SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

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

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company: Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A

Telephone: 551-430-6000

E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2
Reproductive toxicity, Category 1A
Specific target organ toxicity - repeated exposure, Category 2
Long-term (chronic) aquatic hazard, Category 3

H319: Causes serious eye irritation.
H360D: May damage the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms:

Signal word: Danger

Hazard statements:

H319: Causes serious eye irritation.
H360D: May damage the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
Precautionary statements:

**Prevention:**
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Hazardous components which must be listed on the label:
Olmesartan
Hydrochlorothiazide

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olmesartan</td>
<td>144689-63-4</td>
<td>Acute Tox. 4; H302 Eye Irrit. 2; H319 Repr. 1A; H360D</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>STOT RE 1; H372 (Kidney, Parathyroid gland)</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Amlodipine Besylate</td>
<td>652969-01-2</td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.
SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media:
- High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:
- 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 (NOx)
- Chlorine compounds
- Sulphur oxides

5.3 Advice for firefighters

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

Version 1.3 Revision Date: 09.04.2021 SDS Number: 4983488-00004 Date of last issue: 10.10.2020 Date of first issue: 30.09.2019

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olmesartan</td>
<td>144689-63-4</td>
<td>TWA</td>
<td>30 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>300 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Amlodipine Besylate</td>
<td>652969-01-2</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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

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.

Hand protection:
- Material: Chemical-resistant gloves
Skin and body protection : Work uniform or laboratory coat.
Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143
Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| Physical state   | : tablet              |
| Colour           | : No data available  |
| Odour            | : No data available  |
| Odour Threshold  | : No data available  |
| Melting point/freezing point | : No data available |
| Initial boiling point and boiling range | : No data available |
| 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 |
| Flash point      | : No data available  |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Decomposition temperature Decomposition temperature | : No data available |
| pH               | : No data available  |
| Viscosity        | : Not applicable     |
| Viscosity, kinematic | : Not applicable |
| Solubility(ies)  | : No data available  |
| Water solubility | : No data available  |
| Partition coefficient: n-octanol/water | : Not applicable |
| Vapour pressure  | : Not applicable     |
| Relative density | : No data available  |
| Density          | : No data available  |
Relative vapour density : Not applicable

Particle characteristics
Particle size : No data available

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : Not applicable
Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Dust can form an explosive mixture in air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
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: > 2.000 mg/kg
Method: Calculation method
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Omesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

Version 1.3  Revision Date: 09.04.2021  SDS Number: 4983488-00004  Date of last issue: 10.10.2020
Date of first issue: 30.09.2019

Components:

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

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:

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

Olmesartan:
Exposure routes: Skin contact
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Genotoxicity in vitro: Test Type: Mutagenicity (in vitro mammalian cytogenetic test)
Result: negative

Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Result: positive

Genotoxicity in vitro: Test Type: Mouse Lymphoma
Result: negative

Germ cell mutagenicity: 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

Carcinogenicity
Not classified based on available information.

Components:
Olmesartan:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative
Species: Mouse
Application Route: Oral
Exposure time: 6 Months
Result: negative
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:
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
<table>
<thead>
<tr>
<th>Test Type: Development</th>
<th>Reproductive toxicity - Assessment: Positive evidence of adverse effects on development from human epidemiological studies.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Hydrochlorothiazide:</td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td>Effects on fertility:</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: (\geq 1.6 \text{ mg/kg body weight})</td>
<td></td>
</tr>
<tr>
<td>Symptoms: Malformations were observed, Reduced body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Effects on postnatal development</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Fertility</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat, male and female</td>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: oral (feed)</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Fertility: NOAEL: 4 mg/kg body weight</td>
<td>Fertility: NOAEL: 10 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Effects on fertility</td>
<td>Result: No effects on fertility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Fertility</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse, male and female</td>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: oral (feed)</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Fertility: NOAEL: 100 mg/kg body weight</td>
<td>Fertility: NOAEL: 25 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Effects on fertility</td>
<td>Result: No effects on fertility</td>
</tr>
</tbody>
</table>

### Hydrochlorothiazide

<table>
<thead>
<tr>
<th>Test Type: Development</th>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 3.000 mg/kg body weight</td>
<td>Developmental Toxicity: NOAEL: 1.000 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No teratogenic effects</td>
<td>Result: No teratogenic effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Fertility: NOAEL: 10 mg/kg body weight</td>
<td>Fertility: NOAEL: 25 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No effects on fertility</td>
<td>Result: No effects on fertility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Fertility</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Fertility: NOAEL: 25 mg/kg body weight</td>
<td>Result: No effects on fertility</td>
</tr>
</tbody>
</table>

### Amlodipine Besylate

<table>
<thead>
<tr>
<th>Test Type: Development</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 60 mg/kg body weight</td>
<td>Developmental Toxicity: NOAEL: 25 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No effects on fertility</td>
<td>Result: No effects on fertility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rabbit</td>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Fertility: NOAEL: 25 mg/kg body weight</td>
<td>Fertility: NOAEL: 25 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No effects on fertility</td>
<td>Result: No effects on fertility</td>
</tr>
</tbody>
</table>
Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

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 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:

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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

Version 1.3 Revision Date: 09.04.2021 SDS Number: 4983488-00004 Date of last issue: 10.10.2020 Date of first issue: 30.09.2019

Exposure time: 2 yr
Remarks: No significant adverse effects were reported

Species: Dog
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

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

12.1 Toxicity

Components:

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 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

12.2 Persistence and degradability

Components:

Hydrochlorothiazide:
Stability in water: Hydrolysis: 46,2 %(96 h)

12.3 Bioaccumulative potential

Components:

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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of
12.6 Other adverse effects

**Product:**

Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number or ID number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
SAFETY DATA SHEET
generated according to Regulation (EC) No. 1907/2006

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII):
Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59):
Not applicable

REACH - List of substances subject to authorisation (Annex XIV):
Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer:
Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast):
Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals:
Not applicable

Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H302: Harmful if swallowed.
H319: Causes serious eye irritation.
H360D: May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H411: Toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox.: Acute toxicity
Aquatic Chronic: Long-term (chronic) aquatic hazard
### SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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

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**Eye Irrit.** : Eye irritation  
**Repr.** : Reproductive toxicity  
**STOT RE** : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCI - Taiwan Chemical Substance Inventory; 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 Bio-accumulative

**Further information**


**Classification of the mixture:**

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**Classification procedure:**

- Calculation method
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Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

Version 1.3 Revision Date: 09.04.2021 SDS Number: 4983488-00004 Date of last issue: 10.10.2020

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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.

NO / EN