

1. Identification

Product identifier	Sildenafil Citrate		
Other means of identification			
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)		
Company name	Trioiva Pharmaceuticals LLC		
Address	115 W 3rd Street Suite 720 Tulsa, OK 74103		
Telephone	539 770 0720		
Website	www.triovarx.com		
E-mail	quality@triovarx.com		
Emergency phone number	INFOTRAC within US & Canada		1-800-535-5053

2. Hazard(s) identification

Note	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.		
Physical hazards	Not classified.		
Health hazards	Acute toxicity, oral		Category 4
	Serious eye damage/eye irritation		Category 2A
OSHA hazard(s)	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/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)	Not classified.		

3. Composition/information on ingredients

Substance

Hazardous components

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 cautiously with water for several minutes. Get medical attention if irritation develops and persists.
Ingestion	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes.
Indication of immediate medical attention and special treatment needed	Treatment of phosphodiesterase (PDE) 5 inhibitor overdose should be symptomatic and supportive and 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. (Poisindex)
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	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
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.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	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. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.
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

ACGIH

Material	Type	Value
Sildenafil Citrate (CAS 171599-83-0)	TWA	0.35 mg/m ³

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Appropriate engineering controls	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.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to off-white crystalline powder.
Physical state	Solid.
Form	Powder.
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 applicable.
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 in water	Slightly soluble.
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	C ₂₂ H ₃₀ N ₆ O ₄ S . C ₆ H ₈ O ₇
Molecular weight	666.7
Potential for dust explosion	Strong explosion hazard.
Solubility (other)	Soluble in dimethylsulfoxide and in dimethylformamide; slightly soluble in ethanol, in methanol, in isopropyl alcohol, and in acetone; insoluble in hexane and in methylene chloride.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	None known.
Hazardous decomposition products	NO _x . SO _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Based on available data, the classification criteria are not met.
Eye contact	Causes serious eye irritation.
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.
Delayed and immediate effects of exposure	Phosphodiesterase (PDE) 5 inhibitors: Rhinitis. Sinusitis. Low blood pressure.
Medical conditions aggravated by exposure	Cardiovascular disease. Liver impairment. Hypotension. Hypertension. Coronary artery disease. Retinitis pigmentosa. Sickle cell or related anemias. Phosphodiesterase (PDE) 5 inhibitors: Kidney impairment. Bleeding disorders. Peptic ulcer. Retinitis pigmentosa. Use of nitrates.
Acute toxicity	Harmful if swallowed.

Product	Species	Test Results
Sildenafil Citrate (CAS 171599-83-0)		
<i>Dermal</i>		
LD50	Rat	> 2000 mg/kg
<i>Oral</i>		
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 sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Based on available data, the classification criteria are not met.	

Sensitization

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

Germ cell mutagenicity Due to lack of data the classification is not possible.
 Data from germ cell mutagenicity tests were not found.

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.
 This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

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

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

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

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

12. Ecological information

Ecotoxicity May cause long lasting harmful effects to aquatic life.

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

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

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

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 Not available.

Hazardous waste code Not available.

Waste from residues / unused products Dispose of in accordance with local regulations. 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 Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) 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
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)

16. Other information, including date of preparation or last revision

Issue date 01-01-2017

Revision date 01-01-2017

Version # 00

Disclaimer

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