



SAFETY DATA SHEET

Section 1: Identification	
Material	Avanafil Tablets, 50 mg, 100 mg and 200 mg
Recommended use	Pharmaceutical Product
Manufacturer	Hetero Labs Limited, 22-110, IDA, Unit III, Jeedimetla, Hyderabad-500055, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statements	Causes skin irritation Causes serious eye irritation May cause respiratory irritation
Precautionary statements	Avoid breathing dust/fume/gas/mist/vapors/spray Wash thoroughly after handling Use only outdoors or in a well-ventilated area. Wear protective gloves / eye protection / face protection. If on skin: Wash with plenty of water. IF INHALED: Remove person to fresh air and keep comfortable for breathing If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a poison center/doctor if you feel unwell Specific treatment (see on this label). Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention If eye irritation persists: Get medical advice/attention Store in a well-ventilated place. Keep container tightly closed Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations.



Section 3: Composition/Information on Ingredients	
Name	CAS
Avanafil	330784-47-9
Fumaric acid	110-17-8
Hydroxypropyl Cellulose	9004-64-2
Low-Substituted Hydroxypropyl Cellulose	9004-64-2
Magnesium Stearate	557-04-0
Mannitol	69-65-8
Sodium Bicarbonate	144-58-5
Section 4: First-Aid Measures	
Description of first aid measures	
After inhalation	In case of unconsciousness place patient stably in side position for transportation.
After skin contact	Immediately wash with water and soap and rinse thoroughly.
After eye contact	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
After swallowing	If symptoms persist consult doctor.
Information for doctor	
Most important symptoms and effects, both acute and delayed	No further relevant information available.
Indication of any immediate medical attention and special treatment needed	No further relevant information available.
Section 5: Fire-Fighting Measures	
Extinguishing media	
Suitable extinguishing agents	Use fire fighting measures that suit the environment. A solid water stream may be inefficient.
Special hazards arising from the substance or mixture	No further relevant information available.
Advice for firefighters	
Protective equipment	No special measures required.



Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Not required.
Environmental precautions	Do not allow to enter sewers/ surface or ground water.
Methods and material for containment and cleaning up	Ensure adequate ventilation.
Section 7: Handling and Storage	
Handling:	
Precautions for safe handling	No special precautions are necessary if used correctly. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure. Keep away from sources of ignition. Take precautionary measures against static discharge.re.
Information about protection against explosions and fires	No special measures required.
Conditions for safe storage, including any incompatibilities	
Storage	Store in accordance with information listed on the product insert.
Requirements to be met by storerooms and receptacles	No special requirements
Information about storage in one common storage facility	Not required.
Further information about storage conditions	Keep receptacle tightly sealed.
Specific end use(s)	No further relevant information available.
8. Exposure controls / personal protection	
Additional information about design of technical systems	No further data; see section 7.
Control parameters	
Components with limit values that require monitoring at the workplace	Not required.
Additional information	The lists that were valid during the creation were used as basis.
Exposure controls	
Personal protective equipment	
General protective and hygienic measures	Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.



Breathing equipment	In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
Protection of hands	<p>Protective gloves</p> <p>The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.</p> <p>Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.</p> <p>Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation</p>
Material of gloves	The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
Penetration time of glove material	The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
Eye protection	Tightly sealed goggles

Section 9: Physical and Chemical Properties

Physical State	Solid
Description	<p>Avanafil tablets, 50 mg are white to off white, oval shape, biconvex tablets debossed with 'A41' on one side and 'H' on the other side. They are supplied as</p> <p>Bottle of 30 tablets NDC 31722-440-30</p> <p>Bottle of 100 tablets NDC 31722-440-01</p> <p>Avanafil tablets, 100 mg are white to off white, oval shape, biconvex tablets debossed with 'A42' on one side and 'H' on the other side. They are supplied as</p> <p>Bottle of 30 tablets NDC 31722-441-30</p> <p>Bottle of 100 tablets NDC 31722-441-01</p> <p>Avanafil tablets, 200 mg are white to off white, oval shape, biconvex tablets debossed with 'A43' on one side and 'H' on the other side. They are supplied as</p> <p>Bottle of 30 tablets NDC 31722-442-30</p> <p>Bottle of 100 tablets NDC 31722-442-01</p>

Section 10: Stability and Reactivity	
Reactivity	No further relevant information available
Chemical stability	
Thermal decomposition / conditions to be avoided	No decomposition if used according to specifications
Possibility of hazardous reactions	No dangerous reactions known.
Conditions to avoid	No further relevant information available
Incompatible materials	strong oxidizing agents
Hazardous decomposition products	carbon dioxide, carbon monoxide, nitrogen oxides
Section 11: Toxicological Information	
Information on toxicological effects	
Acute toxicity	
Primary irritant effect	
On the skin	Irritant to skin and mucous membranes.
On the eye	Irritating effect.
Sensitization	No sensitizing effects known.
Additional toxicological information	
Carcinogenic categories	
IARC (International Agency for Research on Cancer)	Substance is not listed.
NTP (National Toxicology Program)	Substance is not listed.
OSHA-Ca (Occupational Safety & Health Administration)	Substance is not listed.
Section 12: Ecological Information	
Toxicity	
Aquatic toxicity	No further relevant information available.
Persistence and degradability	No further relevant information available.
Behavior in environmental systems	
Bioaccumulative potential	No further relevant information available.
Mobility in soil	No further relevant information available.
Additional ecological information	
General notes	Water hazard class 1 (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Results of PBT and vPvB assessment	
PBT	Not applicable
vPvB	Not applicable



Other adverse effects	No further relevant information available.
Section 13: Disposal Considerations	
Waste treatment methods	
Recommendation	Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Uncleaned packagings	
Recommendation	Disposal must be made according to official regulations.
Section 14: Transport Information	
UN-Number DOT, IMDG, IATA	Not regulated
UN proper shipping name DOT, IMDG, IATA	Not regulated
Transport hazard class(es) DOT, ADN, IMDG, IATA Class	Not regulated
Packing group DOT, IMDG, IATA	Not regulated
Environmental hazards	Not applicable.
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
UN "Model Regulation"	Not regulated
Section 15: Regulatory Information	
Safety, health and environmental regulations/legislation specific for the substance or mixture	No further relevant information available.
Sara	
Section 355 (extremely hazardous substances)	Substance is not listed.
Section 313 (Specific toxic chemical listings)	Substance is not listed.
TSCA (Toxic Substances Control Act)	Substance is not listed.
Hazardous Air Pollutants	Substance is not listed.
Proposition 65	
Chemicals known to cause cancer	Substance is not listed.
Chemicals known to cause reproductive toxicity for females	Substance is not listed.



Chemicals known to cause reproductive toxicity for males	Substance is not listed.
Chemicals known to cause developmental	Substance is not listed
Carcinogenic categories	
EPA (Environmental Protection Agency)	Substance is not listed.
TLV (Threshold Limit Value)	Substance is not listed.
NIOSH-Ca (National Institute for Occupational Safety and Health)	Substance is not listed.
Chemical safety assessment:	A Chemical Safety Assessment has not been carried out.

Section 16: Other Information, including date of preparation or last revision

Issue Date: 11-10-2024

Version: 00

Further information

Revision date: NA

Revision note: NA

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.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited- reserves the right to revise this SDS.