SAFETY DATA SHEET

Olmesartan / Amlodipine Besylate Formulation

Version 5.4  Revision Date: 10/10/2020  SDS Number: 402656-00012  Date of last issue: 03/23/2020  Date of first issue: 01/07/2016

SECTION 1. IDENTIFICATION

Product name: Olmesartan / Amlodipine Besylate Formulation

Manufacturer or supplier’s details

Company name of supplier: Organon & Co.
Address: 30 Hudson Street, 33rd 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)

Combustible dust

Eye irritation: Category 2A
Carcinogenicity (Inhalation): Category 2
Reproductive toxicity: Category 1A

GHS label elements

Hazard pictograms:

Signal Word: Danger

Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H319 Causes serious eye irritation.
H351 Suspected of causing cancer if inhaled.
H360D May damage the unborn child.

Precautionary Statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P264 Wash skin thoroughly after handling.
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 

Substance / Mixture : Mixture 

Components 

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</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>Amlodipine Besylate</td>
<td>652969-01-2</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 0.1 - &lt; 1</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 : Causes serious eye irritation. 
Suspected of causing cancer if inhaled. 
May damage the unborn child. 
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: None known.

Specific hazards during fire fighting: 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

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 spills cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding 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. 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.

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<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>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>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA (total)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
</tbody>
</table>
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

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

Remarks: Consider double gloving.

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. 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.

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.
SAFETY DATA SHEET
Olmesartan / Amlodipine Besylate Formulation

Appearance : powder
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 : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
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) : No data available
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity : Not applicable
Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

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SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks. 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: 3,354 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

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

Titanium dioxide:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:

Olmesartan:
Remarks : No data available

Titanium dioxide:
Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

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

Amlodipine Besylate:
Species : Rabbit
Result : Severe irritation

Titanium dioxide:
Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.
Components:

Olmesartan:
- Routes of exposure: Skin contact
- Remarks: No data available

Titanium dioxide:
- Test Type: Local lymph node assay (LLNA)
- Routes of exposure: Skin contact
- Species: Mouse
- Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:
- 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

- 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.
### Amlodipine Besylate:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

### Titanium dioxide:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: In vivo micronucleus test</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

**Carcinogenicity**

Suspected of causing cancer if inhaled.

**Components:**

### Cellulose:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Olmesartan:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Amlodipine Besylate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Titanium dioxide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
</tbody>
</table>
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in inhalation studies with animals.

IARC
Group 2B: Possibly carcinogenic to humans
Titanium dioxide 13463-67-7

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.

Test Type: Development
Species: Rat
Application Route: Oral
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.

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: 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: 25 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
Result: Effects on fetal development.
Remarks: Maternal toxicity observed.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Cellulose:
Species: Rat
SAFETY DATA SHEET

Olmesartan / Amlodipine Besylate Formulation

NOAEL: 
Application Route: Ingestion 
Exposure time: 90 Days

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

Titanium dioxide:
Species: Rat 
NOAEL: 24,000 mg/kg 
Application Route: Ingestion 
Exposure time: 28 Days

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
Ingestion: Symptoms: hypotension 
Remarks: May cause harm to the unborn child. 
Based on Human Evidence

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

**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

**Titanium dioxide:**
- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
- Toxicity to algae/aquatic plants: EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
  - Exposure time: 72 h
- Toxicity to microorganisms: EC50: > 1,000 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209

#### Persistence and degradability

**Components:**

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

**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.

SARA 311/312 Hazards : Combustible dust
Carcinogenicity
Reproductive toxicity
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>Ingredient</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Olmesartan</td>
<td>144689-63-4</td>
</tr>
<tr>
<td>Amlodipine Besylate</td>
<td>652969-01-2</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
</tr>
</tbody>
</table>

California Prop. 65
WARNING: This product can expose you to chemicals including Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>PEL Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</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

**NFPA 704:**

- **Flammability:** 0
- **Health:** 2
- **Instability:** 0

**HMIS® IV:**

- **HEALTH:** *
- **FLAMMABILITY:** 3
- **PHYSICAL HAZARD:** 0

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
SAFETY DATA SHEET

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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

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