SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Losartan / Amlodipine Besylate Formulation

Manufacturer or supplier’s details
Company name of supplier: Organon & Co.
Address: Avenida 16 de Septiembre No. 301 Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
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
Serious eye damage: Category 1
Skin sensitization: Category 1
Carcinogenicity (Inhalation): Category 2
Reproductive toxicity: Category 1B

Effects on or via lactation
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Blood, Cardio-vascular system, Stomach, Kidney)

GHS label elements
Hazard pictograms:

Signal Word: Danger

Hazard Statements:
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H351 Suspected of causing cancer if inhaled.
H360D May damage the unborn child.
H362 May cause harm to breast-fed children.
H373 May cause damage to organs (Blood, Cardio-vascular system, Stomach, Kidney) through prolonged or repeated exposure if swallowed.

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.
P263 Avoid contact during pregnancy and while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

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

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<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;= 50 &lt; 70</td>
</tr>
<tr>
<td>Losartan</td>
<td>124750-99-8</td>
<td>&gt;= 10 &lt; 20</td>
</tr>
<tr>
<td>Amlodipine Besylate</td>
<td>652969-01-2</td>
<td>&gt;= 1 &lt; 5</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 0.1 &lt; 1</td>
</tr>
</tbody>
</table>

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 immediately.

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:
May cause an allergic skin reaction.
Causes serious eye damage.
Suspected of causing cancer if inhaled.
May damage the unborn child.
May cause harm to breast-fed children.
May cause damage to organs through prolonged or repeated exposure if swallowed.
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
Chlorine compounds
Nitrogen oxides (NOx)
Metal 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:
Use personal protective equipment.
tive equipment and emergency procedures

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.

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

Avoid contact during pregnancy and while nursing.
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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures

If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.

**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>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Losartan</td>
<td>124750-99-8</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>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**Engineering measures:**
- Minimize workplace exposure concentrations.
- Apply measures to prevent dust explosions.
- Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

**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:**
- Chemical-resistant gloves

**Remarks:**
- Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before
Eye protection: Wear the following personal protective equipment:
Chemical resistant goggles must be worn.
If splashes are likely to occur, wear:
Face-shield

Skin and body protection: Select appropriate protective clothing based on chemical
resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective
clothing (gloves, aprons, boots, etc).

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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: No data available
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: No data available
Relative vapor density: No data available
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-
octanol/water
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
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
  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: > 5,000 mg/kg
  Method: Expert judgment

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
- Losartan: $\text{LD}_50$ (Rabbit) $> 2,000 \text{ mg/kg}$
- Amlodipine Besylate: $\text{LD}_50$ (Rabbit) $> 5,000 \text{ mg/kg}$

### Acute oral toxicity
- **Losartan**:
  - $\text{LD}_50$ (Mouse): $1,257 - 1,590 \text{ mg/kg}$
  - $\text{LD}_{Lo}$ (Rat): $200 \text{ mg/kg}$
  - $\text{LD}_{Lo}$ (Mouse): $400 \text{ mg/kg}$
- **Amlodipine Besylate**:
  - $\text{LD}_50$ (Rat): $393 \text{ mg/kg}$

### Acute inhalation toxicity
- **Titanium dioxide**:
  - $\text{LC}_50$ (Rat): $> 6.82 \text{ mg/l}$
    - 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

#### Losartan:
- **Species**: Rabbit
- **Result**: Mild skin irritation

#### Titanium dioxide:
- **Species**: Rabbit
- **Result**: No skin irritation

### Serious eye damage/eye irritation
Causes serious eye damage.

### Components

#### Losartan:
- **Species**: Rabbit
- **Result**: Severe irritation

#### Amlodipine Besylate:
- **Species**: Rabbit
- **Result**: Severe irritation

#### Titanium dioxide:
- **Species**: Rabbit
<table>
<thead>
<tr>
<th>Components</th>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Assessment</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Losartan</strong></td>
<td>Maximization Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>Probability or evidence of skin sensitization in humans</td>
<td>positive</td>
</tr>
<tr>
<td><strong>Titanium dioxide</strong></td>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
<td>Mouse</td>
<td></td>
<td>negative</td>
</tr>
<tr>
<td><strong>Cellulose</strong></td>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>Ingestion</td>
<td>Mouse</td>
<td></td>
<td>negative</td>
</tr>
<tr>
<td><strong>Losartan</strong></td>
<td>In vitro mammalian cell gene mutation test</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chinese hamster ovary cells</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alkaline elution assay</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Result:**
- No eye irritation
- Respiratory or skin sensitization
- Skin sensitization
  - May cause an allergic skin reaction.
- Respiratory sensitization
  - Not classified based on available information.

**Germ cell mutagenicity**
- Not classified based on available information.
Test Type: Chromosomal aberration  
Result: negative

Genotoxicity in vivo  :  Test Type: Chromosomal aberration  
Result: negative

**Amlodipine Besylate:**  
Genotoxicity in vitro  :  Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Test Type: Chromosome aberration test in vitro  
Result: negative

**Titanium dioxide:**  
Genotoxicity in vitro  :  Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Genotoxicity in vivo  :  Test Type: In vivo micronucleus test  
Species: Mouse  
Result: negative

**Carcinogenicity**  
Suspected of causing cancer if inhaled.

**Components:**

**Cellulose:**  
Species  :  Rat  
Application Route  :  Ingestion  
Exposure time  :  72 weeks  
Result  :  negative

**Losartan:**  
Species  :  Mouse  
Application Route  :  Oral  
Exposure time  :  92 weeks  
Dose  :  200 mg/kg body weight  
Result  :  negative

Species  :  Rat  
Application Route  :  Oral  
Exposure time  :  105 weeks  
Dose  :  270 mg/kg body weight  
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

Titanium dioxide:
Species: Rat
Application Route: inhalation (dust/mist/fume)
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.

Reproductive toxicity
May damage the unborn child.
May cause harm to breast-fed children.

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

Losartan:
Effects on fertility: Test Type: Fertility
Species: Rat, female
Application Route: Oral
Fertility: LOAEL: 200 mg/kg body weight
Result: female reproductive effects
Remarks: Maternal toxicity observed.

Effects on fetal development: Test Type: Development
Species: Rabbit
Application Route: Oral
General Toxicity Maternal: NOAEL: 10 mg/kg body weight
Developmental Toxicity: NOAEL F1: 20 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects.

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Fetotoxicity, No teratogenic effects.

Reproductive toxicity - Assessment:

Clear evidence of adverse effects on development, based on animal experiments.

Studies indicating a hazard to babies during the lactation period

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 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: 10 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
May cause damage to organs (Blood, Cardio-vascular system, Stomach, Kidney) through prolonged or repeated exposure if swallowed.

Components:

Losartan:
Routes of exposure: Ingestion
Target Organs: Blood, Cardio-vascular system, Stomach, Kidney
### Assessment
May cause 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

**Losartan:**
- **Species:** Rat
- **LOAEL:** 15 mg/kg
- **Application Route:** Oral
- **Exposure time:** 309 d
- **Number of exposures:** daily
- **Target Organs:** Blood, Kidney, Cardio-vascular system, Stomach

**Species:** Dog
- **NOAEL:** 5 mg/kg
- **Application Route:** Oral
- **Exposure time:** 1 Months
- **Symptoms:** Salivation, Vomiting

**Species:** Dog
- **LOAEL:** 25 mg/kg
- **Application Route:** Oral
- **Exposure time:** 53 Weeks
- **Number of exposures:** daily
- **Symptoms:** Salivation, Vomiting

**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

**Species:** Rat
- **NOAEL:** 10 mg/m³
- **Application Route:** inhalation (dust/mist/fume)
- **Exposure time:** 2 y
Aspiration toxicity
Not classified based on available information.

Components:

Losartan:
No aspiration toxicity classification

Experience with human exposure

Components:

Losartan:
Eye contact: Symptoms: Eye irritation
Ingestion: Symptoms: hypotension, tachycardia

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

Losartan:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 929 mg/l
Exposure time: 96 h
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 331 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: NOEC (Microcystis aeruginosa (blue-green algae)): 949 mg/l
Exposure time: 10 d
Method: FDA 4.01

NOEC (Selenastrum capricornutum (green algae)): 143 mg/l
Exposure time: 10 d
Method: FDA 4.01

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 10 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 100 mg/l
aquatic invertebrates (Chronic toxicity)  |  Exposure time: 21 d  
|  Method: OECD Test Guideline 211

**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.

**Losartan:**

Stability in water  
Hydrolysis: < 10 % (5 d)

**Bioaccumulative potential**

**Components:**

**Losartan:**

Partition coefficient: n-octanol/water  
log Pow: 1.2

**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
NOM-002-SCT
Not regulated as a dangerous good
Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.
Not applicable

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit value

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 System; GLP - Good Laboratory Practice; 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; IECSC - Inventory of Existing Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transport of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System


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The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.