

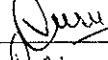
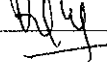


MASTER COPY


	SMS LIFESCIENCES INDIA LIMITED, UNIT-I	
	Title: MATERIAL SAFETY DATA SHEET FOR SILDENAFIL CITRATE	
	MSDS. No.: MSDS/FP/006	Rev : 00
		Effective Date : 30/07/2018
		Page No. : 1 of 10

1. Material Identification

Name of the Product	: Sildenafil Citrate
Trade Name	: Sildenafil Citrate
Application of the Substance	: Active Pharma Ingredient
Chemical Name & Synonyms	: 5-[2-ethoxy-5(4-methylpiperazinylsulfonyl)phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-one.; citrate 1-[4-Ethoxy-3-(6, 7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo [4, 3-d] pyrimidin-5-yl) phernylsulfonyl]-4-methylpiperazine citrate, 1-[[3-(4,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine; citrate, 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-[[3-(6, 7-Dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo [4, 3-d] pyrimidin-5-yl) -4-ethoxy phenyl]sulfonyl] -4-methylpiperazine citrate , 5-[2-Ethoxy-5-((4-methylpiperazin-1-yl) sulfonyl)phenyl]-1-methyl-3-propyl-1, 6-dihydro-7Hpyrazolo[4,3-d]pyrimidin-7-onedihydrogen 2-hydroxy propane-1,2,3-tricarboxylate.
Molecular Formula	: C ₂₂ H ₃₀ N ₆ O ₄ S.C ₆ H ₈ O ₇
Molecular Weight	: 666.70
Chemical family	: Phospho di esterase/PDE5 inhibitors
Manufacturer	: SMS Lifesciences India Limited, Unit-I, Sy No. 180/2, Kazipally Village, Jinnaram Mandal, Sangareddy, Telangana – 502 319, INDIA. Email : qa_unit1@smslife.in
Further Information/ Emergency number	: +91-8458-277067/277068, +91-8374455534
Intended use	: Pharmaceutical Product
*CAS No.	: [171599-83-0]

	Name	Designation	Signature	Date
Prepared by	V. Venkatesh	Officer - QAD		28/07/18
Reviewed by	K. Venu Babu	Asst. Manager - PDL		28/07/18
Approved by	P. D. Varna	AGM - Quality		28/07/18


MASTER COPY




	SMS LIFESCIENCES INDIA LIMITED, UNIT-I		
	Title: MATERIAL SAFETY DATA SHEET FOR SILDENAFIL CITRATE		
	MSDS. No.: MSDS/FP/006	Rev : 00	Effective Date : 30/07/2018 Page No. : 2 of 10

2. Composition/Information on Ingredients


Name	CAS No.	EU *EINECS/ELINCS List	Composition
SILDENAFIL CITRATE	[171599-83-0]	Not listed	Pure material


3. Hazards Identification

Hazard description & Symbol	: Irritant Xi 
Hazard statement	: H320 – Causes eye irritation
Risk Phrases	: R22- Harmful if swallowed
Safety Phrases	: S22- Do not breathe dust S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
Health effects	
Adverse Effects	: Adverse effects most commonly reported in clinical use include difficult digestion (dyspepsia), nose bleed, headache, flushing, insomnia, abnormal redness of skin (erythema), difficulty breathing, muscle pain, fever, gastrointestinal irritation, tingling/itching (paresthesia), transient changes in light perception and color 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, diarrhea, 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

	Name	Designation	Signature	Date
Prepared by	V. Venkatesh	Officer - QAD		28/07/18
Reviewed by	K. Venu Babu	Asst. Manager - PDL		28/07/18
Approved by	P. D. Varna	AGM - Quality		28/07/18




MASTER COPY

	SMS LIFESCIENCES INDIA LIMITED, UNIT-I		
	Title: MATERIAL SAFETY DATA SHEET FOR SILDENAFIL CITRATE		
	MSDS. No.: MSDS/FP/006	Rev : 00	Effective Date : 30/07/2018 Page No. : 3 of 10


		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.
Label elements		
Hazard Pictogram/Symbol	:	
Signal word	:	Warning
Precautionary Statement (s)	:	P280: Wear protective gloves/protective clothing/eye protection/face protection. P285: In case of inadequate ventilation wear respiratory protection. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312: Call a POISON CENTER or doctor/physician if you feel unwell.
Classification (REGULATION (EC) No 1272/2008		
Skin irritation, category 2	:	H315: Causes skin irritation H317: May cause an allergic skin reaction.
Eye irritation, category 2	:	H319: Causes serious eye irritation.
Acute toxicity, category 4	:	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Specific target organ toxicity - single	:	H335: May cause respiratory irritation.

4. First aid Measure

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

	Name	Designation	Signature	Date
Prepared by	V. Venkatesh	Officer - QAD		28/07/18
Reviewed by	K. Venu Babu	Asst. Manager - PDL		28/07/18
Approved by	P. D. Varna	AGM - Quality		28/07/18




MASTER COPY

	SMS LIFESCIENCES INDIA LIMITED, UNIT-I		
	Title: MATERIAL SAFETY DATA SHEET FOR SILDENAFIL CITRATE		
	MSDS. No.: MSDS/FP/006	Rev : 00	Effective Date : 30/07/2018 Page No. : 4 of 10


After Ingestion	:	If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.
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.
Symptoms	:	H320- Causes eye irritation. P264- Wash hands thoroughly after handling. P337+P313-If eye irritation persists: Get medical advice/attention.
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.
General information	:	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 color vision, effects on hearing, and effects on vision.

5. Fire Fighting Measures

Suitable extinguishing Media	:	Use carbon dioxide, dry chemical, or water spray.
For safety reason unsuitable extinguishing agents	:	Formation of toxic gases is possible during heating or fire.
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 buildup of static electricity.
Specific Hazards in case of fire	:	Fine particles (such as dust and mists) may fuel fires/explosions.
Special protective equipment and precaution for fire fighters	:	During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

	Name	Designation	Signature	Date
Prepared by	V. Venkatesh	Officer - QAD		28/07/18
Reviewed by	K. Venu Babu	Asst. Manager - PDL		28/07/18
Approved by	P. D. Varna	AGM - Quality		28/07/18

MASTER COPY




	SMS LIFESCIENCES INDIA LIMITED, UNIT-I		
	Title: MATERIAL SAFETY DATA SHEET FOR SILDENAFIL CITRATE		
	MSDS. No.: MSDS/FP/006	Rev : 00	Effective Date : 30/07/2018 Page No. : 5 of 10

6. Accident Release Measures


Personal related/Health and safety precautions	:	Ensuring personal safety, mark out contaminated area with signs and prevent unauthorised access. Turn leaking containers up to prevent further Evacuate area. Wear self-contained breathing apparatus, rubber boots & 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.
Environmental related precautions	:	Prevent entry into water ways, sewers, surface drainage systems and poorly ventilated areas.
Methods and materials for containment and clean 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.

7. Handling and Storage

Precautions for safe handling	:	Sildenafil citrate is non-hygroscopic substances at normal conditions of temperature and relative humidity. While handle the material avoid all contact and inhalation of dust, and or vapors associated with the material. Wash thoroughly after handling.
Conditions for safe storage, Including incompatibilities	:	Keep container tightly closed.
Storage conditions	:	This material should be handled and stored per label instructions to ensure product integrity. Store protected from light and moisture (as per IP). In Air tight container (as per Ph. Eur.) Preserve in air tight containers (as per USP) Preserve in air tight containers (IH) Do not store above 25°C (by sea)


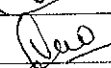
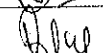
	Name	Designation	Signature	Date
Prepared by	V. Venkatesh	Officer - QAD		28/07/18
Reviewed by	K. Venu Babu	Asst. Manager - PDL		28/07/18
Approved by	P. D. Varna	AGM - Quality		28/07/18

MASTER COPY


	SMS LIFESCIENCES INDIA LIMITED, UNIT-I		
	Title: MATERIAL SAFETY DATA SHEET FOR SILDENAFIL CITRATE		
	MSDS. No.: MSDS/FP/006	Rev : 00	Effective Date : 30/07/2018 Page No. : 6 of 10

8. Exposure Controls/ Personal Protection

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.
Exposure limits	:	Industry : 8-minute *OEL: 350 micrograms/m ³
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.
Respiratory protection	:	Splash goggles. Full suit. Dust respirator. Boots. Gloves. 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. *NOISH / *MSHA-Approved Respirator.
Eye protection	:	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.

	Name	Designation	Signature	Date
Prepared by	V. Venkatesh	Officer - QAD		28/07/18
Reviewed by	K. Venu Babu	Asst. Manager - PDL		28/07/18
Approved by	P. D. Varna	AGM - Quality		28/07/18

MASTER COPY

	SMS LIFESCIENCES INDIA LIMITED, UNIT-I		
	Title: MATERIAL SAFETY DATA SHEET FOR SILDENAFIL CITRATE		
	MSDS. No.: MSDS/FP/006	Rev : 00	Effective Date : 30/07/2018 Page No. : 7 of 10

Skin protection	:	Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin.
-----------------	---	---

9. Physical and chemical prosperities




Appearance/Physical state	:	Crystalline powder
Color	:	White to Off-white
Odour	:	Odor less
Solubility	:	Slightly soluble in water and in methanol.
Flash point	:	376.372°C
Relative/Vapor Pressure	:	0 mmHg at 25°
Decomposition temperature	:	Between 185.0 and 195.0 with decomposition.

10. Stability and Reactivity


Chemical Stability	:	Stable under normal conditions of use.
Possibility of Hazardous reactions	:	Avoid excessive heat. (Temperatures above 70°C may result in exothermic decomposition.)
Conditions to avoid	:	Avoid direct sunlight, conditions that might generate heat and sources of ignition.
Materials to avoid	:	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	:	This material is combustible. When heated to decomposition, material emits toxic fumes of sox, nox and HCl. Emits toxic fumes under fire conditions.

11. Toxicological Information

Acute Toxicity		
Oral Toxicity	:	Rat Oral LDmin. 300-500 mg/kg Mouse Oral LDmin. 500-1000 mg/kg Rat Dermal LD50 > 2000 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.		
Irritation/ Sensitization:		
Irritation/Sensitization	:	Eye Irritation Rabbit Moderate Skin Irritation Rabbit Non-irritating Skin Sensitization Guinea Pig Negative

	Name	Designation	Signature	Date
Prepared by	V. Venkatesh	Officer - QAD		28/07/18
Reviewed by	K. Venu Babu	Asst. Manager - PDL		28/07/18
Approved by	P. D. Varna	AGM - Quality		28/07/18

MASTER COPY

	SMS LIFESCIENCES INDIA LIMITED, UNIT-I		
	Title: MATERIAL SAFETY DATA SHEET FOR SILDENAFIL CITRATE		
	MSDS. No.: MSDS/FP/006	Rev : 00	Effective Date : 30/07/2018 Page No. : 8 of 10




12. Ecological Information

Persistence and degradability	:	The active ingredient in this formulation is water soluble and is expected to remain primarily in water.
Bio-Accumulative potential	:	The active ingredient in this formulation has low potential to bioaccumulation and long-term adverse effects to aquatic organisms are not expected.
Mobility	:	<p>Solubility: This material contains an active pharmaceutical ingredient that for environmental fate predictions has Slightly soluble in water and in methanol.</p> <p>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.</p> <p>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.</p> <p>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.</p>
Aquatic Toxicity	:	<p>Sildenafil citrate</p> <p>Daphnia Magna TAD EC50 48 Hours 14 mg/L</p> <p>Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 9.5 mg/L</p> <p>Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 20 mg/L</p>
Environmental Overview	:	In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater.


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/EC50) is not achievable.

13. Disposal Considerations

Waste disposal/treatment methods	:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community
----------------------------------	---	--

	Name	Designation	Signature	Date
Prepared by	V. Venkatesh	Officer - QAD		28/07/18
Reviewed by	K. Venu Babu	Asst. Manager - PDL		28/07/18
Approved by	P. D. Varna	AGM - Quality		28/07/18

MASTER COPY


	SMS LIFESCIENCES INDIA LIMITED, UNIT-I		
	Title: MATERIAL SAFETY DATA SHEET FOR SILDENAFIL CITRATE		
	MSDS. No.: MSDS/FP/006	Rev : 00	Effective Date : 30/07/2018 Page No. : 9 of 10



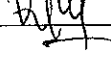
	specific provisions must be considered. Considering the relevant Known environmental and human health hazards of the material review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release.
Recommendation	: It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. Transport Information


UN Number	: Not regulated
UN proper shipping Name	: Not regulated
Transport hazard class	: Not regulated
Packing group	: Not regulated
Marine pollutant	: Not regulated
Additional information	: Not dangerous according to the above specifications.

15. Regulatory Information

Other Regulatory information:	
*DSCL (EEC)	: Unlisted
*HMIS (USA)	: Unlisted
National fire protection association (USA)	NFPA  Health : 0 Flammability : 1 Instability : 0

	Name	Designation	Signature	Date
Prepared by	V. Venkatesh	Officer - QAD		28/07/18
Reviewed by	K. Venu Babu	Asst. Manager - PDL		28/07/18
Approved by	P. D. Varna	AGM - Quality		28/07/18

MASTER COPY

	SMS LIFESCIENCES INDIA LIMITED, UNIT-I		
	Title: MATERIAL SAFETY DATA SHEET FOR SILDENAFIL CITRATE		
	MSDS. No.: MSDS/FP/006	Rev : 00	Effective Date : 30/07/2018 Page No. : 10 of 10

16. Other Information

The above information believed to be correct but does not support to be all inclusive and shall be used only as a guide. SMS Pharmaceuticals Limited (Unit-I) shall not be held liable for any damages resulting from handling or from contact with above product.

*CAS No.: Chemical abstracts service registration number.

*EINECS No.: European inventory of existing chemical substances number.

*OEL: Occupational Exposure Limit.


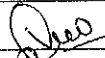
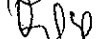
*NIOSH: National institute for occupational safety and health.

*MSHA: Mine safety and health administration.

*HMIS: Hazardous material identification system.

*DSCL(EEC): Dangerous substances classification and labeling

UNCONTROLLED COPY

	Name	Designation	Signature	Date
Prepared by	V. Venkatesh	Officer - QAD		28/07/18
Reviewed by	K. Venu Babu	Asst. Manager - PDL		28/07/18
Approved by	P. D. Varna	AGM - Quality		28/07/18

SOP/EHS/A009/F01-00, Effective date:07/07/2017