

## 1. Identification

<b>Product identifier</b>	<b>Olmesartan Medoxomil</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1478367	
<b>Chemical name</b>	1H-Imidazole-5-carboxylic acid, 4-(1-hydroxy-1-methylethyl)-2-propyl-1-[[2'-(1H-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]methyl]-, (5-methyl-2-oxo-1,3-dioxol-4-yl) methyl ester	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Reproductive toxicity	Category 1
<b>OSHA hazard(s)</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger	
<b>Hazard statement</b>	May damage fertility or the unborn child.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.	
<b>Response</b>	If exposed or concerned: Get medical advice/attention.	
<b>Storage</b>	Store locked up.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	Not classified.	

## 3. Composition/information on ingredients

### Substance

### Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Olmesartan Medoxomil		144689-63-4	100

## 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.

<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Cardiovascular effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Treatment of angiotensin II antagonist overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. Consider gastric lavage if it can be performed soon after ingestion. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. Hemodialysis may not be effective in removal. (Meditext)
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO <sub>2</sub> .
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire-fighting equipment/instructions</b>	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
<b>Methods and materials for containment and cleaning up</b>	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

## 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	No exposure standards allocated.
<b>Appropriate engineering controls</b>	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Skin protection</b>	
<b>Hand protection</b>	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Other</b>	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

<b>Respiratory protection</b>	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

<b>Appearance</b>	White to light yellowish-white powder or crystalline powder.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Odor</b>	Odorless or slight characteristic odor.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	351.7 °F (177.6 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility in water</b>	Practically insoluble.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	815 °F (435 °C)
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Imidazole.
<b>Molecular formula</b>	C <sub>29</sub> H <sub>30</sub> N <sub>6</sub> O <sub>6</sub>
<b>Molecular weight</b>	558.59
<b>Solubility (other)</b>	Sparingly soluble in methanol and in acetone; slightly soluble in acetonitrile and in anhydrous ethanol; practically insoluble in diethyl ether.

## 10. Stability and reactivity

<b>Reactivity</b>	No reactivity hazards known.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	None known.
<b>Incompatible materials</b>	None known.
<b>Hazardous decomposition products</b>	NO <sub>x</sub> . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Based on available data, the classification criteria are not met.
<b>Inhalation</b>	Due to lack of data the classification is not possible.

**Skin contact** Due to lack of data the classification is not possible.

**Eye contact** Due to lack of data the classification is not possible.

**Symptoms related to the physical, chemical, and toxicological characteristics** Angiotensin II antagonists: Nausea. Vomiting. Diarrhea. Indigestion. Headache. Dizziness. Fatigue. Fainting. Bone pain. Muscle pain. Angiodema. Fast heartbeat. Slow breathing.

**Delayed and immediate effects of exposure** Angiotensin II antagonists: Hypotension. Arrhythmia. Kidney failure. Hypokalemia.

**Medical conditions aggravated by exposure** Angiotensin II antagonists: Heart failure. Kidney impairment.

**Acute toxicity** Based on available data, the classification criteria are not met.

Product	Species	Test Results
Olmesartan Medoxomil (CAS 144689-63-4)		
Oral		
LD50	Mouse	> 2000 mg/kg
	Rat	> 2000 mg/kg

**Skin corrosion/irritation** Due to lack of data the classification is not possible.

**Serious eye damage/eye irritation** Due to lack of data the classification is not possible.

**Respiratory sensitization** Due to lack of data the classification is not possible.

**Skin sensitization** Based on available data, the classification criteria are not met.

**Sensitization**

Antigenicity tests  
Result: Negative.  
Species: Guinea pig  
Antigenicity tests  
Result: Negative.  
Species: Mouse

**Germ cell mutagenicity** Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

**Mutagenicity**

Ames assay  
Result: Negative.  
Chromosomal aberrations in cultured cells in vitro  
Result: Positive.  
In vitro Syrian hamster embryo cell transformation assay  
Result: Negative.  
Mouse bone marrow micronucleus test in vivo  
Result: Negative.  
MutaMouse intestine and kidney in vivo  
Result: Negative.  
Thymidine kinase mutations in in vitro mouse lymphoma assay  
Result: Positive.

**Carcinogenicity** Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

1000 mg/kg/day Carcinogenicity study  
Result: No evidence of carcinogenic effects.  
Species: Mouse  
Test Duration: 6 months  
2000 mg/kg/day Carcinogenicity study  
Result: Not carcinogenic.  
Species: Rat  
Test Duration: 2 years

**Reproductive toxicity** May damage fertility or the unborn child. Therapeutic use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy has been associated with fetal and newborn injury and death.

**Reproductivity**

1 mg/kg/day Reproductivity study  
Result: No malformations.  
Species: Rabbit  
1000 mg/kg/day Reproductivity study  
Result: No increase in congenital anomalies.  
Species: Rat

**Specific target organ toxicity - single exposure** Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure** Due to lack of data the classification is not possible.

**Aspiration hazard** Based on available data, the classification criteria are not met.

## 12. Ecological information

### Ecotoxicity

Product	Species	Test Results
Olmesartan Medoxomil (CAS 144689-63-4)		
Fish	LC50	Fish > 10 mg/l

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** Not available.

**Mobility in soil** Not available.

**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

**Local disposal regulations** Not available.

**Hazardous waste code** Not available.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as a hazardous material by DOT.

### IATA

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** No information available.

## 15. Regulatory information

**US federal regulations** CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance** No

**SARA 311/312 Hazardous chemical** No

### Other federal regulations

**Safe Drinking Water Act (SDWA)** Not regulated.

**Food and Drug Administration (FDA)** Not regulated.

**US state regulations** California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

## 16. Other information, including date of preparation or last revision

**Issue date** 12-28-2011

**Revision date** 03-13-2014

**Version #** 02

**Further information** Not available.

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**Revision Information** This document has undergone significant changes and should be reviewed in its entirety.