



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification

Material	Sildenafil Tablets USP, 25 mg, 50 mg and 100 mg
Trade Name	
Manufacturer	Hetero Labs Limited Unit III, TSIC Formulation SEZ, Survey. No 439, 440, 441 & 458, Polepally Village, Jadcherla (Mandal), Mahabubnagar (District). Pin-509301 Telangana, India
Distributor	Camber Pharmaceuticals, Inc. , Piscatway, NJ 08854

Section 2: Hazard(s) Identification

Identification	
Classification of the Substance or Mixture	
GHS - Classification	Serious Eye Damage/Eye Irritation: Category 2B
Label Elements	
Signal Word:	Warning
Hazard Statements:	H320 - Causes eye irritation
Precautionary Statements:	P264 - Wash hands thoroughly after handling P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P337 + P313 - If eye irritation persists: Get medical advice/attention
Note:	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: Composition/Information on Ingredients

Ingredient	CAS Number
Sildenafil citrate	171599-83-0
Titanium dioxide	13463-67-7
Microcrystalline cellulose	9004-34-6
Magnesium stearate	557-04-0
FD & C Blue No. 2, Aluminum lake	16521-38-3
Lactose Monohydrate	64044-51-5
Triacetin	102-76-1
Hydroxypropyl methylcellulose	9004-65-3
Croscarmellose sodium	74811-65-7
Calcium phosphate dibasic, anhydrous	7757-93-9

Section 4: First-Aid Measures

Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
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Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Most Important Symptoms and Effects, Both Acute and Delayed	
Symptoms and Effects of Exposure:	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure	None known
Indication of the Immediate Medical Attention and Special Treatment Needed	None
Notes to Physician:	

Section 5: Fire-Fighting Measures

Extinguishing Media	Extinguish fires with CO ₂ , extinguishing powder, foam, or water
Special Hazards Arising from the Substance or Mixture	Formation of toxic gases is possible during heating or fire
Hazardous Combustion Products:	
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.
Advice for Fire-Fighters	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Additional Information:	Not applicable

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Methods and materials for containment and cleaning/Collecting:	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.
Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7: Handling and Storage



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Precautions for safe handling Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Specific end use(s): Pharmaceutical drug product

Section 8: Exposure Controls/Personal Protection

Control Parameters Refer to available public information for specific member state Occupational Exposure Limits.

Sildenafil citrate	
Pfizer OEL TWA-8 Hr:	350µg/m ³
Titanium dioxide	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³
Estonia OEL - TWA	5 mg/m ³
France OEL - TWA	10 mg/m ³
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	5 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	4 mg/m ³
OSHA - Final PELs - TWAs:	10 mg/m ³
Poland OEL - TWA	15 mg/m ³
Portugal OEL - TWA	10.0 mg/m ³
Romania OEL - TWA	10 mg/m ³
Russia OEL - TWA	10 mg/m ³
	10 mg/m ³



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Spain OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	3 mg/m ³
Switzerland OEL -TWAs	6 mg/m ³
Vietnam OEL – TWAs	5 mg/m ³
Calcium phosphate dibasic, anhydrous	10 mg/m ³
Latvia OEL – TWA	10 mg/m ³
Microcrystalline cellulose	10 mg/m ³
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	4 mg/m ³
France OEL - TWA	2 mg/m ³
Ireland OEL - TWAs	15 mg/m ³
Latvia OEL – TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	10 mg/m ³
Portugal OEL - TWA	6 mg/m ³
Romania OEL - TWA	10 mg/m ³
Russia OEL - TWA	3 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	5 mg/m ³
Vietnam OEL – TWAs	10 mg/m ³
Magnesium stearate	5 mg/m ³
ACGIH Threshold Limit Value (TWA)	5 mg/m ³
Lithuania OEL - TWA	
Sweden OEL – TWAs	
Exposure Controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Engineering Controls:	

Section 9: Physical and Chemical Properties

Physical State	Tablet
Form	Tablets
Colour	White
Odor	Not available
Description	Sildenafil Tablets USP, 25 mg



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	<p>White colored, round-shaped, biconvex, film coated tablets debossed with ' I ' on one side and '35'on the other side.</p> <p>Bottles of 30 tablets NDC 31722-709-30 Bottles of 500 tablets NDC 31722-709-05 Sildenafil Tablets USP, 50 mg White colored, round-shaped, biconvex, film coated tablets debossed with ' I ' on one side and '36'on the other side.</p> <p>Bottles of 30 tablets NDC 31722-710-30 Bottles of 100 tablets NDC 31722-710-01 Bottles of 500 tablets NDC 31722-710-05 Sildenafil Tablets USP, 100 mg White colored, round-shaped, biconvex, film coated tablets debossed with ' I ' on one side and '58' on the other side.</p> <p>Bottles of 30 tablets NDC 31722-711-30 Bottles of 100 tablets NDC 31722-711-01 Bottles of 500 tablets NDC 31722-711-05</p>
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Section 10: Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	No data available
Oxidizing Properties:	None known
Conditions to Avoid:	As a precautionary measure, keep away from strong
Incompatible Materials:	oxidizers
Hazardous Decomposition Products:	No data available

Section 11: Toxicological Information

Information on Toxicological Effects



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General Information:	The information included in this section describes the potential hazards of the individual ingredients.
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.
Known Clinical 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.

Acute Toxicity: (Species, Route, End Point, Dose

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Sildenafil citrate

Rat Oral LD_{min.} 300-500 mg/kg
Mouse Oral LD_{min.} 500-1000 mg/kg
Rat Dermal LD50 > 2000 mg/kg

Hydroxypropylmethylcellulose

Rat Oral LD50 > 10,000 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD50 50 mg/kg

Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

Triacetin

Rat Oral LD 50 3000 mg/kg
Mouse Oral LD 50 1100mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.



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Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

Sildenafil citrate

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Non-irritating

Skin Sensitization Guinea Pig Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sildenafil citrate

6 Month(s) Rat Oral 3 mg/kg/day NOEL Adrenal gland, Liver, Thyroid

6 Month(s) Dog Oral 15 mg/kg/day NOEL Cardiovascular system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point,

Effect(s))

Sildenafil citrate

Reproductive & Fertility Rat Oral 60 mg/kg/day NOEL No effects at maximum dose

Embryo / Fetal Development Rat Oral 50 mg/kg/day NOEL Maternal Toxicity, Not Teratogenic

Embryo / Fetal Development Rabbit Oral 50 mg/kg/day NOEL Maternal Toxicity, Not

Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Sildenafil citrate

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vitro Cytogenetics Human Lymphocytes Negative

In Vivo Micronucleus Chromosome Aberration Mouse Bone Marrow Negative

Lactose Monohydrate

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Sildenafil citrate

24 Month(s) Mouse Oral 5 mg/kg/day NOEL

24 Month(s) Rat Oral 60 mg/kg/day NOEL

Carcinogen Status:

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Titanium dioxide

IARC:

Group 2B (Possibly Carcinogenic to Humans)

Section 12: Ecological Information

Environmental Overview:

In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater



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Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Sildenafil citrate

Daphnia magna (Water Flea) TAD EC50 48 Hours 14 mg/L

Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 9.5 mg/L

Pseudokircnerella subcapitata (Green Alga) OECD EC50 72 Hours 20 mg/L

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.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Sildenafil citrate Activated sludge OECD EC50 > 1000 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Sildenafil citrate

Predicted 7.4 Log D 2.26

Mobility in Soil: No data available

Section 13: Disposal Considerations

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community 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. 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.

Section 14: Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

Section 15: Regulatory Information

U.S State regulations

California Proposition 65: This product does not contain any proposition 65 chemicals

Section 16: Other Information

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The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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