1. Identification

Product identifier: Olmesartan Medoxomil

Other means of identification:
- Catalog number: 1478367
- Chemical name: 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

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information:
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790, US
- Telephone: RS Technical Services 301-816-8129
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300, CHEMTREC outside US & Canada +1 703-527-3887
- Website: www.usp.org
- E-mail: RSTECH@usp.org

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:
- Reproductive toxicity: Category 1

OSHA hazard(s): Not classified.

Label elements:
- Signal word: Danger
- Hazard statement: May damage fertility or the unborn child.
- Precautionary statement:
  - Prevention: 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.
  - Response: If exposed or concerned: Get medical advice/attention.
  - Storage: Store locked up.
  - Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

3. Composition/information on ingredients

Substance: Olmesartan Medoxomil

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olmesartan Medoxomil</td>
<td></td>
<td>144689-63-4</td>
<td>100</td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact: Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact: Rinse with water. Get medical attention if irritation develops and persists.
### 5. Fire-fighting measures

**Suitable extinguishing media**
- Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

**Unsuitable extinguishing media**
- None known.

**Specific hazards arising from the chemical**
- No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters**
- Wear suitable protective equipment.

**Fire-fighting equipment/instructions**
- 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.

**Specific methods**
- Use standard firefighting procedures and consider the hazards of other involved materials.

### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
- 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.

**Methods and materials for containment and cleaning up**
- 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

**Precautions for safe handling**
- 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.

**Conditions for safe storage, including any incompatibilities**
- 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

**Biological limit values**
- No biological exposure limits noted for the ingredient(s).

**Exposure guidelines**
- No exposure standards allocated.

**Appropriate engineering controls**
- 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.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**
- 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.

**Skin protection**
- 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.

**Hand protection**
- Nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Other**
- 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.
Respiratory protection 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).

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance White to light yellowish-white powder or crystalline powder.

Physical state Solid.

Form Powder.

Odor Odorless or slight characteristic odor.

Odor threshold Not available.

pH Not available.

Melting point/freezing point 351.7 °F (177.6 °C)

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility in water Practically insoluble.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature 815 °F (435 °C)

Decomposition temperature Not available.

Viscosity Not available.

Other information

Chemical family Imidazole.

Molecular formula C29H30N6O6

Molecular weight 558.59

Solubility (other) Sparingly soluble in methanol and in acetone; slightly soluble in acetonitrile and in anhydrous ethanol; practically insoluble in diethyl ether.

10. Stability and reactivity

Reactivity No reactivity hazards known.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid None known.

Incompatible materials None known.

Hazardous decomposition products NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion Based on available data, the classification criteria are not met.

Inhalation 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

Delayed and immediate effects of exposure

Medical conditions aggravated by exposure

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olmesartan Medoxomil (CAS 144689-63-4)</td>
<td></td>
</tr>
<tr>
<td><em>Oral</em></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olmesartan Medoxomil (CAS 144689-63-4)</td>
<td>Fish</td>
<td>LC50 &gt; 10 mg/l</td>
</tr>
</tbody>
</table>

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

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

*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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>12-28-2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>03-13-2014</td>
</tr>
<tr>
<td>Version #</td>
<td>02</td>
</tr>
</tbody>
</table>

**Further information**

Not available.

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**Revision Information**

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