

Olmesartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
2.3	10.10.2020	717985-00010	Date of first issue: 01.06.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Olmesartan Formulation

Manufacturer or supplier's details

Company name of supplier : Organon & Co.
Address : Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone : 52 55 57284444
Emergency telephone : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Reproductive toxicity : Category 1A

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.

Precautionary Statements :

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Olmesartan	144689-63-4	>= 5 -< 10
Cellulose	9004-34-6	>= 5 -< 10

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
 When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
 Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
 Remove contaminated clothing and shoes.
 Get medical attention.
 Wash clothing before reuse.
 Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.
 Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
 Get medical attention.
 Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May damage the unborn child.
 Contact with dust can cause mechanical irritation or drying of the skin.
 Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
 Alcohol-resistant foam
 Carbon dioxide (CO₂)
 Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
 Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

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- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.

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- Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage** : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid** : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Olmesartan	144689-63-4	TWA	30 µg/m ³ (OEB 3)	Internal
		Wipe limit	300 µg/100 cm ²	Internal
Cellulose	9004-34-6	VLE-PPT	10 mg/m ³	NOM-010-STPS-2014
		TWA	10 mg/m ³	ACGIH

- Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

- Respiratory protection** : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type** : Particulates type
- Hand protection**
- Material** : Chemical-resistant gloves

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Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	

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Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Olmesartan:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

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LD50 (Mouse): > 2,000 mg/kg

LD50 (Dog): > 1,500 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Olmesartan:

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Olmesartan:

Species : Rabbit
Result : Moderate eye irritation
Method : Draize Test

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Olmesartan:

Routes of exposure : Skin contact
Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

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Components:**Olmesartan:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
- Test Type: Mutagenicity (in vitro mammalian cytogenetic test)
Result: negative
- Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Result: positive
- Test Type: Mouse Lymphoma
Result: negative
- Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative
- Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Cellulose:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
- Test Type: In vitro mammalian cell gene mutation test
Result: negative
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Olmesartan:**

- Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

- Species : Mouse
Application Route : Oral
Exposure time : 6 Months
Result : negative

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Cellulose:

Species : Rat
 Application Route : Ingestion
 Exposure time : 72 weeks
 Result : negative

Reproductive toxicity

May damage the unborn child.

Components:**Olmesartan:**

Effects on fertility : Test Type: Fertility
 Species: Rat
 Application Route: Oral
 Fertility: NOAEL: 1,000 mg/kg body weight
 Result: No effects on fertility.

Effects on fetal development : Test Type: Development
 Species: Rat
 Application Route: Oral
 Dose: 1000 milligram per kilogram
 Result: No teratogenic effects.

Test Type: Development
 Species: Rabbit
 Application Route: Oral
 Dose: 1 milligram per kilogram
 Result: No teratogenic effects.

Test Type: Development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: \geq 1.6 mg/kg body weight
 Symptoms: Malformations were observed., Reduced body weight
 Result: Effects on postnatal development.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Ingestion
 Result: negative

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STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Olmesartan:

Species : Rat
NOAEL : 2,000 mg/kg
Application Route : Oral
Exposure time : 24 Months
Remarks : No significant adverse effects were reported

Cellulose:

Species : Rat
NOAEL : \geq 9,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Olmesartan:

Eye contact : Symptoms: Eye irritation
Ingestion : Symptoms: hypotension
Remarks: May cause harm to the unborn child.
Based on Human Evidence

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): $>$ 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

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Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

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SECTION 16. OTHER INFORMATION**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE- : Time weighted average limit value
PPT

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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