# SAFETY DATA SHEET

## 1. Identification

**Product identifier** **Sildenafil Citrate**

**Other means of identification**

**Catalog number** 1612561

**CAS number** 171599-83-0

**Chemical name** 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)

**Recommended use** Specified quality tests and assay use only.

**Recommended restrictions** Not for use as a drug. Not for administration to humans or animals.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

**Company name** U. S. Pharmacopeia

**Address** 12601 Twinbrook Parkway
Rockville
MD
20852-1790
United States

**Telephone** RS Technical Services 301-816-8129

**Website** www.usp.org

**E-mail** RSTECH@usp.org

**Emergency phone number** CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Acute toxicity, oral Category 4
Serious eye damage/eye irritation Category 2A

**Environmental hazards** Not classified.

**OSHA defined hazards** Not classified.

**Label elements**

**Signal word** Warning

**Hazard statement** Harmful if swallowed. Causes serious eye irritation.

**Precautionary statement**

**Prevention** Wash thoroughly after handling. Wear eye protection/face protection.

**Response** 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.

**Storage** Not available.

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

**Hazard(s) not otherwise classified (HNOC)** This product is supplied in a small quantity which does not constitute a combustible dust hazard. 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 an 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

**Suitable extinguishing media**
Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
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.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire fighting equipment/instructions**
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.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**
No unusual fire or explosion hazards noted.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
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.

**Methods and materials for containment and cleaning up**
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.

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

**Precautions for safe handling**

As a general rule, when handling USP Reference Standards, 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.

**Conditions for safe storage, including any incompatibilities**

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

**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.

**ACGIH**

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

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses 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 USP lot.

**Physical state**

Solid.

**Form**

Crystalline powder.

**Color**

White. Off-white.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

392 - 395.6 °F (200 - 202 °C)

**Initial boiling point and boiling range**

Not available.

**Flash point**

Not available.

**Evaporation rate**

Not available.

**Flammability (solid, gas)**

Not available.

**Upper/lower flammability or explosive limits**

| | |
|---|---|
| **Flammability limit - lower (%)** | Not available. |
| **Flammability limit - upper (%)** | Not available. |
| **Explosive limit - lower (%)** | Not available. |
| **Explosive limit - upper (%)** | Not available. |
| **Vapor pressure** | Not available. |
| **Vapor density** | Not available. |
| **Relative density** | Not available. |
| **Solubility(ies)** | |
| **Solubility (water)** | Slightly soluble. |
| **Solubility (other)** | Dimethylsulfoxide: Soluble.<br>Dimethylformamide: Soluble.<br>Ethanol: Slightly soluble.<br>Methanol: Slightly soluble.<br>Isopropyl alcohol:Slightly soluble.<br>Acetone: Slightly soluble.<br>Hexane: Insoluble.<br>Methylene chloride: Insoluble. |
| **Partition coefficient (n-octanol/water)** | 2.7 |
| **Auto-ignition temperature** | Not available. |
| **Decomposition temperature** | Not available. |
| **Viscosity** | Not available. |
| **Other information** | |
| **Chemical family** | Methylpiperazine. |
| **Dust explosion properties** | |
| **Kst** | 211 bar.m/s |
| **St class** | 2 Strong explosion. |
| **Minimum ignition energy (MIE) - dust cloud** | 3 - 5 mJ |
| **Molecular formula** | C22H30N6O4S . C6H8O7 |
| **Molecular weight** | 666.7 |
| **Potential for dust explosion** | Strong explosion hazard. |

## 10. Stability and reactivity

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

## 11. Toxicological information

**Information on likely routes of exposure**

| | |
|---|---|
| **Inhalation** | Knowledge about health hazard is incomplete. |
| **Skin contact** | Health injuries are not known or expected under normal use. |
| **Eye contact** | Causes serious eye irritation. |
| **Ingestion** | 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 | > 2000 mg/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 sensitization hazard is incomplete.

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

Sensitization test
Result: Non-sensitizing.
Species: Guinea pig
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.

## 12. Ecological information

**Ecotoxicity**

| Product | | Species | Test Results |
|---|---|---|---|
| Sildenafil Citrate (CAS 171599-83-0) | | | |
| **Aquatic** | | | |
| Crustacea | EC50 | Water flea (Daphnia magna) | 14 mg/l, 48 hr |

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential**

**Octanol/water partition coefficient log Kow**
2.7

**Mobility in soil** No data available.

**Other adverse effects** 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

**Disposal instructions** 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.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** 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).

**Contaminated packaging** 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

**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 |
| 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 |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes |
| United 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, including date of preparation or last revision

**Issue date** 02-23-2012

**Revision date** 01-08-2020

| | |
|---|---|
| **Version #** | 04 |
| **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. |
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