SAFETY DATA SHEET

Section 1: Identification	
Material	Olmesartan medoxomil and Amlodipine besylate Tablets
Recommended use	Pharmaceutical product
Manufacturer	**Hetero Labs Limited,Unit-V, TSIIC Formulation SEZ,S. No. 439,440,441 & 458,Polepally Village, Jadcherla**
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854

Section 2: Hazard(s) Identification	
Appearance	Tablets
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	Antihypertensive drug: has blood pressure-lowering properties
Long Term	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
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

Amlodipine besylate	111470-99-6
Starch, pregelatinized	9005-25-8
Silica colloidal	112945-52-5
Microcrystalline cellulose	9004-34-6
Croscarmellose sodium	74811-65-7
Magnesium Stearate	557-04-0
Opadry II Brown	Not Applicable
Opadry II White	Not Applicable
Opadry II Yellow	Not Applicable
Opadry II Beige	Not Applicable

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 self contained 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 generation. 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 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

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

The exposure limit(s) listed for solid components are only relevant if dust may be generated	
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/20 mg are white to off-white, round, biconvex film coated tablets debossed with 'H' on one side and 'A 9' on the other side. They are supplied as follows: Bottle of 30 tablets NDC 31722-445-30 Bottle of 90 tablets NDC 31722-445-90 5 mg/40 mg are cream, round, biconvex film coated tablets debossed with 'H' on one side and 'A 11' on the other side. They are supplied as follows: Bottle of 30 tablets NDC 31722-446-30 Bottle of 90 tablets NDC 31722-446-90 10 mg/20 mg are grayish orange, round, biconvex film coated tablets debossed with 'H' on one side and 'A 10' on the other side. They are supplied as follows: Bottle of 30 tablets NDC 31722-447-30 Bottle of 90 tablets NDC 31722-447-90 10 mg/40 mg are brownish-red, round, biconvex film coated tablets debossed with 'H' on one side and 'A 12' on the other side. They are supplied as follows: Bottle of 30 tablets NDC 31722-448-30 Bottle of 90 tablets NDC 31722-448-90

	Store at 20° to 25°C (68°F 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
Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 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)
Amlodipine besylate
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Non-irritating
Skin Sensitization - GPMT Guinea Pig Negative
Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating
Amlodipine besylate
3 Month(s) Rat Oral 3 mg/kg/day NOAEL Adrenal gland, Heart
1 Month(s) Rat Oral 3.5 mg/kg/day LOEL Heart
1 Year(s) Rat Oral 2 mg/kg/day NOAEL Adrenal gland, Heart

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. IARC:	Group 3 (Not Classifiable)

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

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Amlodipine besylate
Daphnia magna (Water Flea) OECD EC50 48 Hours 9.9 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours 14 mg/L
Green algae OECD EbC50 72 Hours 0.28 mg/L
Green Algae OECD ErC50 72 Hours > 0.91 mg/L

Aquatic Toxicity Comments	A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Amlodipine besylate
Nostoc sp. (Freshwater Cyanobacteria) MIC 20 mg/L
Aspergillus Niger MIC > 100 mg/L
Trichoderma viride MIC > 100 mg/L
Clostridium perfingens MIC >100 mg/L
Bacillus subtilis MIC 80 mg/L

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 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

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	:Present
EU EINECS/ELINCS List	:232-679-6

Silica colloidal, Ph. Eur.

Australia (AICS)	: Present

Croscarmellose sodium

Australia (AICS)	:Present

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 : 14-07-2025

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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