Irritancy test

Result: Irritant.

Species: Rabbit

Organ: Eye

Severity: Moderate.

Irritancy test

Result: Not-irritant.

Species: Rabbit

Organ: Skin

### Respiratory or skin sensitization

**Respiratory sensitization**

Knowledge about health hazard is incomplete.

**Skin sensitization**

Based on available data, the classification criteria are not met.

Sensitization test

Result: Non-sensitizing.

Species: Guinea pig

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Organ: Skin

## Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

### Mutagenicity

In vitro Ames assay in *S. typhimurium*

Result: Negative.

In vitro human lymphocyte assay

Result: Negative.

In vivo micronucleus chromosome aberration assay in mouse bone marrow

Result: Negative.

## Carcinogenicity

Based on available data, the classification criteria are not met.

5 mg/kg/day Carcinogenicity study

Result: No evidence of carcinogenicity.

Species: Mouse

Test Duration: 24 months

60 mg/kg/day Carcinogenicity study

Result: No evidence of carcinogenicity.

Species: Rat

Test Duration: 24 months

## IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

## OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

## US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

## Reproductive toxicity

Based on available data, the classification criteria are not met.

### Reproductivity

50 mg/kg/day Reproductivity study

Result: Maternal toxicity occurred, but there was no evidence of an increased incidence of birth defects.

Species: Rabbit

50 mg/kg/day Reproductivity study

Result: Maternal toxicity occurred, but there was no evidence of an increased incidence of birth defects.

Species: Rat

60 mg/kg/day Reproductivity study

Result: No evidence of adverse reproductivity or fertility effects.

Species: Rat

## Specific target organ toxicity - single exposure

Knowledge about health hazard is incomplete.

## Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

## Aspiration hazard

Based on available data, the classification criteria are not met.

## Further information

Pharmacologically active material. Occupational exposure may cause physiological effects.

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## Ecotoxicity

Product	Species	Test Results
Sildenafil Citrate (CAS 171599-83-0)		
<b>Aquatic</b>		
Crustacea	EC50	Water flea (Daphnia magna) 14 mg/l, 48hr
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>		
Octanol/water partition coefficient log Kow		
2.7		
<b>Mobility in soil</b>	No data available.	
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	

## 13. Disposal Considerations

<b>Disposal instructions</b>	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport Information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

### General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory Information

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## US federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.  
 This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

## Superfund Amendments and Reauthorization Act of 1986 (SARA)

### SARA 302 Extremely hazardous substance

Not listed.

### SARA 311/312 Hazardous chemical

Yes

#### Classified hazard categories

Combustible dust  
 Acute toxicity (any route of exposure)  
 Serious eye damage or eye irritation

### SARA 313 (TRI reporting)

Not regulated.

## Other federal regulations

### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

### Safe Drinking Water Act (SDWA)

Not regulated.

## US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No

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Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Phillipines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
Unites States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other Information

### Further information

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

### Disclaimer

The information in this SDS has been compiled from sources considered dependable, but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product in regards to handling, storage, and/or disposal.

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