

SAFETY DATA SHEET

Section 1: Identification	
Material	Pitavastatin Tablets 1 mg, 2 mg and 4 mg
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sanga Reddy, Telangana 502313, India
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statements	Classified as non-hazardous.
Precautionary statements	<p>Do not handle until all safety precautions have been read and understood.</p> <p>Do not eat, drink or smoke when using this product.</p> <p>If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>Specific treatment (see on this label).</p> <p>Take off contaminated clothing and wash it before reuse.</p> <p>If skin irritation occurs: Get medical advice/attention.</p> <p>If eye irritation persists: Get medical advice/attention,</p> <p>Store locked up.</p> <p>Dispose of contents/container in accordance with local/regional/national/international regulations.</p>
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Pitavastatin Calcium	147526-32-7
Lactose Monohydrate	10039-26-6
Low-Substituted Hydroxypropyl Cellulose	9004-64-2
Hypromellose	9004-65-3
Sodium Carbonate Anhydrous	497-19-8
Magnesium Stearate	557-04-0
Opadry White	NA

Section 4: First-Aid Measures	
General information	Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
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
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	Dispose contaminated material as waste according to item 13
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
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

Section 8: Exposure Controls/Personal Protection	
Additional information about design of technical systems	No further data; see item 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	Not required.
Section 9: Physical and Chemical Properties	
Physical Form	Tablet
Colour	White to off-white
Description	<p>Pitavastatin tablets 1 mg are white to off-white, round, bevel edged biconvex film coated tablets debossed with 'H1' on one side and 'P' on other side. They are supplied as follows: Bottles of 90 tablets NDC 31722-875-90</p> <p>Pitavastatin tablets 2 mg are white to off-white, round, bevel edged biconvex film coated tablets debossed with 'H2' on one side and 'P' on other side. They are supplied as follows: Bottles of 90 tablets NDC 31722-876-90</p> <p>Pitavastatin tablets 4 mg are white to off-white, round, biconvex film coated tablets debossed with 'H4' on one side and 'P' on other side. They are supplied as follows: Bottles of 90 tablets NDC 31722-877-90</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, hydrogen fluoride, nitrogen oxides
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Section 11: Toxicological Information

RTECS Number MJ8047045

Information on toxicological effects

Acute toxicity:

LD/LC50 values that are relevant for classification		
Oral	LDLO	500 mg/kg (rat)
	TDLO	1.68 ml/kg/8W intermittent (man)

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.
- 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 12: Ecological Information

Toxicity	No further relevant information available
· Aquatic toxicity	
Persistence and degradability	No further relevant information available
Behavior in environmental systems:	No further relevant information available
Bioaccumulative potential	
Mobility in soil	No further relevant information available.
Additional ecological information	Water hazard class 1 (Self-assessment): slightly hazardous for water
General notes	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	Must not be disposed of together with household garbage.
Recommendation	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.	
<ul style="list-style-type: none"> · 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 toxicity: Substance is not listed. · Carcinogenic categories · EPA (Environmental Protection Agency) Substance is not listed. · TLV (Threshold Limit Value) Substance is not listed. 	

Section 16: Other Information

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Version : 00

Further information

Revision date: New issue

Revision note: New issue

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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