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SAFETY DATA SHEET

Section 1: Identification

Material Trade Name	**Sildenafil citrate tablets USP 20 mg**
Manufacturer	**Hetero Labs Limited** Unit V, TSIIC 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	
Hazard Statements:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information:	
Short Term:	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 colour vision, effects on hearing, and effects on vision.
EU Indication of danger:	Not classified
Australian Hazard Classification (NOHSC):	Non-Hazardous Substance. Non-Dangerous Goods.
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
Magnesium stearate	557-04-0
Microcrystalline cellulose	9004-34-6

Titanium dioxide	13463-67-7
Calcium phosphate dibasic, anhydrous	7757-93-9
Croscarmellose sodium	74811-65-7
Hypromellose	9004-65-3
Lactose Monohydrate	64044-51-5
Triacetin	102-76-1
Additional Information:	*Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: First-Aid Measures

Ingestion	Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.
Skin Contact	Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.
Eye Contact	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
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.

Section 5: Fire-Fighting Measures

Extinguishing Media	Use carbon dioxide, dry chemical, or water spray
Special Hazards Arising from the Substance or Mixture Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire
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	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize

emergency procedures	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

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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.
Conditions for Safe Storage, Including any Incompatibilities	
Storage Conditions:	Store as directed by product packaging.
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.**
Calcium phosphate dibasic, anhydrous	
Latvia OEL – TWA	= 10 mg/m3 TWA
Magnesium stearate	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m3 TWA except stearates of toxic metals
Australia TWA	= 10 mg/m3 TWA
Belgium OEL - TWA	= 10 mg/m3 TWA
Ireland OEL - TWAs	= 10 mg/m3 TWA except lead stearate
Lithuania OEL - TWA	= 3 mg/m3 IPRV
Portugal OEL - TWA	= 10 mg/m3 TWA does not include stearates of toxic metals
Spain OEL – TWA	= 10 mg/m3 VLA-ED not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m3 LLV
Microcrystalline cellulose	
ACGIH Threshold Limit Value	= 10 mg/m3 TWA

(TWA)	
Australia TWA	= 10 mg/m3 TWA
Belgium OEL – TWA	= 10 mg/m3 TWA
Estonia OEL – TWA	= 10 mg/m3 TWA
France OEL – TWA	= 10 mg/m3 VME
Ireland OEL – TWAs	= 10 mg/m3 TWA
	= 4 mg/m3 TWA
Latvia OEL – TWA	= 2 mg/m3 TWA
OSHA - Final PELS - TWAs:	= 15 mg/m3 TWA total
	= 5 mg/m3 TWA
Portugal OEL – TWA	= 10 mg/m3 TWA
Romania OEL – TWA	= 10 mg/m3 TWA
Spain OEL - TWA	= 10 mg/m3 VLA-ED
Titanium dioxide	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m3 TWA
	= 10 mg/m3 TWA
Australia TWA	= 6 mg/m3 MAK
Austria OEL - MAKs	= 10 mg/m3 TWA
Belgium OEL - TWA	= 10.0 mg/m3 TWA
Bulgaria OEL - TWA	= 6 mg/m3 TWA
Denmark OEL - TWA	= 5 mg/m3 TWA
Estonia OEL - TWA	= 10 mg/m3 VME
France OEL - TWA	= 10 mg/m3 TWA
Greece OEL - TWA	= 5 mg/m3 TWA
Ireland OEL - TWAs	= 10 mg/m3 TWA
	= 4 mg/m3 TWA
Latvia OEL - TWA	= 10 mg/m3 TWA
Lithuania OEL – TWA	= 5 mg/m3 IPRV
Netherlands OEL - TWA	= 10 mg/m3 MAC
OSHA - Final PELS - TWAs:	= 15 mg/m3 TWA total
Poland OEL - TWA	= 10.0 mg/m3 NDS <2% free crystalline silica and containing no asbestos
Portugal OEL - TWA	= 10 mg/m3 TWA
Romania OEL - TWA	= 10 mg/m3 TWA
Spain OEL - TWA	= 10 mg/m3 VLA-ED
Sweden OEL – TWAs	= 5 mg/m3 LLV
Exposure Controls Engineering 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.

Personal Protective Equipment:	
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9: Physical and Chemical Properties

Physical State	**Tablet**
Molecular Formula	**Mixture**
Molecular Weight	**Mixture**
Colour	**White**
Description	**Sildenafil Tablets, USP 20 mg** White to off white colored, round-shaped, biconvex, film coated tablets debossed with ' J ' on one side and '95' on the other side. Bottle of 90's NDC 31722-776-90 Bottle of 500's NDC 31722-776-05 Blister card of 10 NDC 31722-776-31 Unit dose tablets (PVC) Blister pack of 100(10x10's) NDC 31722-776-32 Unit dose tablets (PVC) Blister card of 10 NDC 31722-776-33 Unit dose tablets (PVC/PVdC) Blister pack of 100(10 x 10's) NDC 31722-776-34 Unit dose tablets (PVC/PVdC)

Section 10: Stability and Reactivity

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

Section 11: Toxicological Information

Information on Toxicological Effects

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

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/m^3

Sildenafil citrate
Rat Oral LDmin. 300-500 mg/kg
Mouse Oral LDmin. 500-1000 mg/kg
Rat Dermal LD50 > 2000 mg/kg

Hypromellose
Rat Oral LD50 > 10,000 mg/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Lactose Monohydrate
Rat Oral LD 50 29700 mg/kg

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

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

Sildenafil citrate
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Non-irritating
Skin Sensitization Guinea Pig Negative

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Sildenafil citrate
6 Month(s) Rat Oral 3 mg/kg/day NOAEL Adrenal gland, Liver, Thyroid
6 Month(s) Dog Oral 15 mg/kg/day NOAEL 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

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

Sildenafil citrate

24 Month(s) Mouse Oral 5 mg/kg/day NOAEL Not carcinogenic

24 Month(s) Rat Oral 60 mg/kg/day NOAEL Not carcinogenic

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)
OSHA: Present

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 ground water. Harmful effects to aquatic organisms could occur.

Mobility, Persistence and Degradability: The active ingredient in this formulation is water soluble and is expected to remain primarily in water.

Bioaccumulation and Toxicity: The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. See aquatic toxicity data, below.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
Sildenafil citrate
Daphnia Magna TAD EC50 48 Hours 14 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 9.5 mg/L
Pseudokirchneriella 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: (Species, Method, End Point, Duration, Result)

Sildenafil citrate	Activated sludge OECD EC50 3 Hours > 1000 mg/L

Section 13: Disposal Considerations

Disposal Procedures:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

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

EU Indication of danger:	Not classified
OSHA Label:	Non-hazardous in accordance with international standards for workplace Safety

Section 16: Other Information

Issue Date : 20-06-2018

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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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