SAFETY DATA SHEET

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

SECTION 1. IDENTIFICATION

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

Manufacturer or supplier’s details
Company name of supplier: Organon & Co.
Address: 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
Emergency telephone: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

<table>
<thead>
<tr>
<th>Combustible dust</th>
<th>Eye irritation</th>
<th>Reproductive toxicity</th>
<th>Specific target organ toxicity</th>
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<tbody>
<tr>
<td>:</td>
<td>Category 2A</td>
<td>Category 1A</td>
<td>Category 1 (Kidney, Parathyroid gland)</td>
</tr>
</tbody>
</table>

GHS label elements

Signal Word: Danger

Hazard Statements:
- May form combustible dust concentrations in air.
- 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.
- 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.

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
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
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</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Olmesartan</td>
<td>144689-63-4</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Amlodipine Besylate</td>
<td>652969-01-2</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration 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.
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 (CO2)

Dry chemical

Unsuitable extinguishing media: High volume water jet

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

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: Sweep up or vacuum up spillage and collect in suitable
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.
- 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
Cellulose 9004-34-6 TWA 10 mg/m³ ACGIH
TWA (Respirable) 5 mg/m³ NIOSH REL
TWA (total) 10 mg/m³ NIOSH REL
TWA (total dust) 15 mg/m³ OSHA Z-1
TWA (respirable fraction) 5 mg/m³ OSHA Z-1
Starch 9005-25-8 TWA 10 mg/m³ ACGIH
TWA (Respirable) 5 mg/m³ NIOSH REL
TWA (total) 10 mg/m³ NIOSH REL
TWA (total dust) 15 mg/m³ OSHA Z-1
TWA (respirable fraction) 5 mg/m³ OSHA Z-1
Olmesartan 144689-63-4 TWA 30 µg/m³ (OEB 3) Internal
Wipe limit 300 µg/100 cm² Internal
Hydrochlorothiazide 58-93-5 TWA 100 µg/m³ (OEB 2) Internal
Amlodipine Besylate 652969-01-2 TWA 20 µg/m³ (OEB 3) Internal
Wipe limit 100 µg/100 cm² 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:
General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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.

### 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
SAFETY DATA SHEET

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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<td>4944874-00004</td>
<td>10/10/2020</td>
<td>09/30/2019</td>
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</table>

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
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
  Dust can form an explosive mixture in air.
  Can react with strong oxidizing agents.
Conditions to avoid: Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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: > 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
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.
SAFETY DATA SHEET
Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

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 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
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

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
### 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:
- **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

Species: Mouse
Application Route: Oral
Exposure time: 2 Years
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative

IARC: Group 2B: Possibly carcinogenic to humans
Hydrochlorothiazide: 58-93-5

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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 fetal development: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
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 fetal 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.

Developmental Toxicity: LOAEL: >= 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.

Effect 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.

Effect on fetal development: 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.
Effects on fetal development:

Test Type: Embryofetal development
Species: Rat
Application Route: Ingestion
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Effects on fetal development.

Test Type: Embryofetal development
Species: Rabbit
Application Route: Ingestion
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: No effects on fetal development.

Test Type: Embryofetal development
Species: Mouse
Application Route: Ingestion
Developmental Toxicity: LOAEL: 1.6 mg/kg body weight
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: >= 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Starch:

Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 28 Days
Method: OECD Test Guideline 410

**Olmesartan:**
- Species: Rat
- NOAEL: 2,000 mg/kg
- Application Route: Oral
- Exposure time: 24 Months
- Remarks: No significant adverse effects were reported

**Hydrochlorothiazide:**
- Species: Rat, male and female
- LOAEL: 10 mg/kg
- Application Route: Oral
- Exposure time: 2 y
- Target Organs: Kidney, Parathyroid gland
- Remarks: No significant adverse effects were reported

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

**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
  - 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 aquatic invertebrates**
  - EC50 (Daphnia magna (Water flea)): 3.2 mg/l
  - Exposure time: 48 h
- **Toxicity to algae/aquatic plants**
  - IC50 (Pseudokirchneriella subcapitata (green algae)): 5.6 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

#### Persistence and degradability

**Components:**

**Cellulose:**
- **Biodegradability**
  - Result: Readily biodegradable.

**Hydrochlorothiazide:**
- **Stability in water**
  - Hydrolysis: 46.2 % (96 h)
Bioaccumulative potential

Components:

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

Mobility in soil
No data available

Other adverse effects
No data available

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.

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.
SAFETY DATA SHEET

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

SARA 311/312 Hazards:
- Combustible dust
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)
- Serious eye damage or eye irritation

SARA 313:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
</tr>
<tr>
<td>Olmesartan</td>
<td>144689-63-4</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
</tr>
<tr>
<td>Amlodipine Besylate</td>
<td>652969-01-2</td>
</tr>
</tbody>
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California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Permissible Exposure Limit</th>
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<tbody>
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<td>9004-34-6</td>
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<tr>
<td>Starch</td>
<td>9005-25-8</td>
</tr>
</tbody>
</table>

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

Version 2.0 Revision Date: 04/09/2021 SDS Number: 4944874-00004 Date of last issue: 10/10/2020 Date of first issue: 09/30/2019

NFPA 704:

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<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
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HMIS® IV:

<table>
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<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
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</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA: 8-hour, time-weighted average
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; IECS - 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; KECL - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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 sub-

Revision Date: 04/09/2021

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

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