1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Losartan / Hydrochlorothiazide Formulation

Manufacturer or supplier’s details

Company: MSD
Address: 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance: powder
Colour: yellow
Odour: odourless

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. May cause damage to organs through prolonged or repeated exposure.

GHS Classification

Acute toxicity (Oral): Category 5
Serious eye damage/eye irritation: Category 1
Skin sensitisation: Category 1
Reproductive toxicity: Category 1B

Effects on or via lactation
Specific target organ toxicity - repeated exposure: Category 2

GHS label elements
Hazard pictograms:
Losartan / Hydrochlorothiazide Formulation

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.
H373 May cause damage to organs through prolonged or repeated exposure.

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/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/doctor.
P312 Call a POISON CENTER/doctor if you feel unwell.
P333 + P331 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.

Physical and chemical hazards
Not classified based on available information.

Health hazards
May be harmful if swallowed. Causes serious eye damage. May cause an allergic skin reaction.
May damage the unborn child. May cause harm to breast-fed children. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards
Not classified based on available information.
Other hazards which do not result in classification
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

4. FIRST AID MEASURES

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

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

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

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
 If easy to do, remove contact lens, if worn.
 Get medical attention 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.
May cause damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin.

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

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

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)
Chlorine compounds
Sulphur 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 firefighters:
In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.
7. HANDLING AND STORAGE

Handling
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.
Avoidance of contact: Oxidizing agents

Storage
Conditions for safe storage: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types: Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PC-TWA</td>
<td>10 mg/m³</td>
<td>GBZ 2.1-2007</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>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

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

**Skin and body protection**: Work uniform or laboratory coat.

**Hand protection**

**Material**: Chemical-resistant gloves

**Hygiene measures**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: powder

**Colour**: yellow

**Odour**: odourless

**Odour 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.
**Losartan / Hydrochlorothiazide Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date: 09/13/2019</th>
<th>SDS Number: 17060-00014</th>
<th>Date of last issue: 2019/04/24</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>No data available</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>Not applicable</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>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**10. STABILITY AND REACTIVITY**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks. Avoid dust formation.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

**11. TOXICOLOGICAL INFORMATION**

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td></td>
</tr>
<tr>
<td>Skin contact</td>
<td></td>
</tr>
</tbody>
</table>
Losartan / Hydrochlorothiazide Formulation

**Ingestion**
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
Losartan / Hydrochlorothiazide Formulation

**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 sensitisation**

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

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Losartan:**
Test Type: Maximisation Test  
Exposure routes: Skin contact  
Species: Guinea pig  
Assessment: Probability or evidence of skin sensitisation 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
<table>
<thead>
<tr>
<th>Losartan:</th>
<th>Hydrochlorothiazide:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro: Test Type: in vitro assay</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
</tr>
<tr>
<td>Result: negative</td>
<td>Result: negative</td>
</tr>
<tr>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>Test Type: Chromosomal aberration</td>
</tr>
<tr>
<td>Test system: Chinese hamster ovary cells</td>
<td>Test system: Chinese hamster ovary cells</td>
</tr>
<tr>
<td>Result: negative</td>
<td>Result: negative</td>
</tr>
<tr>
<td>Test Type: Alkaline elution assay</td>
<td>Test Type: sister chromatid exchange assay</td>
</tr>
<tr>
<td>Result: negative</td>
<td>Test system: Chinese hamster ovary cells</td>
</tr>
<tr>
<td>Test Type: Chromosomal aberration</td>
<td>Result: positive</td>
</tr>
<tr>
<td>Result: negative</td>
<td>Test Type: in vitro assay</td>
</tr>
<tr>
<td>Test system: mouse lymphoma cells</td>
<td>Test system: mouse lymphoma cells</td>
</tr>
<tr>
<td>Result: positive</td>
<td>Result: positive</td>
</tr>
<tr>
<td>Genotoxicity in vivo: Test Type: Chromosomal aberration</td>
<td>Germ cell mutagenicity - Assessment</td>
</tr>
<tr>
<td>Species: Chinese hamster</td>
<td>Weight of evidence does not support classification as a germ cell mutagen.</td>
</tr>
<tr>
<td>Cell type: Bone marrow</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td>Test Type: in vivo assay</td>
<td>Cateness of Information - Classification</td>
</tr>
<tr>
<td>Species: Mouse</td>
<td>Not classified based on available information.</td>
</tr>
<tr>
<td>Cell type: Bone marrow</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

**Components:**

**Cellulose:**
Species: Rat
Losartan / Hydrochlorothiazide Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>72 weeks</td>
<td>negative</td>
</tr>
</tbody>
</table>

**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 foetal development**
  - Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

**Losartan:**

- **Species:**
- **Application Route:**
- **Exposure time:**
- **Dose:**
- **Result:**
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 foetal development: Test Type: Development
Species: Rat
Application Route: Oral
Development: 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: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 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 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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Losartan / Hydrochlorothiazide Formulation

Version: 4.6
Revision Date: 09/13/2019
SDS Number: 17060-00014
Date of last issue: 2019/04/24
Date of first issue: 2014/09/30

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Losartan:
- Exposure routes: 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:
- 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
- NOAEL: 25 mg/kg
- Application Route: Oral
- Exposure time: 53 Weeks
- Number of exposures: daily
- Symptoms: Salivation, Vomiting

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  

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  

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 / Hydrochlorothiazide Formulation

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 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:

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-
log Pow: 1.2
Losartan / Hydrochlorothiazide Formulation

13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations
- UNRTDG: Not regulated as a dangerous good
- IATA-DGR: Not regulated as a dangerous good
- IMDG-Code: Not regulated as a dangerous good
- Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable for product as supplied.

National Regulations
- GB 6944/12268: Not regulated as a dangerous good
- Special precautions for user: Not applicable

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Losartan / Hydrochlorothiazide Formulation

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16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

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

ACGIH / TWA: 8-hour, time-weighted average
GBZ 2.1-2007 / PC-TWA: Permissible concentration - time weighted average

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 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

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