# SAFETY DATA SHEET

## Losartan / Hydrochlorothiazide Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

**Product name**: Losartan / Hydrochlorothiazide Formulation

**Manufacturer or supplier’s details**

- **Company name of supplier**: MSD
- **Address**: Avenida 16 de Septiembre No. 301, Xaltocan - Xochimilco Mexico 16090
- **Telephone**: 52 55 57284444
- **Telefax**: 908-735-1496
- **Emergency telephone**: 1-908-423-6000
- **E-mail address**: EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

- **Recommended use**: Pharmaceutical

## SECTION 2. HAZARDS IDENTIFICATION

**GHS Classification**

- **Acute toxicity (Oral)**: Category 5
- **Serious eye damage**: Category 1
- **Skin sensitization**: Category 1
- **Reproductive toxicity**: Category 1B

**Effects on or via lactation**

- **Specific target organ toxicity - repeated exposure**: Category 1 (Kidney, Parathyroid gland)
- **Specific target organ toxicity - repeated exposure (Oral)**: Category 2 (Blood, Cardio-vascular system, Stomach, Kidney)

**GHS label elements**

- **Hazard pictograms**: ![Hazard Pictogram](image)
- **Signal Word**: Danger

**Hazard Statements**

- H303 May be harmful if swallowed.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H360D May damage the unborn child.
- H362 May cause harm to breast-fed children.
- H372 Causes damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.
- 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.
P312 Call a POISON CENTER or doctor/ physician if you feel unwell.
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 disposal 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>Components</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>Losartan</td>
<td>124750-99-8</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>&gt;= 1 - &lt; 5</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 be harmful if swallowed.
May cause an allergic skin reaction.
Causes serious eye damage.
May damage the unborn child.
May cause harm to breast-fed children.
Causes damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin.

Protection of first-aiders

: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician

: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media

: None known.

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.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products

: Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)
Chlorine compounds
Sulfur oxides

Specific extinguishing methods

: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do
Section 6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided.
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:
Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
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.

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.

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>Starch</td>
<td>9005-25-8</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
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<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</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>
</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**:
- Chemical-resistant gloves

**Eye protection**:
- Wear safety glasses with side shields or goggles.
- If the work environment or activity involves dusty conditions,
mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Color</td>
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</tr>
<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
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</tr>
<tr>
<td>Initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</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>Vapor pressure</td>
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<tr>
<td>Relative vapor density</td>
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<tr>
<td>Relative density</td>
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<tr>
<td>Density</td>
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<tr>
<td>Solubility (ies)</td>
<td>Water solubility: No data available</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
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<tr>
<td>Autoignition 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>
</tbody>
</table>
Viscosity, kinematic: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
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:
May be harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 2,273 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

Losartan:
Acute oral toxicity: LD50 (Mouse): 1,257 - 1,590 mg/kg
LDLo (Rat): 200 mg/kg
LDLo (Mouse): 400 mg/kg

**Starch:**
Acute oral toxicity  :  LD50 (Mouse): > 5,000 mg/kg

**Hydrochlorothiazide:**
Acute oral toxicity  :  LD50 (Rat): 10,000 mg/kg
LD50 (Mouse): 10,000 mg/kg
Acute toxicity (other routes of administration)  :  LD50 (Rat): 990 mg/kg
Application Route: Intravenous
LD50 (Dog): 250 mg/kg
Application Route: Intravenous

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

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

**Hydrochlorothiazide:**
Species  :  Rabbit
Result  :  No skin irritation

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

**Components:**

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

**Hydrochlorothiazide:**
Species  :  Rabbit
Result  :  Mild eye irritation

**Respiratory or skin sensitization**

**Skin sensitization**
May cause an allergic skin reaction.

**Respiratory sensitization**
Not classified based on available information.
Components:

Losartan:

Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Assessment: Probability or evidence of skin sensitization in humans
Result: positive

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

Losartan:

Genotoxicity in vitro:
Test Type: in vitro test
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Result: negative
Test Type: Alkaline elution assay
Result: negative
Test Type: Chromosomal aberration
Result: negative

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

Hydrochlorothiazide:

Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative
Test Type: sister chromatid exchange assay
Test system: Chinese hamster ovary cells  
Result: positive

Test Type: in vitro test  
Test system: mouse lymphoma cells  
Result: positive

Genotoxicity in vivo  
Test Type: Chromosomal aberration  
Species: Chinese hamster  
Cell type: Bone marrow  
Result: negative

Species: Mouse  
Cell type: Bone marrow  
Result: negative

Germ cell mutagenicity  
Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity  
Not classified based on available information.

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

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

**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

**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 fetal 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.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Causes damage to organs (Kidney, Parathyroid gland) through prolonged or 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.

Hydrochlorothiazide:
Target Organs: Kidney, Parathyroid gland
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity
Components:

Cellulose:
Species: Rat
NOAEL: >= 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
## Losartan:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>15 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>309 d</td>
</tr>
<tr>
<td>Number of exposures</td>
<td>daily</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Kidney, Cardio-vascular system, Stomach</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 Months</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Salivation, Vomiting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>25 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>53 Weeks</td>
</tr>
<tr>
<td>Number of exposures</td>
<td>daily</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Salivation, Vomiting</td>
</tr>
</tbody>
</table>

## Hydrochlorothiazide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male and female</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 y</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney, Parathyroid gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse, male and female</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>300 - 550 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 y</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

## Aspiration toxicity

Not classified based on available information.

## Components:

### Losartan:

No aspiration toxicity classification

### Hydrochlorothiazide:

No aspiration toxicity classification
Experience with human exposure

Components:

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

Hydrochlorothiazide:
- Eye contact: Symptoms: Eye irritation
- Ingestion: Symptoms: Dizziness, Headache, Fatigue, Nausea, Abdominal pain, hypotension, dry mouth, electrolyte imbalance, eye pain

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

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

Persistence and degradability

Components:

Cellulose:
Biodegradability: Result: Readily biodegradable.

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

Hydrochlorothiazide:
Stability in water: Hydrolysis: 46.2 % (96 h)

Bioaccumulative potential

Components:

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

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.
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.

Special precautions for user

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

AICS - Australian Inventory of Chemical Substances; 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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect

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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.

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