SAFETY DATA SHEET
Losartan / Hydrochlorothiazide Formulation

SECTION 1. IDENTIFICATION

Product name : Losartan / Hydrochlorothiazide Formulation
Other means of identification : No data available

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

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
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 :

Signal Word : Danger
Hazard Statements :
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.
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 and 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.
- P308 + P313 IF exposed or concerned: Get medical attention.
- P333 + P313 If skin irritation or rash occurs: Get medical attention.
- P362 + P364 Take off contaminated clothing and wash it before reuse.

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

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

### Other hazards
Contact with dust can cause mechanical irritation or drying of the skin.
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>Mixture</th>
</tr>
</thead>
</table>

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 60 *</td>
</tr>
<tr>
<td>Losartan</td>
<td>No data available</td>
<td>124750-99-8</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Starch</td>
<td>Sago starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>No data available</td>
<td>58-93-5</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret
SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention 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. 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 method: Use extinguishing measures that are appropriate to local cir-
SAFETY DATA SHEET

Losartan / Hydrochlorothiazide Formulation

Version 6.5  Revision Date: 04/09/2021  SDS Number: 17054-00017  Date of last issue: 10/16/2020  Date of first issue: 09/30/2014

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ods

Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant 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.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</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>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</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.
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. 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: yellow
Odor: odorless
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor density: Not applicable
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Autoignition 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.
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: 2,201 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 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

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

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

Starch:
Species: Rabbit
Result: No eye 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

Starch:
Test Type: Maximization Test
Routes of exposure: Skin contact
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
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:**

<table>
<thead>
<tr>
<th>Genotoxicity category</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>in vitro</td>
<td>in vitro test</td>
<td>negative</td>
</tr>
<tr>
<td>in vitro mammalian cell gene mutation test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test system: Chinese hamster ovary cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alkaline elution assay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Starch:**

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

**Hydrochlorothiazide:**

<table>
<thead>
<tr>
<th>Genotoxicity category</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>in vitro</td>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test system: Chinese hamster ovary cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>sister chromatid exchange assay</td>
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<td>Test system: Chinese hamster ovary cells</td>
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<tr>
<td>Result: positive</td>
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<tr>
<td>in vitro test</td>
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</tr>
<tr>
<td>Test system: mouse lymphoma cells</td>
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<td></td>
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<tr>
<td>Result: positive</td>
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</table>

<table>
<thead>
<tr>
<th>Genotoxicity category</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>in vivo</td>
<td>Chromosomal aberration</td>
<td></td>
</tr>
<tr>
<td>Species: Chinese hamster</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cell type: Bone marrow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Germ cell mutagenicity -</th>
<th>Weight of evidence does not support classification as a germ</th>
</tr>
</thead>
</table>
Assessment 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.

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.
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: \( \geq 9,000 \text{ mg/kg} \)
- 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

Starch:
Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 28 Days
Method: OECD Test Guideline 410

Hydrochlorothiazide:
Species: Rat, male and female
LOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 2 y
Target Organs: Kidney, Parathyroid gland

Species: Mouse, male and female
NOAEL: 300 - 550 mg/kg
Application Route: Oral
Exposure time: 2 y
Remarks: No significant adverse effects were reported

Species: Dog
Application Route: Oral
Exposure time: 9 Months
Target Organs: Parathyroid gland

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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
</tr>
</thead>
</table>
| **Cellulose:** | : | : | : | : | :
| Toxicity to fish | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials |
| 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 |
| 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 aquatic invertebrates (Chronic toxicity) | NOEC (Daphnia magna (Water flea)): 100 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 |
| **Losartan:** | : | : | : | : | :
| Toxicity to fish | LC50 (Oncorhyncus 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 |
| 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 aquatic invertebrates (Chronic toxicity) | NOEC (Daphnia magna (Water flea)): 100 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 |
| **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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Biodegradability</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cellulose:</strong></td>
<td>Result: Readily biodegradable.</td>
</tr>
<tr>
<td><strong>Losartan:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Hydrochlorothiazide:</strong></td>
<td></td>
</tr>
</tbody>
</table>
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.

Domestic regulation

TDG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS : not determined
SAFETY DATA SHEET
Losartan / Hydrochlorothiazide Formulation

Version 6.5
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DSL: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL: Canada. British Columbia OEL
CA QC OEL: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA: 8-hour, time-weighted average
CA AB OEL / TWA: 8-hour Occupational exposure limit
CA BC OEL / TWA: 8-hour time weighted average
CA QC OEL / TWAEV: Time-weighted average exposure value

AIIC - 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 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 Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of 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 - Transportation 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

Sources of key data used to: Internal technical data, data from raw material SDSs, OECD

Revision Date : 04/09/2021
Date format : mm/dd/yyyy

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.

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