

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

Version 1.2      Revision Date: 10.10.2020      SDS Number: 4944865-00003      Date of last issue: 23.03.2020  
Date of first issue: 30.09.2019

---

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

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

**Manufacturer or supplier's details**

Company : MSD  
Address : 26 Talavera Road, Talavera Corp Centre, Macquarie Park  
New South Wales, 2113 Australia  
Telephone : (61)-02-8988-8000  
Emergency telephone number : (61)-02-8988-8000  
E-mail address : EHSDATASTEWARD@msd.com  
Telefax : 908-735-1496

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

Recommended use : Pharmaceutical

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

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 : 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/ fume/ gas/ mist/ vapours/ spray.  
P281 Use personal protective equipment as required.

---

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

Version 1.2      Revision Date: 10.10.2020      SDS Number: 4944865-00003      Date of last issue: 23.03.2020  
Date of first issue: 30.09.2019

**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 which do not result in classification**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 -< 60
Starch	9005-25-8	>= 30 -< 60
Olmesartan	144689-63-4	>= 10 -< 30
Hydrochlorothiazide	58-93-5	>= 1 -< 10
Amlodipine Besylate	652969-01-2	< 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 : 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.
- Most important symptoms and effects, both acute and delayed : 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

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

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.2	10.10.2020	4944865-00003	Date of first issue: 30.09.2019

---

Protection of first-aiders : the skin.  
 : 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. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : 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.

---

### 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

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

Version 1.2      Revision Date: 10.10.2020      SDS Number: 4944865-00003      Date of last issue: 23.03.2020  
Date of first issue: 30.09.2019

certain local or national requirements.

### 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, fume, gas, mist, vapours or spray.  
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.
- 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 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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	AU OEL
Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica				

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

Version 1.2      Revision Date: 10.10.2020      SDS Number: 4944865-00003      Date of last issue: 23.03.2020  
 Date of first issue: 30.09.2019

		TWA	10 mg/m <sup>3</sup>	ACGIH
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	AU OEL
Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica				
		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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Colour : No data available

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

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

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.2	10.10.2020	4944865-00003	Date of first issue: 30.09.2019

---

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

---

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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

Version 1.2      Revision Date: 10.10.2020      SDS Number: 4944865-00003      Date of last issue: 23.03.2020  
Date of first issue: 30.09.2019

---

**SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes : Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 2,000 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

**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

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

Version 1.2      Revision Date: 10.10.2020      SDS Number: 4944865-00003      Date of last issue: 23.03.2020  
Date of first issue: 30.09.2019

---

**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**

Not classified based on available information.

**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

**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



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

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.2	10.10.2020	4944865-00003	Date of first issue: 30.09.2019

---

Species : Guinea pig  
Result : negative

### Olmesartan:

Exposure routes : Skin contact  
Remarks : No data available

### Chronic toxicity

#### 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  
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

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

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.2	10.10.2020	4944865-00003	Date of first issue: 30.09.2019

---

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

### Carcinogenicity

Not classified based on available information.

### Components:

#### Cellulose:

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

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

Version 1.2      Revision Date: 10.10.2020      SDS Number: 4944865-00003      Date of last issue: 23.03.2020  
Date of first issue: 30.09.2019

---

**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.

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

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

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion

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

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.2	10.10.2020	4944865-00003	Date of first issue: 30.09.2019

---

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

Effects on foetal 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

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

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.2	10.10.2020	4944865-00003	Date of first issue: 30.09.2019

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.

### 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.

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

Version 1.2      Revision Date: 10.10.2020      SDS Number: 4944865-00003      Date of last issue: 23.03.2020  
Date of first issue: 30.09.2019

---

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

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

**Starch:**

Species : Rat  
NOAEL :  $\geq 2,000$  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  
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

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

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.2	10.10.2020	4944865-00003	Date of first issue: 30.09.2019

**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

**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

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	:	EC50 (Daphnia magna (Water flea)): 3.2 mg/l
-------------------------------	---	---

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

Version 1.2      Revision Date: 10.10.2020      SDS Number: 4944865-00003      Date of last issue: 23.03.2020  
Date of first issue: 30.09.2019

---

aquatic invertebrates      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

---

**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.

---



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

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.2	10.10.2020	4944865-00003	Date of first issue: 30.09.2019

**National Regulations****ADG**

Not regulated as a dangerous good

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

AICS : not determined  
DSL : not determined  
IECSC : not determined

**SECTION 16. OTHER INFORMATION****Further information**

Revision Date : 10.10.2020  
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/>  
Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA : 8-hour, time-weighted average  
AU OEL / TWA : Exposure standard - time weighted average

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

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

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.2	10.10.2020	4944865-00003	Date of first issue: 30.09.2019

---

- 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.

AU / EN