SAFETY DATA SHEET

Section 1: Identification	
Product Name	Olmesartan Medoxomil Tablets USP, 5 mg, 20 mg, and 40 mg
Recommended use	Treatment for Hypertension
Manufacturer	Hetero Labs Limited Unit V, Survey. No 439, 440, 441 & 458, Polepally Village, Mahabubnagar, Telangana 509301, India
Distributor	**Camber Pharmaceuticals, Inc., Piscataway, NJ 08854**
Section 2: Hazard(s) Identification	
Statement of Hazard	Causes severe eye damage. Suspected of damaging the unborn child. Toxic to aquatic life with long lasting effects.
Additional Hazard Information **Short Term:** **Long Term:**	 Antihypertensive drug: has blood pressure-lowering properties In humans, the use of drugs in this class can cause fetal and neonatal toxicity, including low blood pressure and kidney failure, when they are taken during the second and third trimesters of pregnancy.
Known Clinical Effects	Effects reported during clinical use include dizziness, headache, lethargy, changes in blood pressure, nausea, and abdominal pain.
EU Indication of danger	Toxic to Reproduction: Category 3 Dangerous for the Environment
EU Risk Phrases:	R41 - Risk of serious damage to eyes. R63 - Possible risk of harm to the unborn child. R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Australian Hazard Classification (NOHSC):	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	
Ingredients	**CAS**
Olmesartan Medoxomil	144689-63-4
Hydroxypropyl Cellulose	9004-64-2
Lactose monohydrate	10039-26-6
Microcrystaline Cellulose	9004-34-6
Lactose Monohydrate	64044-51-5
Magnesium Stearate.	557-04-0
Opadry yellow	NA
Opadry White	NA
Section 4: First-Aid Measures	
Eye contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
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
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately
Section 5: Fire-Fighting Measures	
Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including selfcontained breathing apparatus.
Fire / Explosion Hazards:	Not determined
Section 6: Accidental Release Measures	
Health and Safety Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust eneration. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid nvironmental 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	
General 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 hands and any exposed skin after removal of PPE. 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.
Storage Conditions	Store as directed by product packaging
Section 8: Exposure Controls/Personal Protection	
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
Environmental Exposure Controls	Refer to specific Member State legislation for requirements under Community environmental legislation
Personal Protective Equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
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	Tablets

Description	5 mg: Yellow, round, biconvex film coated tablets debossed with 'H' on one side and '01' on the other side. Bottles of 30 tablets NDC 31722-852-30 Bottles of 90 tablets NDC 31722-852-90 20 mg: White to off white round, biconvex film coated tablets debossed with 'H' on one side and '03' on the other side. Bottles of 30 tablets NDC 31722-853-30 Bottles of 90 tablets NDC 31722-853-90 40 mg: White to off white oval, biconvex film coated tablets debossed with 'H' on one side and '04' on the other side. Bottles of 30 tablets NDC 31722-854-30 Bottles of 90 tablets NDC 31722-854-90 Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Section 10: Stability and Reactivity

Chemical Stability	Stable under normal conditions of use
Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/explosions
Incompatible Materials	As a precautionary measure, keep away from strong oxidizers

Section 11: Toxicological Information

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

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

Amlodipine besylate

Rat (M) Oral LD50 393 mg/kg

Rat (F) Oral LD50 686 mg/kg

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

Amlodipine besylate

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Non-irritating

Skin Sensitization - GPMT Guinea Pig Negative

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

Olmesartan medoxomil

Reproductive & Fertility Rat Oral 1000 mg/kg/day NOAEL No effects at maximum dose

Amlodipine besylate

Fertility and Embryonic Development Rat Oral 25 mg/kg/day NOAEL Not teratogenic, Maternal toxicity
Peri-/Postnatal Development Rat Oral 4 mg/kg/day NOAEL Fetotoxicity, Fetal mortality
Prenatal & Postnatal Development Rat Oral 25 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rabbit Oral 25 mg/kg/day NOAEL Not Teratogenic

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

Olmesartan medoxomil

In Vitro Bacterial Mutagenicity (Ames) Salmonella Negative

In Vitro Cell Transformation Assay Hamster Negative

In Vitro Chromosome Aberration Hamster Positive

In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Positive

In Vivo Micronucleus Mouse Bone Marrow Negative

Amlodipine besylate

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

In Vivo Cytogenetics Mouse Bone Marrow Negative

In Vitro Chromosome Aberration Human Lymphocytes Negative

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

Olmesartan medoxomil

2 Year(s) Rat Oral, in feed 2000 mg/kg/day NOAEL Not carcinogenic

6 Month(s) Mouse Oral, in feed 1000 mg/kg/day NOAEL Not carcinogenic

Amlodipine besylate

24 Month(s) Rat Oral, in feed 2.5 mg/kg/day NOAEL Not carcinogenic,No effects at maximum dose

24 Month(s) Mouse Oral, in feed 0.5 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Silica colloidal, Ph. Eur. Group 3 (Not Classifiable)
IARC:

Section 12: Ecological Information	
Environmental Overview	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

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	
EU Symbol	Xn N
EU Indication of danger	Toxic to Reproduction: Category 3 Dangerous for the Environment
EU Risk Phrases	R41 - Risk of serious damage to eyes. R63 - Possible risk of harm to the unborn child. R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
EU Safety Phrases	S22 - Do not breathe dust. S36/37 - Wear suitable protective clothing and gloves. S53 - Avoid exposure - obtain special instructions before use. S57 - Use appropriate containment to avoid environmental contamination
OSHA Label: DANGER Causes severe eye damage. Suspected of damaging the unborn child. Toxic to aquatic life with long lasting effects.	
Canada - WHMIS: Classifications **WHMIS hazard class:** Class D, Division 2, Subdivision A	

Starch, pregelatinized	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the	
obligations of Register	
EU EINECS/ELINCS List	232-679-6
Silica colloidal, Ph. Eur.	
Australia (AICS):	Present
Croscarmellose sodium	Present
Australia (AICS):	
Microcrystalline cellulose	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

Section 16: Other Information

Issue Date : 07-04-2025
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 Unit-V shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited Unit-V reserves the right to revise this SDS.