

Losartan / Hydrochlorothiazide Formulation



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

SECTION 1. IDENTIFICATION

Product name : Losartan / Hydrochlorothiazide Formulation

Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000 Emergency telephone : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Serious eye damage : Category 1

Skin sensitization : Category 1

Reproductive toxicity : Category 1B

Effects on or via lactation

Specific target organ toxicity

- repeated exposure

Category 1 (Kidney, Parathyroid gland)

Specific target organ toxicity

- repeated exposure (Oral)

Category 2 (Blood, Cardio-vascular system, Stomach, Kidney)

GHS label elements

Hazard pictograms :







Signal Word : Dange

Hazard Statements : H317 May cause an allergic skin reaction.

H318 Causes serious eye damage. H360D May damage the unborn child. H362 May cause harm to breast-fed children.

H372 Causes damage to organs (Kidney, Parathyroid gland)

through prolonged or repeated exposure.

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



Losartan / Hydrochlorothiazide Formulation

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

exposure if swallowed.

Precautionary Statements

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe dust.

P263 Avoid contact during pregnancy and while nursing.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER.

P308 + P313 IF exposed or concerned: Get medical attention. P333 + P313 If skin irritation or rash occurs: Get medical atten-

P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)		
Cellulose	No data availa- ble	9004-34-6	>= 30 - < 60 *		
Losartan	No data availa- ble	124750-99-8	>= 10 - < 30 *		
Starch	Sago starch	9005-25-8	>= 10 - < 30 *		
Hydrochlorothiazide	No data availa- ble	58-93-5	>= 1 - < 5 *		

Actual concentration or concentration range is withheld as a trade secret



Losartan / Hydrochlorothiazide Formulation



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

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.

May cause an allergic skin reaction.

Causes serious eye damage.

May damage the unborn child.

May cause harm to breast-fed children.

Causes damage to organs through prolonged or repeated

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

Most important symptoms

delayed

and effects, both acute and

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

concentrations, and in the presence of an ignition source is

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- : Use extinguishing measures that are appropriate to local cir-



Losartan / Hydrochlorothiazide Formulation



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10/16/2020

 6.5
 04/09/2021
 17054-00017
 Date of first issue: 09/30/2014

ods 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.

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.



Losartan / Hydrochlorothiazide Formulation



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

Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	CA AB OEL
		TWA (Total dust)	10 mg/m³	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m³	CA BC OEL
		TWAEV (to- tal dust)	10 mg/m³	CA QC OEL
		TWA	10 mg/m ³	ACGIH
Losartan	124750-99-8	TWA	100 μg/m3 (OEB 2)	Internal
Starch	9005-25-8	TWA	10 mg/m ³	CA AB OEL
		TWAEV (to- tal dust)	10 mg/m³	CA QC OEL
		TWA (Total dust)	10 mg/m ³	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m³	CA BC OEL
		TWA	10 mg/m ³	ACGIH
Hydrochlorothiazide	58-93-5	TWA	100 μg/m3 (OEB 2)	Internal

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



ORGANON

Losartan / Hydrochlorothiazide Formulation

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

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type Hand protection Material

Particulates type

Chemical-resistant gloves

Eye protection Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Skin and body protection

Work uniform or laboratory coat. Hygiene measures

If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures. industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance powder

Color yellow

Odor odorless

Odor Threshold No data available

No data available pΗ

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

Not applicable Flash point

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



Losartan / Hydrochlorothiazide Formulation

ORGANON

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

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure Not applicable

Relative vapor density Not applicable

Relative density No data available

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature No data available

Decomposition temperature No data available

Viscosity

Not applicable Viscosity, kinematic

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

Not classified as a reactivity hazard. Reactivity 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.

Incompatible materials

Oxidizing agents Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.



Losartan / Hydrochlorothiazide Formulation

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

Product:

Acute oral toxicity : Acute toxicity estimate: 2,201 mg/kg

Method: Calculation method

Components:

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Losartan:

Acute oral toxicity : LD50 (Mouse): 1,257 - 1,590 mg/kg

LDLo (Rat): 200 mg/kg

LDLo (Mouse): 400 mg/kg

Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Hydrochlorothiazide:

Acute oral toxicity : LD50 (Rat): > 2,750 mg/kg

LD50 (Mouse): > 2,830 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Rat): 990 mg/kg

Application Route: Intravenous

LD50 (Mouse): 590 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Components:

Losartan:

Species : Rabbit

Result : Mild skin irritation

Hydrochlorothiazide:

Species : Rabbit

Result : No skin irritation



Losartan / Hydrochlorothiazide Formulation



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

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Losartan:

Species : Rabbit

Result : Severe irritation

Starch:

Species : Rabbit

Result : No eye irritation

Hydrochlorothiazide:

Species : Rabbit

Result : Mild eye irritation

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

Losartan:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Assessment : Probability or evidence of skin sensitization in humans

Result : positive

Starch:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo



Losartan / Hydrochlorothiazide Formulation



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

cytogenetic assay) Species: Mouse

Application Route: Ingestion

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 - : Weight of evidence does not support classification as a germ



Losartan / Hydrochlorothiazide Formulation



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

Assessment cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Losartan:

Species : Mouse
Application Route : Oral
Exposure time : 92 weeks

Dose : 200 mg/kg body weight

Result : negative

Species : Rat Application Route : Oral

Exposure time : 105 weeks

Dose : 270 mg/kg body weight

Result : negative

Hydrochlorothiazide:

Species : Mouse, female

Application Route : Oral Exposure time : 2 Years Result : negative

Species : Mouse, male

Application Route : Oral
Exposure time : 2 Years
Result : equivocal

Species : Rat, male and female

Application Route : Oral
Exposure time : 2 Years
Result : negative

Reproductive toxicity

May damage the unborn child.

May cause harm to breast-fed children.

Components:

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative



Losartan / Hydrochlorothiazide Formulation



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

Effects on fetal development : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Losartan:

Effects on fertility : Test Type: Fertility

Species: Rat, female Application Route: Oral

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

Effects on fetal development : Test Type: Development

Species: Rabbit Application Route: Oral

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

No teratogenic effects.

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.



Losartan / Hydrochlorothiazide Formulation



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

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

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

Components:

Losartan:

Routes of exposure : Ingestion

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

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Hydrochlorothiazide:

Target Organs : Kidney, Parathyroid gland

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Cellulose:

Species : Rat

NOAEL : >= 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



Losartan / Hydrochlorothiazide Formulation

→ ORGANON

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

Application Route : Oral
Exposure time : 53 Weeks
Number of exposures : daily

Symptoms : Salivation, Vomiting

Starch:

Species : Rat

NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

Hydrochlorothiazide:

Species : Rat, male and female

LOAEL : 10 mg/kg
Application Route : Oral
Exposure time : 2 y

Target Organs : Kidney, Parathyroid gland

Species : Mouse, male and female

NOAEL : 300 - 550 mg/kg

Application Route : Oral Exposure time : 2 y

Remarks : No significant adverse effects were reported

Species : Dog

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



Losartan / Hydrochlorothiazide Formulation

♣ ORGANON

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

Ingestion : Symptoms: Dizziness, Headache, Fatigue, Nausea, Ab-

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

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

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

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

TDG

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined



Losartan / Hydrochlorothiazide Formulation



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10/16/2020

 6.5
 04/09/2021
 17054-00017
 Date of first issue: 09/30/2014

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWAEV : Time-weighted average exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature: SDS - Safety Data Sheet: TCSI - Taiwan Chemical Substance Inventory: TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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



Losartan / Hydrochlorothiazide Formulation

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

compile the Material Safety

Data Sheet

eChem Portal search results and European Chemicals Agen-

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

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8