1. PRODUCT AND COMPANY IDENTIFICATION

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

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

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

2. HAZARDS IDENTIFICATION

Emergency Overview

| Appearance | tablet |
| Colour     | No data available |
| Odour      | No data available |

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

GHS Classification

Serious eye damage/eye irritation : Category 2A
Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure : Category 2
Short-term (acute) aquatic hazard : Category 3
Long-term (chronic) aquatic hazard : Category 3

GHS label elements
Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

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.
- H412 Harmful to aquatic life with long lasting effects.

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.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ 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 advice/ attention.
- P337 + P313 IF eye irritation persists: Get medical advice/ attention.

**Storage:**
- P405 Store locked up.

**Disposal:**
- P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.

Health hazards
Causes serious eye irritation. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards
Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

Other hazards which do not result in classification
- May form explosible dust-air mixture if dispersed.
- Contact with dust can cause mechanical irritation or drying of the skin.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Starch</td>
</tr>
<tr>
<td></td>
<td>Olmesartan</td>
</tr>
<tr>
<td></td>
<td>Hydrochlorothiazide</td>
</tr>
<tr>
<td></td>
<td>Amlodipine Besylate</td>
</tr>
</tbody>
</table>

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. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: 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.

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical
### Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

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</tr>
</tbody>
</table>

#### 4.1.1.4 Unsuitable extinguishing media
High volume water jet

#### 4.1.1.5 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.

#### 4.1.1.6 Hazardous combustion products
- Carbon oxides
- Nitrogen oxides (NOx)
- Chlorine compounds
- Sulphur oxides

#### 4.1.1.7 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.

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

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 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).

#### 6.2.2 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.

#### 6.3.3 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.

### 7. HANDLING AND STORAGE

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

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.

Avoidance of contact: Oxidizing agents

Storage:
- Conditions for safe storage: Keep in properly labelled 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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>PC-TWA</td>
<td>10 mg/m³</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</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>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>

Engineering measures: Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### Personal protective equipment

**Respiratory protection**
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - **Filter type**: Particulates type
  - **Eye/face 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.

**Hand protection**
- Material: Chemical-resistant gloves

**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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>tablet</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>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

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</table>

### Flammability (liquids)
- No data available

### 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.

### Molecular weight
- No data available

### Particle size
- No data available

### 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.

### Toxicoological Information

- **Exposure routes**: 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**:
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Omesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

Acute oral toxicity: LD50 (Rat): 393 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Olmesartan:

Remarks: No data available

Hydrochlorothiazide:

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Starch:

Species: Rabbit
Result: No eye irritation

Olmesartan:

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

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:

Starch:

Test Type: Maximisation Test
Exposure routes: Skin contact
### Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

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</tr>
</tbody>
</table>

**Species**: Guinea pig

**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

**Genotoxicity in vivo**
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative

**Starch**:

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

**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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

Assessment

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:

Cellulose:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 72 weeks
- Result: negative
Olmesartan:  
Species: Rat  
Application Route: Oral  
Exposure time: 2 Years  
Result: negative

Species: Mouse  
Application Route: Oral  
Exposure time: 6 Months  
Result: negative

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

Species: Mouse, male  
Application Route: Oral  
Exposure time: 2 Years  
Result: equivocal

Species: Rat, male and female  
Application Route: Oral  
Exposure time: 2 Years  
Result: negative

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

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

Reproductive toxicity:  
May damage the unborn child.

Components:

Cellulose:  
Effects on fertility: Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development: Test Type: Fertility/early embryonic development  
Species: Rat
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

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 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

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.

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

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 foetal development:
Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 3,000 mg/kg body weight
Result: No teratogenic effects
Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Result: No teratogenic effects

**Amlodipine Besylate:**

**Effects on fertility:**
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Ingestion
- Fertility: NOAEL: 10 mg/kg body weight
- Result: No effects on fertility

- Test Type: Fertility/early embryonic development
  - Species: Rabbit
  - Application Route: Ingestion
  - Fertility: NOAEL: 25 mg/kg body weight
  - Result: No effects on fertility

**Effects on foetal development:**
- Test Type: Embryo-foetal development
  - 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.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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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 yr |
| Target Organs | Kidney, Parathyroid gland |

| Species | Mouse, male and female |
| NOAEL | 300 - 550 mg/kg |
| Application Route | Oral |
| 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

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

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

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

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.

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.

National Regulations

GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

16. OTHER INFORMATION

Further information

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

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
ACGIH / TWA : 8-hour, time-weighted average
CN OEL / PC-TWA : Permissible concentration - time weighted average

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-
Disclaimer

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.