

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

Version 1.2      Revision Date: 10/10/2020      SDS Number: 4944863-00003      Date of last issue: 03/23/2020  
Date of first issue: 09/30/2019

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## SECTION 1. IDENTIFICATION

Product name : Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation  
Other means of identification : No data available

### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - U.S.A. 07033  
Telephone : 908-740-4000  
Telefax : 908-735-1496  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Pharmaceutical


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## SECTION 2. HAZARDS IDENTIFICATION

### GHS classification in accordance with the Hazardous Products Regulations

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

### 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, fume, gas, mist, vapors or spray.  
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 and face protection.

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**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 attention.

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

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

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	>= 5 - < 10 *
Amlodipine Besylate	652969-01-2	>= 1 - < 5 *

\* Actual concentration or concentration range is withheld as a trade secret

**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.

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Most important symptoms and effects, both acute and delayed	:	Rinse mouth thoroughly with water. Causes serious eye irritation. May damage the unborn child. Causes 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.

### SECTION 5. FIRE-FIGHTING 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 Sulfur 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 fire-fighters	:	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

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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.

### 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, vapors 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.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respir-)	3 mg/m <sup>3</sup>	CA BC OEL

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		able dust fraction)		
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC 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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	tablet
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	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)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive

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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.

**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

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

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

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

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**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



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**Hydrochlorothiazide:**

Species	:	Rabbit
Result	:	Mild eye irritation

**Amlodipine Besylate:**

Species	:	Rabbit
Result	:	Severe irritation

**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
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**Olmesartan:**

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

**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.

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**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:**

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

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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
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Effects on fetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative
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#### 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.
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Effects on fetal development	:	Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects.
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	:	Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram Result: No teratogenic effects.
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	:	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.
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Reproductive toxicity - Assessment	:	Positive evidence of adverse effects on development from human epidemiological studies.
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#### Hydrochlorothiazide:

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- 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 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

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Result: Effects on fetal development.  
Remarks: Maternal toxicity observed.

**STOT-single exposure**

Not classified based on available information.

**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 :  $\geq 9,000$  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 y  
Target Organs : Kidney, Parathyroid gland

Species : Mouse, male and female  
NOAEL : 300 - 550 mg/kg  
Application Route : Oral  
Exposure time : 2 y

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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

### 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

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

### Components:

#### Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
 Exposure time: 48 h

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Remarks: Based on data from similar materials

**Hydrochlorothiazide:**Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l  
Exposure time: 96 hToxicity 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 hToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3.2 mg/l  
Exposure time: 48 hToxicity 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.



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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

### Domestic regulation

#### TDG

Not regulated as a dangerous good

## SECTION 15. REGULATORY INFORMATION

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

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

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWA	:	Time-weighted average exposure value

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 Sys-

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

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tem; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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Date format : mm/dd/yyyy

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.

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