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

1.1 Product identifier
   Trade name : Olmesartan / Amlodipine Besylate 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  H319: Causes serious eye irritation.
   Reproductive toxicity, Category 1A  H360D: May damage the unborn child.
   Long-term (chronic) aquatic hazard, Category 3  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.
   H412  Harmful to aquatic life with long lasting effects.
   Precautionary statements : Prevention:
                            P201  Obtain special instructions before use.
                            P264  Wash skin thoroughly after handling.
                            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

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.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</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>Amlodipine Besylate</td>
<td>652969-01-2</td>
<td>Acute Tox. 4; H302 Eye Irrit. 2; H319 Aquatic Chronic 2; H411</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

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. 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: None known.

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. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon 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.

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. Take precautionary measures against static discharges. 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

<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>Cellulose</td>
<td>9004-34-6</td>
<td>TWA OEL-RL (Respirable dust)</td>
<td>5 mg/m3</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA OEL-RL (inhalable dust)</td>
<td>10 mg/m3</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL (Dust)</td>
<td>20 mg/m3</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>

Further information: Recommended Limit
8.2 Exposure controls

Engineering measures
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

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
Remarks : Consider double gloving.
Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Flash point : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
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.

9.2 Other information
Flammability (liquids) : No data available
Particle size : 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 : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
10.4 Conditions to avoid

Conditions to avoid: Heat, flames and sparks. 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 toxicological effects

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

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

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

Serious eye damage/eye irritation

Causes serious eye irritation.
Components:

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

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: 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

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
### Reproductive Toxicity - Assessment

**Amlodipine Besylate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Fertility</th>
<th>Developmental Toxicity</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effects on Fertility</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type: Fertility/early embryonic development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>NOAEL: 10 mg/kg body weight</td>
<td>LOAEL: &gt;= 1,6 mg/kg body weight</td>
<td>No effects on fertility</td>
<td></td>
</tr>
<tr>
<td>Test Type: Fertility/early embryonic development</td>
<td>Rabbit</td>
<td>Ingestion</td>
<td>NOAEL: 25 mg/kg body weight</td>
<td></td>
<td>No effects on fertility</td>
<td></td>
</tr>
<tr>
<td><strong>Effects on Foetal Development</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>NOAEL: 10 mg/kg body weight</td>
<td>LOAEL: 10 mg/kg body weight</td>
<td>Effects on foetal development</td>
<td></td>
</tr>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td>Rabbit</td>
<td>Ingestion</td>
<td>NOAEL: 10 mg/kg body weight</td>
<td></td>
<td>No effects on foetal development</td>
<td></td>
</tr>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td>Mouse</td>
<td>Ingestion</td>
<td>NOAEL: 10 mg/kg body weight</td>
<td>LOAEL: 1,6 mg/kg body weight</td>
<td>Effects on foetal development</td>
<td>Maternal toxicity observed.</td>
</tr>
</tbody>
</table>

### STOT - Single Exposure

Not classified based on available information.

### STOT - Repeated Exposure

Not classified based on available information.
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

**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.

Experience with human exposure

**Product:**

**Ingestion**

- Symptoms: Fatigue, Dizziness, Headache, Nausea

**Components:**

**Olmesartan:**

- **Eye contact**
  - Symptoms: Eye irritation
  - **Remarks:** May cause harm to the unborn child.
  - **Based on Human Evidence**

- **Ingestion**
  - Symptoms: Hypotension

**Amlodipine Besylate:**

- **Eye contact**
  - Symptoms: Severe irritation
- **Ingestion**
  - Symptoms: Nausea, Abdominal pain, Fatigue, Headache, Oedema, Palpitation

SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**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
No data available

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 0.1% or higher.

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
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good
SAFETY DATA SHEET
Olmesartan / Amlodipine Besylate Formulation

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 Transport in bulk according to Annex II of Marpol and the IBC Code
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
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.
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
Eye Irrit.: Eye irritation
Repr.: Reproductive toxicity
ZA OEL: South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL: Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL: Short term occupational exposure limits - recommended limit
ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Rail
Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Property</th>
<th>Classification</th>
<th>Calculation procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 1A</td>
<td>H360D</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 3</td>
<td>H412</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

ZA / EN