

## Losartan / Hydrochlorothiazide Formulation

Version **Revision Date:** SDS Number: Date of last issue: 20.03.2023 26.09.2023 17053-00021 Date of first issue: 30.09.2014 7.1

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Losartan / Hydrochlorothiazide Formulation

Manufacturer or supplier's details

: Organon & Co. Company

Address : Rua Treze de Maio, 1161

Campinas, São Paulo, Brazil 13106-054

Telephone +55 (19) 3758-2000

: +55 (11) 3173-4931 Emergency telephone

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 ABNT NBR 14725 Standard

Acute toxicity (Oral) Category 5

Serious eye damage Category 1

Skin sensitization Category 1

Reproductive toxicity Category 1B

Effects on or via lactation

Specific target organ toxicity - :

repeated exposure

Category 2 (Kidney, Parathyroid gland)

repeated exposure (Oral)

Specific target organ toxicity - : Category 2 (Blood, Cardio-vascular system, Stomach, Kidney)

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms

Signal Word Danger

**Hazard Statements** H303 May be harmful if swallowed.



## **Losartan / Hydrochlorothiazide Formulation**



Version **Revision Date:** SDS Number: Date of last issue: 20.03.2023 26.09.2023 17053-00021 Date of first issue: 30.09.2014 7.1

> 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 (Kidney, Parathyroid

gland) through prolonged or repeated exposure.

H373 May cause damage to organs (Blood, Cardio-vascular system, Stomach, Kidney) through prolonged or repeated ex-

posure if swallowed.

**Precautionary Statements** 

#### Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P263 Avoid contact during pregnancy/ while nursing.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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.

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

### 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.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture Mixture

#### Components

Chemical name	CAS-No.	Classification Concentration (% w/w	
Cellulose	9004-34-6		>= 30 -< 50
Losartan	124750-99-8	Acute toxicity (Oral), Category 4 Serious eye damage, Category 1 Skin sensitization, Category 1 Reproductive toxicity, Category 1B Effects on or via lactation, Specific target organ toxicity - repeated exposure (Oral) (Blood, Cardiovascular system, Stomach, Kidney), Category 2	>= 20 -< 30
Starch	9005-25-8		>= 10 -< 20



## **Losartan / Hydrochlorothiazide Formulation**



Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

Hydrochlorothiazide

| 58-93-5 | Acute toxicity (Oral), Category 5 | Specific target organ toxicity - repeated exposure (Kidney, Parathyroid gland), Category 1 | >= 1 -< 5

**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, 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.

**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 fire : Avoid generating dust; fine dust dispersed in air in sufficient







Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

fighting 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 prod-

ucts

Carbon oxides

Chlorine compounds Nitrogen oxides (NOx) Chlorine compounds

Sulfur oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 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 emer-

gency 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.



## **Losartan / Hydrochlorothiazide Formulation**



Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

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.

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

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Losartan	124750-99-8	TWA	100 μg/m3 (OEB 2)	Internal
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	ACGIH
Hydrochlorothiazide	58-93-5	TWA	100 μg/m3 (OEB 2)	Internal

**Engineering measures** : Use feasible engineering controls to minimize exposure to



## **Losartan / Hydrochlorothiazide Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 20.03.2023

 7.1
 26.09.2023
 17053-00021
 Date of first issue: 30.09.2014

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

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

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



## Losartan / Hydrochlorothiazide Formulation



Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

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 reac-

tions

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. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

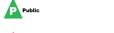
**Acute toxicity** 

May be harmful if swallowed.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 2.201 mg/kg

Method: Calculation method



## **Losartan / Hydrochlorothiazide Formulation**

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

**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.



## Losartan / Hydrochlorothiazide Formulation



Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

**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



## Losartan / Hydrochlorothiazide Formulation

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

Result: negative

Losartan:

Genotoxicity in vitro : Test Type: in vitro test

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Result: negative

Test Type: Alkaline elution assay

Result: negative

Test Type: Chromosomal aberration

Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration

Result: negative

Starch:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Hydrochlorothiazide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells

Result: negative

Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells

Result: positive

Test Type: in vitro test

Test system: mouse lymphoma cells

Result: positive

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: Chinese hamster Cell type: Bone marrow

Result: negative

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.



## **Losartan / Hydrochlorothiazide Formulation**



Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

### 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



## **Losartan / Hydrochlorothiazide Formulation**



Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

Species: Rat

Application Route: Ingestion

Result: negative

Losartan:

Effects on fertility : Test Type: Fertility

Species: Rat, female Application Route: Oral

Fertility: LOAEL: 200 mg/kg body weight Result: female reproductive effects Remarks: Maternal toxicity observed.

Effects on fetal development : Test Type: Development

Species: Rabbit

Application Route: Oral

General Toxicity Maternal: NOAEL: 10 mg/kg body weight Developmental Toxicity: NOAEL F1: 20 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses,

No teratogenic effects.

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 10 mg/kg body weight

Result: Fetotoxicity., No teratogenic effects.

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

Studies indicating a hazard to babies during the lactation

period

Hydrochlorothiazide:

Effects on fertility : Test Type: Fertility

Species: Rat, male and female Application Route: oral (feed)

Fertility: NOAEL: 4 mg/kg body weight

Result: Effects on fertility.

Test Type: Fertility

Species: Mouse, male and female Application Route: oral (feed)

Fertility: NOAEL: 100 mg/kg body weight

Result: Effects on fertility.

Effects on fetal development : Test Type: Development

Species: Mouse Application Route: Oral

Developmental Toxicity: NOAEL: 3.000 mg/kg body weight

Result: No teratogenic effects.

Test Type: Development

Species: Rat



## **Losartan / Hydrochlorothiazide Formulation**



Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

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 (Kidney, Parathyroid gland) through prolonged or repeated expo-

May cause damage to organs (Blood, Cardio-vascular system, Stomach, Kidney) through prolonged or repeated exposure if swallowed.

### Components:

#### Losartan:

Routes of exposure : Ingestion

Target Organs : Blood, Cardio-vascular system, Stomach, Kidney

Assessment : May cause damage to organs through prolonged or repeated

exposure.

#### Hydrochlorothiazide:

Target Organs : Kidney, Parathyroid gland

Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

## Cellulose:

Species : Rat

NOAEL : >= 9.000 mg/kg

Application Route : Ingestion Exposure time : 90 Days

### Losartan:

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



**™**ORGANON

## Losartan / Hydrochlorothiazide Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 20.03.2023

 7.1
 26.09.2023
 17053-00021
 Date of first issue: 30.09.2014

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

50 - 200 mg/kg

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, Ab-



## **Losartan / Hydrochlorothiazide Formulation**



Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

dominal pain, hypotension, dry mouth, electrolyte imbalance,

eye pain

#### **SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity** 

**Components:** 

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Losartan:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 929 mg/l

Exposure time: 96 h Method: FDA 4.11

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 331 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

NOEC (Microcystis aeruginosa (blue-green algae)): 949 mg/l

Exposure time: 10 d Method: FDA 4.01

NOEC (Selenastrum capricornutum (green algae)): 143 mg/l

Exposure time: 10 d Method: FDA 4.01

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 10 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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 / Hydrochlorothiazide Formulation**

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

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

Other adverse effect

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

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** 

ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable



## **Losartan / Hydrochlorothiazide Formulation**

Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

#### **SECTION 15. REGULATORY INFORMATION**

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

: Not applicable

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-

National List of Carcinogenic Agents for Humans - (LINACH)

Group 2B: Possibly carcinogenic to humans

Hydrochlorothiazide 58-93-5

Brazil. List of chemicals controlled by the Federal

Police

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 26.09.2023 Date format : dd.mm.yyyy

**Further information** 

Sources of key data used to compile the Material Safety

compile the Material Sale

Data Sheet cy, http://echa.europa.eu/

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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;



## **Losartan / Hydrochlorothiazide Formulation**

Version Revision Date: SDS Number: Date of last issue: 20.03.2023 7.1 26.09.2023 17053-00021 Date of first issue: 30.09.2014

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; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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.

BR / Z8