



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	Ezetimibe Tablets USP 10 mg
Recommended use	Pharmaceutical product
Manufacturer	Hetero Labs Limited Unit III 22-110, Part-II, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Precautionary statements P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of contents/container in accordance with local/regional/national/international regulations Other hazards · Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable.	
Section 3: Composition/Information on Ingredients	
Ingredients	Ezetimibe
CAS	163222-33-1
Section 4: First-Aid Measures	
Inhalation	Supply fresh air; consult doctor in case of complaints.
Skin Contact	Generally, the product does not irritate the skin.
Eye Contact	Rinse opened eye for several minutes under running water
Section 5: Fire-Fighting Measures	
Extinguishing Media	Use firefighting measures that suit the environment. A solid water stream may be inefficient.
Special Firefighting Procedures	No further relevant information available
Section 6: Accidental Release Measures	
Methods and material for containment and cleaning up	Pick up mechanically.
Personal Precautions:	Not required.
Environmental Precautions:	Do not allow to enter sewers/ surface or ground water.



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Section 7: Handling and Storage	
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.
Storage:	Store as per package insert label.
Section 8: Exposure Controls/Personal Protection	
Protection of hands	The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the Degradation.
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.
Eye protection	Not required.
Section 9: Physical and Chemical Properties	
Physical Form	Tablet
Colour	White to off-white
Description	Ezetimibe tablets USP, 10 mg is white to off-white, capsule shaped, flat faced bevel edged tablets debossed with 'I' on one side and '83' on the other side. They are supplied as follows: Bottle of 30 tablets NDC 31722-628-30 Bottle of 90 tablets NDC 31722-628-90 Bottle of 100 tablets NDC 31722-628-01 Carton of 100 (10x10) (Clear PVC/Aclar-Alu) NDC 31722-628-31 Carton of 70 (10x7) unit-dose NDC 31722-628-32
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.



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Incompatible materials	Strong oxidizing agents	
Hazardous decomposition products	Carbon oxides, hydrogen fluoride, nitrogen oxides.	
Section 11: Toxicological Information		
Acute toxicity:		
LD/LC50 values that are relevant for classification:		
Oral	TDLO	0.7 mg/kg//7D (intermittent) (rat) 32.22 mg/kg//180D (continuous) (wmn)
Primary irritant effect:		
<ul style="list-style-type: none">· On the skin : No irritant effect.· On the eye : No 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		
<ul style="list-style-type: none">· 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.· Ecotoxicological effects:· Remark: Very toxic for fish· Additional ecological information:· General notes: <p>Water hazard class 2 (Self-assessment): hazardous for water Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground. Very toxic for aquatic organisms.</p> Results of PBT and vPvB assessment		
<ul style="list-style-type: none">· PBT : Not applicable.· vPvB : Not applicable.· Other adverse effects : No further relevant information available.		
Section 13: Disposal Considerations		
Waste treatment methods		
<ul style="list-style-type: none">· Recommendation: <p>Must not be disposed of together with household garbage. Do not allow product to reach sewage system.</p> <ul style="list-style-type: none">· Uncleaned packagings:· Recommendation: Disposal must be made according to official regulations.		
Section 14: Transport Information		
UN-Number		
DOT, IMDG, IATA	Not regulated	



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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	Environmentally hazardous substance, solid
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	
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	
Issue Date : 02-07-2022	
Version : 00	
Further information	
Revision date: New issue	
Revision note: New issue	
<p>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.</p>	
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