SAFETY DATA SHEET

Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	19350-00022	Date of first issue: 2014/10/07

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Losartan Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia

Telephone : +1-551-430-6000

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

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

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.

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/ 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

Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

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	>= 30 -< 60
Starch	9005-25-8	>= 10 -< 30

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 (CO2) 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 (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

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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly 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

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	NAB	10 mg/m3	ID OEL
		TWA	10 mg/m3	ACGIH
Losartan	124750-99-8	TWA	100 µg/m3 (OEB 2)	Internal
Starch	9005-25-8	NAB	10 mg/m3	ID OEL
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			
		TWA	10 mg/m3	ACGIH

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).
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	White to light yellow
Odour	:	No data available
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	:	No data available
Evaporation rate	:	No data available
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	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1 g/cm³
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	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 size	:	No data available

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

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.

Components:

Cellulose:

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

Application Route: Ingestion
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

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

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

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 - Assessment	:	Clear evidence of adverse effects on development, based on 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

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 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

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable

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.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

Revision Date	:	2023/09/26

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/
Date format	:	yyyy/mm/dd

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ID OEL	:	Indonesia. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
ID OEL / NAB	:	Long term exposure limit

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

perature; 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.

ID / EN