# SAFETY DATA SHEET

# Losartan / Hydrochlorothiazide Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 03/23/2020 |
|---|---|---|---|
| 8.4 | 10/16/2020 | 17082-00016 | Date of first issue: 09/30/2014 |

## SECTION 1. IDENTIFICATION

Product name : Losartan / Hydrochlorothiazide Formulation

**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

## SECTION 2. HAZARDS IDENTIFICATION

**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Combustible dust

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 : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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 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 must 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 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.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P363 Wash contaminated clothing 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.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| Cellulose | 9004-34-6 | >= 30 - < 50 |
| Losartan | 124750-99-8 | >= 20 - < 30 |
| Starch | 9005-25-8 | >= 10 - < 20 |
| Hydrochlorothiazide | 58-93-5 | >= 1 - < 5 |

Actual concentration is withheld as a trade secret

## 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.<br>Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | May cause an allergic skin reaction.<br>Causes serious eye damage.<br>May damage the unborn child.<br>May cause harm to breast-fed children.<br>Causes damage to organs through prolonged or repeated exposure.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>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.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides<br>Chlorine compounds<br>Nitrogen oxides (NOx)<br>Chlorine compounds<br>Sulfur oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>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.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>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.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Avoid contact during pregnancy and while nursing.<br>Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the |

environment.

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/m³ | ACGIH |
| | | TWA (Respirable) | 5 mg/m³ | NIOSH REL |
| | | TWA (total) | 10 mg/m³ | NIOSH REL |
| | | TWA (total dust) | 15 mg/m³ | OSHA Z-1 |
| | | TWA (respirable fraction) | 5 mg/m³ | OSHA Z-1 |
| Losartan | 124750-99-8 | TWA | 100 µg/m3 (OEB 2) | Internal |
| Starch | 9005-25-8 | TWA | 10 mg/m³ | ACGIH |
| | | TWA (Respirable) | 5 mg/m³ | NIOSH REL |
| | | TWA (total) | 10 mg/m³ | NIOSH REL |
| | | TWA (total dust) | 15 mg/m³ | OSHA Z-1 |
| | | TWA (respirable fraction) | 5 mg/m³ | OSHA Z-1 |
| 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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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.

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 |
| 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 | : | No data available |

| | | |
|---|---|---|
| flammability limit | | |
| 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 | | |
| 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid | : | Heat, flames and sparks.<br>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.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: 2,200 mg/kg<br>Method: Calculation method |

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 5.8 mg/l<br>Exposure time: 4 h<br>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<br><br>LDLo (Rat): 200 mg/kg<br><br>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<br><br>LD50 (Mouse): > 2,830 mg/kg |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 990 mg/kg<br>Application Route: Intravenous<br><br>LD50 (Mouse): 590 mg/kg<br>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 |

**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)<br>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
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.

**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 |

**IARC** Group 2B: Possibly carcinogenic to humans
Hydrochlorothiazide 58-93-5

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

**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
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 - 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 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
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 |
| 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 |
| 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<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials |

**Losartan:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 929 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 331 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | NOEC (Microcystis aeruginosa (blue-green algae)): 949 mg/l<br>Exposure time: 10 d<br>Method: FDA 4.01<br><br>NOEC (Selenastrum capricornutum (green algae)): 143 mg/l<br>Exposure time: 10 d<br>Method: FDA 4.01 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 10 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 100 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211 |

**Hydrochlorothiazide:**

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

**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.<br>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**

**49 CFR**

Not regulated as a dangerous good

## SECTION 15. REGULATORY INFORMATION

**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Combustible dust
Respiratory or skin sensitization
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
Serious eye damage or eye irritation

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations**

**Pennsylvania Right To Know**

| | |
|---|---|
| Cellulose | 9004-34-6 |
| D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate | 64044-51-5 |
| Losartan | 124750-99-8 |
| Starch | 9005-25-8 |
| Hydrochlorothiazide | 58-93-5 |

**California Permissible Exposure Limits for Chemical Contaminants**

| | |
|---|---|
| Cellulose | 9004-34-6 |
| Starch | 9005-25-8 |

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

AICS : not determined

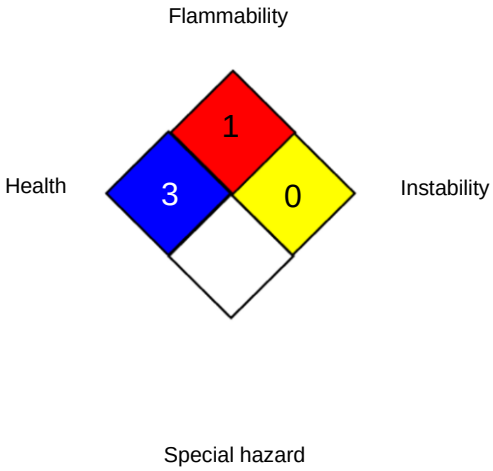
DSL : not determined

IECSC : not determined

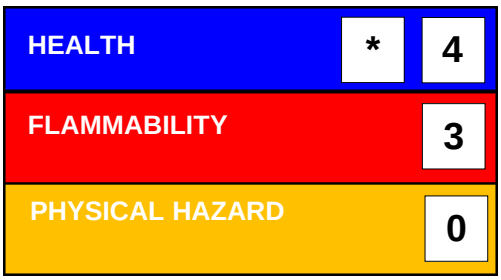
## SECTION 16. OTHER INFORMATION

### Further information

**NFPA 704:**




**HMIS® IV:**




HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| NIOSH REL | : | USA. NIOSH Recommended Exposure Limits |
| OSHA Z-1 | : | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| NIOSH REL / TWA | : | Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |
| OSHA Z-1 / TWA | : | 8-hour time weighted average |

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable

Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

| | | |
|---|---|---|
| Sources of key data used to compile the Material Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |
| Revision Date | : | 10/16/2020 |

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.

US / Z8