

# Losartan / Hydrochlorothiazide Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 17083-00017      Date of last issue: 16.10.2020  
Date of first issue: 30.09.2014

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## 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 Sub-stance/Mixture : Pharmaceutical

### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
30 Hudson Street, 33rd 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

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## 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.

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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.

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

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Losartan	124750-99-8	Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Sens. 1; H317 Repr. 1B; H360D Lact.H362 STOT RE 2; H373 (Blood, Cardiovascular system, Stomach, Kidney)	>= 20 - < 30
Hydrochlorothiazide	58-93-5 200-403-3	STOT RE 1; H372 (Kidney, Parathyroid gland)	>= 1 - < 10

For explanation of abbreviations see section 16.

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**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.
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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)
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Dry chemical

Unsuitable extinguishing media : None known.

## 5.2 Special hazards arising from the substance or mixture

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 (NO<sub>x</sub>)  
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.

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## 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 dis-

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posal 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.<br>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.<br>Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>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.<br>Wash contaminated clothing before re-use.<br>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:<br>Strong oxidizing agents<br>Organic peroxides  |

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Explosives  
Gases

**7.3 Specific end use(s)**

Specific use(s) : No data available

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	TWA OEL-RL (Respirable dust)	5 mg/m <sup>3</sup>	ZA OEL
Further information: Recommended Limit				
		TWA OEL-RL (inhalable dust)	10 mg/m <sup>3</sup>	ZA OEL
Further information: Recommended Limit				
		STEL OEL-RL (Dust)	20 mg/m <sup>3</sup>	ZA OEL
Further information: Recommended Limit				
Losartan	124750-99-8	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Starch	9005-25-8	TWA OEL-RL (Respirable dust)	5 mg/m <sup>3</sup>	ZA OEL
Further information: Recommended Limit				
		TWA OEL-RL (inhalable dust)	10 mg/m <sup>3</sup>	ZA OEL
Further information: Recommended Limit				
Hydrochlorothiazide	58-93-5	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal

**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 faceshield 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 expo-

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Filter type : sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
: Particulates type (P)

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**SECTION 9: Physical and chemical properties****9.1 Information on basic 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.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition 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.

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**9.2 Other information**

Flammability (liquids) : No data available

Particle size : No data available

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**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.

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**SECTION 11: Toxicological information****11.1 Information on toxicological effects**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  
LDLo (Rat): 200 mg/kg  
LDLo (Mouse): 400 mg/kg



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**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

**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

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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.

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**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 off-

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spring 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 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

**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.

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**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  
 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  
 : 50 - 200 mg/kg  
 Application Route : Oral  
 Exposure time : 9 Months  
 Target Organs : Parathyroid gland

**Aspiration toxicity**

Not classified based on available information.

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**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

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**SECTION 12: Ecological information****12.1 Toxicity****Components:****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: 10 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 100 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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**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

**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 Other adverse effects****Product:**

Endocrine disrupting potential : 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.

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**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

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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.

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**SECTION 14: Transport information****14.1 UN 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 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks : Not applicable for product as supplied.

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**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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.

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**SECTION 16: Other information**

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**Full text of H-Statements**

H302 : Harmful if swallowed.

H317 : May cause an allergic skin reaction.

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 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  
 ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits  
 ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit  
 ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

**Further information**

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

## Losartan / Hydrochlorothiazide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
4.5	09.04.2021	17083-00017	Date of first issue: 30.09.2014

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compile the Safety Data Sheet

eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>**Classification of the mixture:**

Eye Dam. 1	H318
Skin Sens. 1	H317
Repr. 1B	H360D
Lact.	H362
STOT RE 2	H373

**Classification procedure:**

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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