SAFETY DATA SHEET

Olmesartan / Amlodipine Besylate (3.5%) / Hydrochlorothiazide Formulation

Version 2.0  Revision Date: 09.04.2021  SDS Number: 4944868-00004  Date of last issue: 10.10.2020

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

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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

GHS label elements
Hazard pictograms: 
Signal word: Danger
Hazard statements:

- H319 Causes serious eye irritation.
- H360D May damage the unborn child.
- H373 May cause damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.
- H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
- P203 Obtain, read and follow all safety instructions before use.
- 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.
- P318 IF exposed or concerned, get medical advice.
- P337 + P317 If eye irritation persists: Get medical help.

Storage:
- P405 Store locked up.

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

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

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Starch</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Olmesartan</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Amlodipine Besylate</td>
<td>&gt;= 2.5 - &lt; 5</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.
### 5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media:</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO₂)</td>
</tr>
<tr>
<td>Unsuitable extinguishing media:</td>
<td>High volume water jet</td>
</tr>
<tr>
<td>Specific hazards during firefighting:</td>
<td>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.</td>
</tr>
<tr>
<td>Hazardous combustion products:</td>
<td>Carbon oxides</td>
</tr>
<tr>
<td></td>
<td>Nitrogen oxides (NOₓ)</td>
</tr>
<tr>
<td></td>
<td>Chlorine compounds</td>
</tr>
<tr>
<td></td>
<td>Sulphur oxides</td>
</tr>
<tr>
<td>Specific extinguishing methods:</td>
<td>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.</td>
</tr>
<tr>
<td>Special protective equipment for firefighters:</td>
<td>In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.</td>
</tr>
</tbody>
</table>
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 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

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 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

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>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
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

Hygiene measures: Work uniform or laboratory coat.
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>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
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.

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.

**Components:**

**Starch:**
Species: Rabbit
Result: No eye irritation

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

**Hydrochlorothiazide:**
Species: Rabbit
Result: Mild eye irritation
**SAFETY DATA SHEET**

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

**Version** 2.0  
**Revision Date:** 09.04.2021  
**SDS Number:** 4944868-00004  
**Date of last issue:** 10.10.2020  
**Date of first issue:** 30.09.2019

---

**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  
- **Species:** Guinea pig  
- **Result:** negative

**Olmesartan:**
- **Exposure routes:** 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

- **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
| 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 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 |
| | 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

**Hydrochlorothiazide:**

| Effects on fertility | Test Type: Fertility |
| | Species: Rat, male and female |
| | Application Route: oral (feed) |

Reproductive toxicity - Assessment: Positive evidence of adverse effects on development from human epidemiological studies.
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 (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: \( \geq 9,000 \text{ mg/kg} \)
- Application Route: Ingestion
- Exposure time: 90 Days

Starch:
- Species: Rat
- NOAEL: \( \geq 2,000 \text{ mg/kg} \)
- Application Route: Skin contact
- Exposure time: 28 Days
- Method: OECD Test Guideline 410

Olmesartan:
- Species: Rat
- NOAEL: \( 2,000 \text{ mg/kg} \)
- 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

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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA: 8-hour, 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; EnS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with
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.