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<b>OLMESARTAN MEDOXOMIL</b>		<b>15629.OLM</b>

## 1. Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

**Trade name** : OLMESARTAN MEDOXOMIL  
**Product code** : 15629.OLM  
**Chemical formula** : C29H30N6O6  
**RTECS nr** : No data available.

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Use** : Pharmaceutical industry.

### 1.3. Details of the supplier of the safety data sheet

**Company identification** : MOEHS IBÉRICA, S.L.  
 Roma, 8 - P.I. Cova Solera  
 Tel. +34 93 586 05 20 / Fax + 34 93 699 8350  
 08191 Rubi SPAIN  
 hse@moehs.com

MOEHS CATALANA, S.L.  
 Cesar Martinell i Brunet, 12A - P.I. Rubi Sud  
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 08191 Rubi SPAIN  
 hse@moehs.com

### 1.4. Emergency telephone number

**Phone nr** : Tel. +34 93 586 05 20 [9:00-17:00 h] [ Office hours ]

## 2. Hazards identification

### 2.1. Classification of the substance or mixture

#### Classification EC 67/548 or EC 1999/45


**Classification** : Xn; R20/21/22  
 Xi; R36/37/38

#### Hazard Class and Category Code Regulation EC 1272/2008 (CLP)

**Health hazards** : Acute toxicity, Oral - Category 4 - Warning (CLP : Acute Tox. 4) H302  
 Acute toxicity, dermal - Category 4 - Warning (CLP : Acute Tox. 4) H312  
 Acute toxicity, Inhalation - Category 4 - Warning (CLP : Acute Tox. 4) H332  
 Skin irritation - Category 2 - Warning (CLP : Skin Corr. 2) H315  
 Eye irritation - Category 2A - Warning (CLP : Eye Irrit. 2) H319  
 Specific Target Organ Toxicity - Single exposure - Respiratory tract irritation -  
 Category 3 - Warning (CLP : STOT SE 3) H335  
 Specific Target Organ Toxicity - Repeated exposure - Category 2 - Warning (CLP :  
 STOT RE 2) H373

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## 2. Hazards identification (continued)

### 2.2. Label elements

#### Labelling EC 67/548 or EC 1999/45

Symbol(s)



Symbol(s)

: Xn : Harmful

R Phrase(s)

: R20/21/22 : Harmful by inhalation, in contact with skin and if swallowed.  
R48 : Danger of serious damage to health by prolonged exposure.  
R36/37/38 : Irritating to eyes, respiratory system and skin.

S Phrase(s)

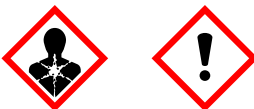
: S36/37 : Wear suitable protective clothing and gloves.

Contains

: (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl 5-(2-hydroxypropan-2-yl)-2-propyl-3-[[4-[2-(2H-tetrazol-5-yl)phenyl]phenyl]methyl]imidazole-4-carboxylate

#### Labelling Regulation EC 1272/2008 (CLP)

Hazard pictograms



Signal words

: Warning

Hazard statements

: H302 : Harmful if swallowed.  
H312 : Harmful in contact with skin.  
H319 : Causes serious eye irritation.  
H315 : Causes skin irritation.  
H332 : Harmful if inhaled.  
H335 : May cause respiratory irritation.  
H373 : May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

• Prevention


: P280: Wear protective gloves, protective clothing, eye protection, face protection.  
P280: Wear eye protection, face protection.  
P260: Do not breathe dust, fume, gas, mist, vapours, spray.  
P264: Wash thoroughly after handling.  
P270: Do not eat, drink or smoke when using this product.  
P271: Use only outdoors or in a well-ventilated area.

• Response

: P322: Specific measures (see on this label).  
P330: Rinse mouth.  
P337+P313: If eye irritation persists: Get medical advice/attention.  
P321: Specific treatment (see on this label).  
P304+P340: IF INHALED : Remove to fresh air and keep at rest in a position comfortable for breathing.  
P302+P352: IF ON SKIN : Wash with plenty of soap and water.  
P301+P312: IF SWALLOWED : Call a POISON CENTER or doctor if you feel unwell.  
P332+P313: If skin irritation occurs : Get medical advice.  
P363: Wash contaminated clothing before reuse.

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## 2. Hazards identification (continued)

- **Storage** : P403+P233: Store in well-ventilated place. Keep container tightly closed.  
P405: Store locked up.
- **Disposal considerations** : P501: Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
- Contains** : (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl 5-(2-hydroxypropan-2-yl)-2-propyl-3-[[4-[2-(2H-tetrazol-5-yl)phenyl]phenyl]methyl]imidazole-4-carboxylate

### 2.3. Other hazards

None under normal conditions.

## 3. Composition/information on ingredients

- Substance / Preparation** : (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl 5-(2-hydroxypropan-2-yl)-2-propyl-3-[[4-[2-(2H-tetrazol-5-yl)phenyl]phenyl]methyl]imidazole-4-carboxylate  
CAS No :144689-63-4  
EC No :---  
Annex No :---  
Substance.
- Molecular Formula** : C29H30N6O6
- SMILE** : CCCC1=NC(=C(N1CC1=CC=C(C=C1)C1=CC=CC=C1C1=NNN=N1)C(=O)OCC1=C(C)OC(=O)O1)C(C)(C)O (Canonical SMILE)
- Synonymous** : 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
- Components** : This product is hazardous.

Substance name	Contents	CAS No	EC No	Annex No	REACH Ref.	Classification
(5-methyl-2-oxo-1,3-dioxol-4-yl)methyl 5-(2-hydroxypropan-2-yl)-2-propyl-3-[[4-[2-(2H-tetrazol-5-yl)phenyl]phenyl]methyl]imidazole-4-carboxylate	100 %	144689-63-4	----	----	----	Xn; R20/21/22 Xi; R36/37/38 ----- STOT RE 2 Acute Tox. 4 (skin) Acute Tox. 4 (inhal) Acute Tox. 4 (oral) Eye Irrit. 2 Skin Irrit. 2 STOT SE 3

Contains no other components or impurities which will influence the classification of the product.


## 4. First aid measures

### 4.1. Description of first aid measures

- Inhalation** : IF INHALED : Remove to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor. Specific treatment is urgent.
- Skin contact** : IF ON SKIN : Gently wash with plenty of soap and water. Immediately call a POISON CENTER or doctor. Specific treatment.  
IF ON SKIN : Wash with plenty of soap and water. Take off contaminated clothing and wash before reuse. If skin irritation occurs : Get medical advice. Specific treatment.

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#### 4. First aid measures (continued)

- Eye contact** : IF IN EYES : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists : Get medical advice.
- Ingestion** : IF SWALLOWED : Rinse mouth. Immediately call a POISON CENTER or doctor. Specific treatment.

#### 4.2. Most important symptoms and effects, both acute and delayed

- Symptoms relating to use** : Not expected to present a significant hazard under anticipated conditions of normal use.

#### 4.3. Indication of any immediate medical attention and special treatment needed

- General information** : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

#### 5. Fire-fighting measures

##### 5.1. Extinguishing media

- Suitable extinguishing media** : Foam. Water spray. Dry powder. Carbon dioxide. Sand.
- Unsuitable extinguishing media** : Do not use a heavy water stream.
- Surrounding fires** : Use water spray or fog for cooling exposed containers.

##### 5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : Under fire conditions, hazardous fumes will be present.

##### 5.3. Advice for fire-fighters

- Protection against fire** : Do not enter fire area without proper protective equipment, including respiratory protection.
- Special procedures** : Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.

#### 6. Accidental release measures

##### 6.1. Personal precautions, protective equipment and emergency procedures


- For emergency responders** : Equip cleanup crew with proper protection. Ventilate area.
- For non-emergency personnel** : Evacuate unnecessary personnel.

##### 6.2. Environmental precautions

- Environmental precautions** : Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

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## 6. Accidental release measures (continued)

### 6.3. Methods and material for containment and cleaning up

**Clean up methods** : On land, sweep or shovel into suitable containers. Minimize generation of dust.

### 6.4. Reference to other sections

See section 8. Exposure controls/personal protection

## 7. Handling and storage

### 7.1. Precautions for safe handling

**Handling** : Wash hands and other exposed areas with mild soap and water before eat, drink or smoke and when leaving work.

**Technical protective measures** : Provide good ventilation in process area to prevent formation of vapour.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage** : Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

**Storage - away from** : Strong bases. Strong acids. Sources of ignition. Direct sunlight.

### 7.3. Specific end use(s)

None.

## 8. Exposure controls/personal protection

### 8.1. Exposure controls

#### Personal protection



#### Personal protection


- **Respiratory protection** : Avoid all unnecessary exposure.
- **Hand protection** : Where excessive dust may result, wear approved mask.
- **Skin protection** : Wear protective gloves.
- **Eye protection** : Wear suitable protective clothing.
- **Others** : Chemical goggles or safety glasses.
- **Others** : When using, do not eat, drink or smoke.

### 8.2. Control parameters

No data available.

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## 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state at 20 °C	: Powder.
Molecular weight	: 558.6 (g/mol)
Colour	: White.
Odour	: Characteristic.
Melting point [°C]	: 175 - 180
Auto-ignition temperature [°C]	: No data available.
Flammability (solid, gas)	: No data available.
Flash point [°C]	: 440.2
Initial boiling point [°C]	: 804.2 (at 760 mmHg )
Density [g/cm <sup>3</sup> ]	: 1.38
Solubility in water	: Partially soluble.
Log P octanol / water at 20°C	: 5.9 Experimental

### 9.2. Other information

Explosive properties	: No data available.
• Layer minimum flammability temperature	: No data available.
• Cloud minimum flammability temperature [°C]	: No data available.
• Minimum ignition energy [mJ]	: No data available.
- Explosion Class	: No data available.
• Minimum explosive concentration [g/m <sup>3</sup> ]	: No data available.
• Explosivity Pmax [bar-g]	: No data available.
• Explosión severity factor Kmax [bar-m/s]	: No data available.
Oxidising properties	: No data available.

## 10. Stability and reactivity

### 10.1. Reactivity

Reactivity	: Not established.
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### 10.2. Chemical stability


Chemical stability	: Stable under recommended storage conditions.
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### 10.3. Possibility of hazardous reactions

Hazardous reactions	: Not established.
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## 10. Stability and reactivity (continued)

### 10.4. Conditions to avoid

Conditions to avoid : Extremely high or low temperatures. Direct sunlight.

### 10.5. Incompatible materials

Materials to avoid : Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

Hazardous decomposition products : Fumes. Carbon monoxide. NOx. Carbon dioxide.

## 11. Toxicological information

### 11.1. Information on toxicological effects

#### Acute toxicity

- Inhalation : Harmful if inhaled.
  - Dermal : Harmful in contact with skin.
  - Ingestion : Harmful if swallowed.
  - Other : Not established.
- Corrosion : Not established.
- Irritation : Causes serious eye irritation.  
Causes skin irritation.  
May cause respiratory irritation.
- Sensitization : Not established.
- Mutagenicity : Not established.
- Carcinogenicity : Not established.
- Toxic for reproduction : Not established.
- STOT-single exposure : Not established.
- STOT-repeated exposure : May cause damage to organs through prolonged or repeated exposure.  
May cause damage to organs through prolonged or repeated exposure.
- Aspiration hazard : Not established.

## 12. Ecological information

### 12.1. Toxicity


Toxicity information : Not established.

### 12.2. Persistence - degradability

Persistence - degradability : No data available.

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## 12. Ecological information (continued)

### 12.3. Bioaccumulative potential

Bioaccumulative potential : Not established.

### 12.4. Mobility in soil

Mobility in soil : Not established.

### 12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not applicable.

### 12.6. Other adverse effects

Environmental precautions : Avoid release to the environment.

## 13. Disposal considerations

### 13.1. Waste treatment methods

General : Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.

## 14. Transport information

### 14.1. Land transport (ADR-RID)

General information : Not regulated.

### 14.2. Sea transport (IMDG) [English only]

General information : Not regulated.

### 14.3. Air transport (ICAO-IATA) [English only]

General information : Not regulated.

## 15. Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture


Safety, health and environmental regulations/legislation specific for the substance or mixture : Ensure all national/local regulations are observed.

### 15.2. Chemical Safety Assessment

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#### 15. Regulatory information (continued)

**Chemical Safety Assessment** : It has not been carried out.

#### 16. Other information

**Revision** : Revision - See : \*

**Abbreviations and acronyms** : Not applicable.

**Sources of key data used** : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

**List of relevant R phrases (heading 3)** : R20/21/22 : Harmful by inhalation, in contact with skin and if swallowed.  
R36/37/38 : Irritating to eyes, respiratory system and skin.  
R48 : Danger of serious damage to health by prolonged exposure.

**List of full text of H-statements in section 3** : H302 : Harmful if swallowed.  
H312 : Harmful in contact with skin.  
H319 : Causes serious eye irritation.  
H315 : Causes skin irritation.  
H332 : Harmful if inhaled.  
H335 : May cause respiratory irritation.  
H373 : May cause damage to organs through prolonged or repeated exposure.

**Use** : Active Ingredient for Medicinal / pharmaceutical use.

**Therapeutic Category** : Angiotensin II Type 1 Receptor Blockers. Antihypertensive Agents

**Further information** : See product bulletin for detailed information.

The contents and format of this SDS are in accordance with REACH Regulation (CE) N° 1907/2006.

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