

# SAFETY DATA SHEET



## Losartan Formulation



Version 8.0      Revision Date: 2024/04/06      SDS Number: 19356-00023      Date of last issue: 2023/09/26  
Date of first issue: 2014/10/07

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Losartan Formulation

#### Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

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

Telephone : +1-551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : +1-215-631-6999

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Acute toxicity (Oral) : Category 4

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

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H302 Harmful if swallowed.  
H317 May cause an allergic skin reaction.

# SAFETY DATA SHEET



## Losartan Formulation



Version 8.0      Revision Date: 2024/04/06      SDS Number: 19356-00023      Date of last issue: 2023/09/26  
Date of first issue: 2014/10/07

---

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 (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 should not be allowed out of the workplace.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.  
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/ doctor.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it 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

Important symptoms and out- : Contact with dust can cause mechanical irritation or drying of  
lines of the emergency as- the skin.  
sumed May form explosive dust-air mixture during processing, handling or other means.

---

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

# SAFETY DATA SHEET



## Losartan Formulation



Version 8.0      Revision Date: 2024/04/06      SDS Number: 19356-00023      Date of last issue: 2023/09/26  
Date of first issue: 2014/10/07

### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cellulose	9004-34-6	>= 30 - < 40	
Losartan	124750-99-8	>= 30 - < 40	
Starch	9005-25-8	>= 10 - < 20	8-98

### 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 : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.  
May cause an allergic skin reaction.  
Causes serious eye damage.  
May damage the unborn child.  
May cause harm to breast-fed children.  
May cause damage to organs through prolonged or repeated exposure if swallowed.  
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.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

# SAFETY DATA SHEET



## Losartan Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
8.0	2024/04/06	19356-00023	Date of first issue: 2014/10/07

---

- 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 (NOx)
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
- 

### 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.
- 

### 7. HANDLING AND STORAGE

#### Handling

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding
-

# SAFETY DATA SHEET



## Losartan Formulation



Version 8.0      Revision Date: 2024/04/06      SDS Number: 19356-00023      Date of last issue: 2023/09/26  
Date of first issue: 2014/10/07

- Local/Total ventilation : and bonding, or inert atmospheres.  
: 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.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents  
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.

### Storage

- 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
- Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

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

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
8.0	2024/04/06	19356-00023	Date of first issue: 2014/10/07

---

**Engineering measures** : Minimize workplace exposure concentrations.  
Apply measures to prevent dust explosions.  
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).  
If sufficient ventilation is unavailable, use with local exhaust ventilation.

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type  
Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:  
Chemical resistant goggles must be worn.  
If splashes are likely to occur, wear:  
Face-shield

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

---

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : powder  
Colour : White to light yellow  
Odour : No data available  
Odour Threshold : No data available  
Melting point/freezing point : No data available  
Boiling point, initial boiling point and boiling range : No data available

# SAFETY DATA SHEET



## Losartan Formulation



Version 8.0      Revision Date: 2024/04/06      SDS Number: 19356-00023      Date of last issue: 2023/09/26  
Date of first issue: 2014/10/07

---

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Upper per flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Density and / or relative density  
Relative density : No data available

Density : 1 g/cm<sup>3</sup>

Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Minimum ignition energy : > 300 mJ

Particle characteristics  
Particle size : No data available

# SAFETY DATA SHEET



## Losartan Formulation



Version 8.0      Revision Date: 2024/04/06      SDS Number: 19356-00023      Date of last issue: 2023/09/26  
Date of first issue: 2014/10/07

---

### 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.

---

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 1,502 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



## Losartan Formulation

Version 8.0      Revision Date: 2024/04/06      SDS Number: 19356-00023      Date of last issue: 2023/09/26  
Date of first issue: 2014/10/07

---

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

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **Losartan:**

Species : Rabbit  
Result : Mild 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

### **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

### **Germ cell mutagenicity**

Not classified based on available information.

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
8.0	2024/04/06	19356-00023	Date of first issue: 2014/10/07

---

**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
Genotoxicity in vivo	:	Result: negative
		Test Type: Alkaline elution assay
		Result: negative
		Test Type: Chromosomal aberration
Genotoxicity in vivo	:	Result: negative
		Test Type: Chromosomal aberration

**Starch:**

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

**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

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
8.0	2024/04/06	19356-00023	Date of first issue: 2014/10/07

---

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

**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.
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 - As-	: Clear evidence of adverse effects on development, based on

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
8.0	2024/04/06	19356-00023	Date of first issue: 2014/10/07

---

Assessment animal experiments.

Studies indicating a hazard to babies during the lactation period

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

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.

**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

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
8.0	2024/04/06	19356-00023	Date of first issue: 2014/10/07

---

**Starch:**

Species	: Rat
NOAEL	: >= 2,000 mg/kg
Application Route	: Skin contact
Exposure time	: 28 Days
Method	: OECD Test Guideline 410

**Aspiration toxicity**

Not classified based on available information.

**Components:****Losartan:**

|| No aspiration toxicity classification

**Experience with human exposure****Components:****Losartan:**

Eye contact	: Symptoms: Eye irritation
Ingestion	: Symptoms: hypotension, tachycardia

**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

# SAFETY DATA SHEET



## Losartan Formulation



Version 8.0      Revision Date: 2024/04/06      SDS Number: 19356-00023      Date of last issue: 2023/09/26  
Date of first issue: 2014/10/07

---

	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

### Persistence and degradability

#### Components:

##### Cellulose:

Biodegradability : Result: Readily biodegradable.

##### Losartan:

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

### Bioaccumulative potential

#### Components:

##### Losartan:

Partition coefficient: n-octanol/water : log Pow: 1.2

#### Mobility in soil

No data available

#### Hazardous to the ozone layer

Not applicable

#### Other adverse effects

No data available

---

## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.

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.

---

## 14. TRANSPORT INFORMATION

### International Regulations

UNRTDG

---

# SAFETY DATA SHEET



## Losartan Formulation



Version 8.0      Revision Date: 2024/04/06      SDS Number: 19356-00023      Date of last issue: 2023/09/26  
Date of first issue: 2014/10/07

---

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

### **IATA-DGR**

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

### **IMDG-Code**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

### **National Regulations**

Refer to section 15 for specific national regulation.

### **Special precautions for user**

Not applicable

---

## 15. REGULATORY INFORMATION

### **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### **Industrial Safety and Health Law**

#### **Harmful Substances Prohibited from Manufacture**

Not applicable

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
8.0	2024/04/06	19356-00023	Date of first issue: 2014/10/07

---

### **Harmful Substances Required Permission for Manufacture**

Not applicable

### **Substances Prevented From Impairment of Health**

Not applicable

### **Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

### **Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

### **Substances Subject to be Notified Names**

Not applicable

### **Substances Subject to be Indicated Names**

Not applicable

### **Substances Subject to be Indicated Names**

Not applicable

### **Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

|| Not applicable

### **Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

### **Ordinance on Prevention of Lead Poisoning**

Not applicable

### **Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

### **Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

### **Poisonous and Deleterious Substances Control Law**

Not applicable

### **Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

### **High Pressure Gas Safety Act**

Not applicable

### **Explosive Control Law**

Not applicable



# SAFETY DATA SHEET



## Losartan Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
8.0	2024/04/06	19356-00023	Date of first issue: 2014/10/07

---

### Vessel Safety Law

Not regulated as a dangerous good

### Aviation Law

Not regulated as a dangerous good

### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

### Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

### Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

## 16. OTHER INFORMATION

### Further information

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/>

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

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, 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

# SAFETY DATA SHEET



## Losartan Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
8.0	2024/04/06	19356-00023	Date of first issue: 2014/10/07

---

- 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

JP / EN