

# SAFETY DATA SHEET



## Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation



Version 1.3      Revision Date: 09.04.2021      SDS Number: 4944870-00004      Date of last issue: 10.10.2020  
Date of first issue: 30.09.2019

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide 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

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Eye irritation : Category 2A  
Reproductive toxicity : Category 1A  
Specific target organ toxicity - repeated exposure : Category 1 (Kidney, Parathyroid gland)

#### GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H319 Causes serious eye irritation.  
H360D May damage the unborn child.  
H372 Causes damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water

# Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

|                |                              |                              |   |
|----------------|------------------------------|------------------------------|---|
| Version<br>1.3 | Revision Date:<br>09.04.2021 | SDS Number:<br>4944870-00004 | Date of last issue: 10.10.2020<br>Date of first issue: 30.09.2019 |
|----------------|------------------------------|------------------------------|---|

for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P337 + P313 If eye irritation persists: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

May form explosible dust-air mixture if dispersed.

Contact with dust can cause mechanical irritation or drying of the skin.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name       | CAS-No.     | Concentration (% w/w) |
|---------------------|-------------|-----------------------|
| Cellulose           | 9004-34-6   | >= 30 -< 50           |
| Starch              | 9005-25-8   | >= 30 -< 50           |
| Olmesartan          | 144689-63-4 | >= 10 -< 20           |
| Hydrochlorothiazide | 58-93-5     | >= 5 -< 10            |
| Amlodipine Besylate | 652969-01-2 | >= 1 -< 5             |

## 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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

# SAFETY DATA SHEET



## Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation



|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 10.10.2020  |
| 1.3     | 09.04.2021     | 4944870-00004 | Date of first issue: 30.09.2019 |

---

|   |   |   |
|---|---|---|
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye irritation.<br>May damage the unborn child.<br>Causes damage to organs through prolonged or repeated exposure.<br>Contact with dust can cause mechanical irritation or drying of the skin. |
| 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.   |

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### SECTION 5. FIRE-FIGHTING MEASURES

|  |   |   |
|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media                 | : | High volume water jet   |
| 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.<br>Do not use a solid water stream as it may scatter and spread fire.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products                  | : | Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )<br>Chlorine compounds<br>Sulfur oxides  |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area.   |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

|   |   |   |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.  |

# SAFETY DATA SHEET



## Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation



|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 10.10.2020  |
| 1.3     | 09.04.2021     | 4944870-00004 | Date of first issue: 30.09.2019 |

---

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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Do not eat, drink or smoke when using this product.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.   |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Organic peroxides<br>Explosives  |

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## Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation



Version 1.3      Revision Date: 09.04.2021      SDS Number: 4944870-00004      Date of last issue: 10.10.2020  
Date of first issue: 30.09.2019

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             |
|---------------------|-------------|-------------------------------|--|-------------------|
| Cellulose           | 9004-34-6   | VLE-PPT                       | 10 mg/m <sup>3</sup>                           | NOM-010-STPS-2014 |
|                     |             | TWA                           | 10 mg/m <sup>3</sup>                           | ACGIH             |
| Starch              | 9005-25-8   | VLE-PPT                       | 10 mg/m <sup>3</sup>                           | NOM-010-STPS-2014 |
|                     |             | TWA                           | 10 mg/m <sup>3</sup>                           | ACGIH             |
| Olmesartan          | 144689-63-4 | TWA                           | 30 µg/m <sup>3</sup> (OEB 3)                   | Internal          |
|                     |             | Wipe limit                    | 300 µg/100 cm <sup>2</sup>                     | Internal          |
| Hydrochlorothiazide | 58-93-5     | TWA                           | 100 µg/m <sup>3</sup> (OEB 2)                  | Internal          |
|                     |             |                               |  |                   |
| Amlodipine Besylate | 652969-01-2 | TWA                           | 20 µg/m <sup>3</sup> (OEB 3)                   | Internal          |
|                     |             | Wipe limit                    | 100 µg/100 cm <sup>2</sup>                     | Internal          |

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### 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 : Chemical-resistant gloves

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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Color : No data available

Odor : No data available

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Version 1.3      Revision Date: 09.04.2021      SDS Number: 4944870-00004      Date of last issue: 10.10.2020  
Date of first issue: 30.09.2019

---

|  |   |  |
|--|---|--|
| 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                                      | : | No data available  |
| Evaporation rate                                 | : | Not applicable   |
| Flammability (solid, gas)                        | : | No data available  |
| 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                                   | : | Not applicable   |
| Relative vapor density                           | : | Not applicable   |
| Relative density                                 | : | No data available  |
| Density  | : | No data available  |
| Solubility(ies)<br>Water solubility              | : | No data available  |
| Partition coefficient: n-octanol/water           | : | Not applicable   |
| Autoignition temperature                         | : | No data available  |
| Decomposition temperature                        | : | No data available  |
| Viscosity<br>Viscosity, kinematic                | : | Not applicable   |
| 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  |

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### SECTION 10. STABILITY AND REACTIVITY

# SAFETY DATA SHEET



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Version 1.3      Revision Date: 09.04.2021      SDS Number: 4944870-00004      Date of last issue: 10.10.2020  
Date of first issue: 30.09.2019

---

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Dust can form an explosive mixture in air.  
Can react with strong oxidizing agents.  
Conditions to avoid : Avoid dust formation.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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### 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:

##### **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

##### **Starch:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

##### **Olmesartan:**

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

# SAFETY DATA SHEET



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Version 1.3      Revision Date: 09.04.2021      SDS Number: 4944870-00004      Date of last issue: 10.10.2020  
Date of first issue: 30.09.2019

---

### Hydrochlorothiazide:

Acute oral toxicity : LD50 (Rat): > 2,750 mg/kg  
LD50 (Mouse): > 2,830 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 990 mg/kg  
Application Route: Intravenous  
LD50 (Mouse): 590 mg/kg  
Application Route: Intravenous

### Amlodipine Besylate:

Acute oral toxicity : LD50 (Rat): 393 mg/kg

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Olmesartan:

Remarks : No data available

#### Hydrochlorothiazide:

Species : Rabbit  
Result : No skin irritation

### Serious eye damage/eye irritation

Causes serious eye irritation.

### Components:

#### Starch:

Species : Rabbit  
Result : No eye irritation

#### Olmesartan:

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

#### Hydrochlorothiazide:

Species : Rabbit  
Result : Mild eye irritation

#### Amlodipine Besylate:

Species : Rabbit  
Result : Severe irritation



**Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation**

Version 1.3      Revision Date: 09.04.2021      SDS Number: 4944870-00004      Date of last issue: 10.10.2020  
Date of first issue: 30.09.2019

---

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Starch:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

**Olmesartan:**

Routes of exposure : Skin contact  
Remarks : No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****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

**Starch:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

**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

**Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 10.10.2020  |
| 1.3     | 09.04.2021     | 4944870-00004 | Date of first issue: 30.09.2019 |

---

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.

**Hydrochlorothiazide:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: negative

Test Type: sister chromatid exchange assay  
Test system: Chinese hamster ovary cells  
Result: positive

Test Type: in vitro test  
Test system: mouse lymphoma cells  
Result: positive

Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: Chinese hamster  
Cell type: Bone marrow  
Result: negative

Test Type: in vivo assay  
Species: Mouse  
Cell type: Bone marrow  
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**Amlodipine Besylate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

**Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation**

Version 1.3      Revision Date: 09.04.2021      SDS Number: 4944870-00004      Date of last issue: 10.10.2020  
Date of first issue: 30.09.2019

---

**Carcinogenicity**

Not classified based on available information.

**Components:****Cellulose:**

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

**Olmesartan:**

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

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

**Hydrochlorothiazide:**

Species : Mouse, female  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

Species : Mouse, male  
Application Route : Oral  
Exposure time : 2 Years  
Result : equivocal

Species : Rat, male and female  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

**Amlodipine Besylate:**

Species : Mouse  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

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

**Reproductive toxicity**

May damage the unborn child.

# Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 10.10.2020  |
| 1.3     | 09.04.2021     | 4944870-00004 | Date of first issue: 30.09.2019 |

---

**Components:****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

**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.

**Hydrochlorothiazide:**

Effects on fertility : Test Type: Fertility  
Species: Rat, male and female  
Application Route: oral (feed)  
Fertility: NOAEL: 4 mg/kg body weight  
Result: Effects on fertility.

Test Type: Fertility  
Species: Mouse, male and female

**Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 10.10.2020  |
| 1.3     | 09.04.2021     | 4944870-00004 | Date of first issue: 30.09.2019 |

---

Application Route: oral (feed)  
 Fertility: NOAEL: 100 mg/kg body weight  
 Result: Effects on fertility.

Effects on fetal development : Test Type: Development  
 Species: Mouse  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 3,000 mg/kg body weight  
 Result: No teratogenic effects.

Test Type: Development  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 1,000 mg/kg body weight  
 Result: No teratogenic effects.

**Amlodipine Besylate:**

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Ingestion  
 Fertility: NOAEL: 10 mg/kg body weight  
 Result: No effects on fertility.

Test Type: Fertility/early embryonic development  
 Species: Rabbit  
 Application Route: Ingestion  
 Fertility: NOAEL: 25 mg/kg body weight  
 Result: No effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Ingestion  
 Developmental Toxicity: LOAEL: 10 mg/kg body weight  
 Result: Effects on fetal development.

Test Type: Embryo-fetal development  
 Species: Rabbit  
 Application Route: Ingestion  
 Developmental Toxicity: NOAEL: 10 mg/kg body weight  
 Result: No effects on fetal development.

Test Type: Embryo-fetal development  
 Species: Mouse  
 Application Route: Ingestion  
 Developmental Toxicity: LOAEL: 1.6 mg/kg body weight  
 Result: Effects on fetal development.  
 Remarks: Maternal toxicity observed.

**STOT-single exposure**

Not classified based on available information.

# Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 10.10.2020  |
| 1.3     | 09.04.2021     | 4944870-00004 | Date of first issue: 30.09.2019 |

---

**STOT-repeated exposure**

Causes damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.

**Components:****Hydrochlorothiazide:**

|               |   |   |
|---------------|---|---|
| Target Organs | : | Kidney, Parathyroid gland                                       |
| Assessment    | : | Causes damage to organs through prolonged or repeated exposure. |

**Repeated dose toxicity****Components:****Cellulose:**

|                   |   |                |
|-------------------|---|----------------|
| Species           | : | Rat            |
| NOAEL             | : | >= 9,000 mg/kg |
| Application Route | : | Ingestion      |
| Exposure time     | : | 90 Days        |

**Starch:**

|                   |   |                         |
|-------------------|---|-------------------------|
| Species           | : | Rat                     |
| NOAEL             | : | >= 2,000 mg/kg          |
| Application Route | : | Skin contact            |
| Exposure time     | : | 28 Days                 |
| Method            | : | OECD Test Guideline 410 |

**Olmesartan:**

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

**Hydrochlorothiazide:**

|                   |   |                           |
|-------------------|---|---------------------------|
| Species           | : | Rat, male and female      |
| LOAEL             | : | 10 mg/kg                  |
| Application Route | : | Oral                      |
| Exposure time     | : | 2 y                       |
| Target Organs     | : | Kidney, Parathyroid gland |

|                   |   |  |
|-------------------|---|--|
| Species           | : | Mouse, male and female                       |
| NOAEL             | : | 300 - 550 mg/kg                              |
| Application Route | : | Oral   |
| Exposure time     | : | 2 y  |
| Remarks           | : | No significant adverse effects were reported |

|                   |   |                |
|-------------------|---|----------------|
| Species           | : | Dog            |
|                   | : | 50 - 200 mg/kg |
| Application Route | : | Oral           |
| Exposure time     | : | 9 Months       |

# SAFETY DATA SHEET



## Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

Version 1.3      Revision Date: 09.04.2021      SDS Number: 4944870-00004      Date of last issue: 10.10.2020  
Date of first issue: 30.09.2019

---

Target Organs : Parathyroid gland

### Amlodipine Besylate:

Species : Rat  
NOAEL : 15 mg/kg  
Application Route : Oral  
Exposure time : 90 d  
Remarks : No significant adverse effects were reported

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Hydrochlorothiazide:

No aspiration toxicity classification

### 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

#### Hydrochlorothiazide:

Eye contact : Symptoms: Eye irritation  
Ingestion : Symptoms: Dizziness, Headache, Fatigue, Nausea, Abdominal pain, hypotension, dry mouth, electrolyte imbalance, eye pain

#### Amlodipine Besylate:

Eye contact : Symptoms: Severe irritation  
Ingestion : Symptoms: Nausea, Abdominal pain, Fatigue, Headache, Edema, Palpitation

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## 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

#### Hydrochlorothiazide:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l  
Exposure time: 96 h

# SAFETY DATA SHEET



## Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation



|                |                              |                              |   |
|----------------|------------------------------|------------------------------|---|
| Version<br>1.3 | Revision Date:<br>09.04.2021 | SDS Number:<br>4944870-00004 | Date of last issue: 10.10.2020<br>Date of first issue: 30.09.2019 |
|----------------|------------------------------|------------------------------|---|

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l  
Exposure time: 48 h

### **Amlodipine Besylate:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 2.7 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3.2 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : IC50 (Pseudokirchneriella subcapitata (green algae)): 5.6 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

### **Persistence and degradability**

#### **Components:**

##### **Cellulose:**

Biodegradability : Result: Readily biodegradable.

##### **Hydrochlorothiazide:**

Stability in water : Hydrolysis: 46.2 %(96 h)

### **Bioaccumulative potential**

#### **Components:**

##### **Amlodipine Besylate:**

Partition coefficient: n-octanol/water : log Pow: 3

##### **Mobility in soil**

No data available

##### **Other adverse effects**

No data available

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## 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.

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## SECTION 14. TRANSPORT INFORMATION

### **International Regulations**



# SAFETY DATA SHEET



## Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation



Version 1.3      Revision Date: 09.04.2021      SDS Number: 4944870-00004      Date of last issue: 10.10.2020  
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### 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

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## 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;

# SAFETY DATA SHEET



## Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation



|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
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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/>

Revision Date : 09.04.2021

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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