

SAFETY DATA SHEET



Losartan / Hydrochlorothiazide Formulation



Version 4.8 Revision Date: 16.10.2020 SDS Number: 17048-00016 Date of last issue: 23.03.2020
Date of first issue: 30.09.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Losartan / Hydrochlorothiazide Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Serious eye damage/eye irritation : Category 1

Skin sensitisation : Category 1

Reproductive toxicity : Category 1B

Effects on or via lactation

Specific target organ toxicity - repeated exposure : Category 2 (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 : 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 (Kidney, Parathyroid gland) through prolonged or repeated exposure.

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H373 May cause damage to organs (Blood, Cardio-vascular system, Stomach, Kidney) through prolonged or repeated 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/ 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/ eye protection/ face protection.
P281 Use personal protective equipment as required.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and 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 or doctor/ physician.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

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

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. | Concentration (% w/w) |
|---------------------|-------------|-----------------------|
| Cellulose | 9004-34-6 | >= 30 -< 60 |
| Losartan | 124750-99-8 | >= 10 -< 30 |
| Starch | 9005-25-8 | >= 10 -< 30 |
| Hydrochlorothiazide | 58-93-5 | >= 1 -< 10 |

SECTION 4. FIRST AID MEASURES

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| | | |
|---|---|--|
| General advice | : | In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : | If inhaled, remove to fresh air. Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. |
| In case of eye contact | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately. |
| If swallowed | : | If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | May 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. FIREFIGHTING MEASURES

| | | |
|---------------------------------------|---|---|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire-fighting | : | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides Chlorine compounds Nitrogen oxides (NO _x) Chlorine compounds Sulphur oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. |

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Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency 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.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.

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- 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 labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid** : Do not store with the following product types:
Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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 | AU OEL |
| | Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica | | | |
| | | TWA | 10 mg/m ³ | ACGIH |
| Losartan | 124750-99-8 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| Starch | 9005-25-8 | TWA | 10 mg/m ³ | AU OEL |
| | Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica | | | |
| | | TWA | 10 mg/m ³ | ACGIH |
| Hydrochlorothiazide | 58-93-5 | TWA | 100 µg/m ³ (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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type** : Particulates type
- Hand protection**

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| 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 |
| 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. |
| Flammability (liquids) | : | No data available |
| 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 |

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| | | |
|---------------------------|---|--|
| 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. |
| 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 reactions | : | 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

| | | |
|-----------------|---|--|
| Exposure routes | : | 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:**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 |

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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.

Components:**Losartan:**

Species : Rabbit
Result : Severe irritation

Starch:

Species : Rabbit
Result : No eye irritation

Hydrochlorothiazide:

Species : Rabbit
Result : Mild eye irritation

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Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Losartan:

| | |
|-----------------|---|
| Test Type | : Maximisation Test |
| Exposure routes | : Skin contact |
| Species | : Guinea pig |
| Assessment | : Probability or evidence of skin sensitisation in humans |
| Result | : positive |

Starch:

| | |
|-----------------|---------------------|
| Test Type | : Maximisation Test |
| Exposure routes | : Skin contact |
| Species | : Guinea pig |
| Result | : negative |

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) |
| | Result: negative |
| Genotoxicity in vivo | : Test Type: In vitro mammalian cell gene mutation test |
| | Result: negative |
| Genotoxicity in vivo | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) |
| | Species: Mouse |
| | Application Route: Ingestion |
| | Result: negative |

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 |

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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 assay
Test system: mouse lymphoma cells
Result: positive

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

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

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

Carcinogenicity

Not classified based on available information.

Components:**Cellulose:**

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

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Losartan:

Species : Mouse
 Application Route : Oral
 Exposure time : 92 weeks
 Dose : 200 mg/kg body weight
 Result : negative

Species : Rat
 Application Route : Oral
 Exposure time : 105 weeks
 Dose : 270 mg/kg body weight
 Result : negative

Hydrochlorothiazide:

Species : Mouse, female
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Species : Mouse, male
 Application Route : Oral
 Exposure time : 2 Years
 Result : equivocal

Species : Rat, male and female
 Application Route : Oral
 Exposure time : 2 Years
 Result : negative

Reproductive toxicity

May damage the unborn child.
 May cause harm to breast-fed children.

Components:**Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

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

Losartan:

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.

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Effects on foetal development : Test Type: Development
 Species: Rabbit
 Application Route: Oral
 General Toxicity Maternal: NOAEL: 10 mg/kg body weight
 Developmental Toxicity: NOAEL F1: 20 mg/kg body weight
 Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects

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 (Kidney, Parathyroid gland) through prolonged or repeated exposure.

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

Components:**Losartan:**

| | | |
|-----------------|---|--|
| Exposure routes | : | Ingestion |
| Target Organs | : | Blood, Cardio-vascular system, Stomach, Kidney |
| Assessment | : | May cause damage to organs through prolonged or repeated exposure. |

Hydrochlorothiazide:

| | | |
|---------------|---|---|
| Target Organs | : | Kidney, Parathyroid gland |
| Assessment | : | Causes damage to organs through prolonged or repeated exposure. |

Repeated dose toxicity**Components:****Cellulose:**

| | | |
|-------------------|---|----------------|
| Species | : | Rat |
| NOAEL | : | >= 9,000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

Losartan:

| | | |
|---------------------|---|--|
| Species | : | Rat |
| LOAEL | : | 15 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 309 d |
| Number of exposures | : | daily |
| Target Organs | : | Blood, Kidney, Cardio-vascular system, Stomach |

| | | |
|-------------------|---|----------------------|
| Species | : | Dog |
| NOAEL | : | 5 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 1 Months |
| Symptoms | : | Salivation, Vomiting |

| | | |
|---------------------|---|----------------------|
| Species | : | Dog |
| LOAEL | : | 25 mg/kg |
| 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 |

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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.

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

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Cellulose:**

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

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

Hydrochlorothiazide:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

Persistence and degradability**Components:****Cellulose:**

- Biodegradability : Result: Readily biodegradable.

Losartan:

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

Hydrochlorothiazide:

- Stability in water : Hydrolysis: 46.2 %(96 h)

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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.

National Regulations

ADG

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

| | | |
|-------|---|----------------|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

SECTION 16. OTHER INFORMATION**Further information**

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|---|---|---|
| Revision Date | : | 16.10.2020 |
| Sources of key data used to compile the Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |
| Date format | : | dd.mm.yyyy |

Full text of other abbreviations

| | | |
|--------------|---|--|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| AU OEL | : | Australia. Workplace Exposure Standards for Airborne Contaminants. |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| AU OEL / TWA | : | Exposure standard - time weighted average |

AIC - 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;

SAFETY DATA SHEET



Losartan / Hydrochlorothiazide Formulation



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|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 4.8 | 16.10.2020 | 17048-00016 | Date of first issue: 30.09.2014 |

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.

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