SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Losartan / Hydrochlorothiazide Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : Organon & Co.
              30 Hudson Street, 33nd floor
              07302 Jersey City, New Jersey, U.S.A
   Telephone : 551-430-6000
   E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number
   215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

   Classification (REGULATION (EC) No 1272/2008)
   Serious eye damage, Category 1 : H318: Causes serious eye damage.
   Skin sensitisation, Category 1 : H317: May cause an allergic skin reaction.
   Reproductive toxicity, Category 1B : H360D: May damage the unborn child.
   Effects on or via lactation : H362: May cause harm to breast-fed children.
   Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

   Labelling (REGULATION (EC) No 1272/2008)
   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.
   H373 May cause damage to organs through prolonged or repeated exposure.
Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy and while nursing.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:
Losartan
Hydrochlorothiazide

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Losartan</td>
<td>124750-99-8</td>
<td></td>
<td>Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Sens. 1; H317 Repr. 1B; H360D Lact.H362 STOT RE 2; H373 (Blood, Cardiovascular system,</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.
SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

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
Sulphur oxides

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.
6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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:
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.
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m3</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used</td>
<td></td>
<td></td>
<td></td>
<td></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>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>4 mg/m3</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>TWA</td>
<td>100 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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
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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection Material: Chemical-resistant gloves

Skin and body protection: Work uniform or laboratory coat.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: powder
Colour: yellow
Odour: odourless
Odour Threshold: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: 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

Flash point: Not applicable

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Decomposition temperature: No data available

pH: No data available

Viscosity: Not applicable

Viscosity, kinematic: Not applicable

Solubility(ies): Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Vapour pressure: Not applicable
Relative density: No data available
Density: No data available
Relative vapour density: Not applicable
Particle characteristics
  Particle size: No data available

9.2 Other information
Explosives: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
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: > 2,000 mg/kg
  - Method: Calculation method

**Components:**

**Losartan:**

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

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:

Losartan:
Genotoxicity in vitro: Test Type: in vitro assay
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 assay
Test system: mouse lymphoma cells
Result: positive

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

Test Type: in vivo assay
Species: Mouse
Cell type: Bone marrow
Result: negative

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

Carcinogenicity
Not classified based on available information.

Components:

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:

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 foetal 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

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

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

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

Studies indicating a hazard to babies during the lactation period
**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

**Losartan / Hydrochlorothiazide Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 16.10.2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.5</td>
<td>09.04.2021</td>
<td>17067-00017</td>
<td>Date of first issue: 30.09.2014</td>
</tr>
</tbody>
</table>

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**
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:**

**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

**Hydrochlorothiazide:**
- Species: Rat, male and female
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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

11.2 Information on other hazards
Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

12.1 Toxicity

Components:

Losartan:
Toxicity to fish
Exposure time: 96 h
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants
Exposure time: 10 d
Method: FDA 4.01

Toxicity to fish (Chronic toxicity)
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Hydrochlorothiazide:
Toxicity to fish
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates
Exposure time: 48 h

12.2 Persistence and degradability

Components:

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

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

**Components:**

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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

**Product:**
Assessment  
:  This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
Assessment  
:  The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:**
:  Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

14.1 UN number or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good
14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
   Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

   REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
   REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
   REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
   Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
   Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
      : Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
   AICS : not determined
   DSL : not determined
   IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version
Full text of H-Statements

H302 : 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 through prolonged or repeated exposure.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Eye Dam. : Serious eye damage
Lact. : Effects on or via lactation
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Losartan / Hydrochlorothiazide Formulation

Version 4.5  
Revision Date: 09.04.2021  
SDS Number: 17067-00017  
Date of last issue: 16.10.2020  
Date of first issue: 30.09.2014

SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States);  
UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information
Sources of key data used to compile the Safety Data Sheet:  

Classification of the mixture:  
Eye Dam. 1 H318 Calculation method  
Skin Sens. 1 H317 Calculation method  
Repr. 1B H360D Calculation method  
Lact. H362 Calculation method  
STOT RE 2 H373 Calculation method

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.

IE / EN