

# SAFETY DATA SHEET



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



Version 2.0      Revision Date: 09.04.2021      SDS Number: 4944873-00004      Date of last issue: 10.10.2020  
Date of first issue: 30.09.2019

### 1. PRODUCT AND COMPANY IDENTIFICATION

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

#### Manufacturer or supplier's details

Company : Organon & Co.  
Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302  
Telephone : 551-430-6000  
Emergency telephone number : 215-631-6999  
E-mail address : EHSSTEWARD@organon.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

### 2. HAZARDS IDENTIFICATION

#### GHS Classification

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

#### GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H319 Causes serious eye irritation.  
H360D May damage the unborn child.  
H373 May cause 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.

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P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water 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 which do not result in classification

May form explosible dust-air mixture if dispersed.  
Contact with dust can cause mechanical irritation or drying of the skin.

### 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	>= 1 -< 10
Amlodipine Besylate	652969-01-2	>= 2.5 -< 10

### 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.

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- If swallowed : 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.
- Most important symptoms and effects, both acute and delayed : Causes serious eye irritation.  
May damage the unborn child.  
May cause damage to organs through prolonged or repeated exposure.  
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.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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.  
Do not use a solid water stream as it may scatter and spread fire.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Chlorine compounds  
Sulphur oxides
- 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

### 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.

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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.

### 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.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
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.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled 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

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
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		(Form of exposure)	ters / Permissible concentration	
Cellulose	9004-34-6	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Starch	9005-25-8	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		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

Material : 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.

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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Colour : No data available

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Odour	:	No data available
Odour 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
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity 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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## 10. STABILITY AND REACTIVITY

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.

## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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### Acute toxicity

Not classified based on available information.

### Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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### 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

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**II****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



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## Respiratory or skin sensitisation

### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Starch:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

#### Olmesartan:

Exposure routes	:	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
Genotoxicity in vivo	:	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

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		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 assay 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

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**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.

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

- |                               |   |   |
|-------------------------------|---|---|
| Effects on fertility          | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative      |

**Olmesartan:**

- |                                    |   |   |
|------------------------------------|---|---|
| Effects on fertility               | : | Test Type: Fertility<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 1,000 mg/kg body weight<br>Result: No effects on fertility   |
| Effects on foetal development      | : | Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Dose: 1000 milligram per kilogram<br>Result: No teratogenic effects  |
|                                    |   | Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Dose: 1 milligram per kilogram<br>Result: No teratogenic effects  |
|                                    |   | Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: >= 1.6 mg/kg body weight<br>Symptoms: Malformations were observed., Reduced body weight<br>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<br>Species: Rat, male and female<br>Application Route: oral (feed)<br>Fertility: NOAEL: 4 mg/kg body weight<br>Result: Effects on fertility |
|                      |   | Test Type: Fertility<br>Species: Mouse, male and female  |

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

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

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

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

**STOT - single exposure**

Not classified based on available information.

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**STOT - repeated exposure**

May cause 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 yr
Target Organs	:	Kidney, Parathyroid gland

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

Species	:	Dog
	:	50 - 200 mg/kg
Application Route	:	Oral

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Exposure time : 9 Months  
 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, Oedema, Palpitation

## 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

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Exposure time: 96 h  
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

## 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.

## 14. TRANSPORT INFORMATION

### International Regulations



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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.

## 15. REGULATORY INFORMATION

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

### Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and  
Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

## 16. OTHER INFORMATION

### Further information

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

SG OEL : Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances

# SAFETY DATA SHEET



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



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2.0	09.04.2021	4944873-00004	Date of first issue: 30.09.2019

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ACGIH / TWA : 8-hour, time-weighted average  
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIIC - 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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN