according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	19361-00023	Date of first issue: 07.10.2014

#### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier Trade name	:	Losartan Formulation
1.2	Relevant identified uses of th	e s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	Organon & Co. 30 Hudson Street, 33nd floor 07302 Jersey City, New Jersey, U.S.A
	Telephone	:	+1-551-430-6000
	E-mail address of person responsible for the SDS	:	EHSSTEWARD@organon.com

#### **1.4 Emergency telephone number**

+1-215-631-6999

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4 Serious eye damage, Category 1 Skin sensitisation, Category 1 Reproductive toxicity, Category 1B Effects on or via lactation Specific target organ toxicity - repeated exposure, Category 2 H302: Harmful if swallowed.
H318: Causes serious eye damage.
H317: May cause an allergic skin reaction.
H360D: May damage the unborn child.
H362: May cause harm to breast-fed children.
H373: May cause damage to organs through prolonged or repeated exposure.

#### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

•

Hazard pictograms



Signal word

1 / 18

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version 4.2	Revision Date: 06.04.2024	SDS Number: 19361-00023	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
Hazar	d statements	H317 May ca H318 Causes H360D May da H362 May ca	ul if swallowed. ause an allergic skin reaction. s serious eye damage. amage the unborn child. ause harm to breast-fed children. ause damage to organs through prolonged or sure.
Preca	utionary statements	P260 Do not P263 Avoid o	special instructions before use. breathe dust. contact during pregnancy and while nursing. protective gloves/ protective clothing/ eye protec- ction.
		with water for s sent and easy POISON CEN	P338 + P310 IF IN EYES: Rinse cautiously several minutes. Remove contact lenses, if pre- to do. Continue rinsing. Immediately call a FER/ doctor. IF exposed or concerned: Get medical advice/

Hazardous components which must be listed on the label: Losartan

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)
---------------	--------------------------------	----------------	--------------------------

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Versi 4.2	ion	Revision Date: 06.04.2024	SDS Ni 19361-			last issue: 26.09.2023 first issue: 07.10.2014	
Γ				Registration	number		
	Losarta	IN		124750-99-	3	Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Sens. 1; H317 Repr. 1B; H360D Lact.H362 STOT RE 2; H373 (Blood, Cardio- vascular system, Stomach, Kidney)	>= 30 - < 50

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

an Booonption of mot ala modoa		5
General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
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).
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.
4.2 Most important symptoms an	nd e	effects, both acute and delayed
Risks	:	Harmful if swallowed. May cause an allergic skin reaction.

Causes serious eye damage. May damage the unborn child.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Versio 4.2	n Revision Date: 06.04.2024		S Number: 361-00023	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
				m to breast-fed children. nage to organs through prolonged or repeated
			Contact with du the skin.	ist can cause mechanical irritation or drying of
4.3 Inc	lication of any immediate	med	lical attention a	nd special treatment needed
Ti	reatment	:	Treat symptom	atically and supportively.
SECT	ION 5: Firefighting mea	sur	es	
5.1 Ex	tinguishing media			
S	uitable extinguishing media	:	Water spray Alcohol-resistar Carbon dioxide Dry chemical	
	nsuitable extinguishing edia	:	None known.	
5.2 Sp	ecial hazards arising from	the	substance or r	nixture
	pecific hazards during fire- ghting	:	concentrations, potential dust e	ng dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a explosion hazard. mbustion products may be a hazard to health.
	azardous combustion prod- cts	:	Carbon oxides Chlorine compo Nitrogen oxides	
5.3 Ad	vice for firefighters			
	pecial protective equipment r firefighters	:		fire, wear self-contained breathing apparatus. rotective equipment.
S	pecific extinguishing meth- ds	:	cumstances an Use water spra	ing measures that are appropriate to local cir- d the surrounding environment. y to cool unopened containers. naged containers from fire area if it is safe to do

### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	Use personal protective equipment.
	Follow safe handling advice (see section 7) and personal pro-
	tective equipment recommendations (see section 8).

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	19361-00023	Date of first issue: 07.10.2014

#### 6.2 Environmental precautions

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.

#### 6.3 Methods and material for containment and cleaning up

certain local or national requirements.		Methods for cleaning up	<ul> <li>Sweep up or vacuum up spillage and collect in suitable container for disposal.</li> <li>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).</li> <li>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.</li> <li>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.</li> <li>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</li> </ul>
---	--	-------------------------	--

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

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 as- sessment 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version 4.2	Revision Date: 06.04.2024	-	OS Number: 361-00023	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014		
Hygier	e measures	:	environment. If exposure to che flushing systems place. When usin work clothing sho	rent spills, waste and minimize release to the emical is likely during typical use, provide eye and safety showers close to the working g do not eat, drink or smoke. Contaminated uld not be allowed out of the workplace. ed clothing before re-use.		
7.2 Conditi	ons for safe storage,	incl	luding any incompatibilities			
Requirements for storage areas and containers		:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.			
Advice	on common storage	:	Strong oxidizing a	stances and mixtures		
-	<b>c end use(s)</b> c use(s)	:	No data available			

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Dust

5 mg/m3 Value type (Form of exposure): TWA (respirable dust) Basis: FOR-2011-12-06-1358

10 mg/m3 Value type (Form of exposure): TWA (total dust) Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Losartan	124750-99- 8	TWA	100 µg/m3 (OEB 2)	Internal

#### 8.2 Exposure controls

#### **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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version 4.2	Revision Date: 06.04.2024	SDS Number: 19361-00023	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014		
Pers	sonal protective equip	ment			
Eye/face protection		Chemical re If splashes a Face-shield	Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield Equipment should conform to NS EN 166		
Han	d protection	Equipmont			
Ν	laterial	: Chemical-re	sistant gloves		
R	Remarks	on the conce stance and s determined f applications, chemicals of	res to protect hands against chemicals depending entration and quantity of the hazardous sub- specific to place of work. Breakthrough time is not for the product. Change gloves often! For special we recommend clarifying the resistance to the aforementioned protective gloves with the acturer. Wash hands before breaks and at the day.		
Skin	and body protection	: Select appro sistance data tial. Skin contact	Select appropriate protective clothing based on chemical re- sistance data and an assessment of the local exposure poten-		
Res	piratory protection	: If adequate I sure assess ommended g	ocal exhaust ventilation is not available or expo- ment demonstrates exposures outside the rec- guidelines, use respiratory protection. should conform to NS EN 143		
F	ilter type	: Particulates			

### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic 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
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Losartan Formulation**

Vers 4.2	sion	Revision Date: 06.04.2024		S Number: 361-00023	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
	Lower explosion limit / Lower flammability limit		:	No data available	9
	Flash point		:	No data available	9
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	No data available	9
	Solubil Wat	ity(ies) ter solubility	:	No data available	9
	Partitio octano	n coefficient: n- I/water	:	No data available	2
	Vapou	rpressure	:	No data available	9
	Relativ	e density	:	No data available	9
	Density	/	:	1 g/cm <sup>3</sup>	
	Relativ	e vapour density	:	No data available	9
		e characteristics ticle size	:	No data available	9
9.2		nformation			
	Explos	ives	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapor	ation rate	:	No data available	9
	Minimu	im ignition energy	:	> 300 mJ	
	Molecu	ılar weight	:	No data available	9

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Losartan Formulation**

Vers 4.2	sion	Revision Date: 06.04.2024	-	DS Number: 361-00023	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014			
10.2		cal stability under normal conditio	ons.					
10.3	Possik	oility of hazardous re	eacti	ons				
Hazardous reactions				May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.				
10.4	Condit	tions to avoid						
	Conditi	ons to avoid	:	Heat, flames a Avoid dust forr				
10.5	Incom	patible materials						
	Materia	als to avoid	:	Oxidizing agen	ts			
10.6		dous decomposition ardous decompositio	-					
SEC	CTION	11: Toxicological i	infoi	mation				
11 1	Inform	ation on hazard clas	2002	as defined in R	egulation (EC) No 1272/2008			
		ation on likely routes o		Inhalation Skin contact Ingestion Eye contact				
		<b>toxicity</b> Il if swallowed.						
	Produc	<u>ct:</u>						
	Acute of	oral toxicity	:	Acute toxicity es Method: Calcula	stimate: 1.502 mg/kg ation method			
	Compo	onents:						
	Losart	an:						
	Acute of	oral toxicity	:	LD50 (Mouse):	1.257 - 1.590 mg/kg			
				LDLo (Rat): 200	) mg/kg			
				LDLo (Mouse):	400 mg/kg			
		orrosion/irritation ssified based on avai	lable	information.				
	Compo	onents:						
	Losart	an:						
	Specie Result	S	:	Rabbit Mild skin irritatio	on			

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	19361-00023	Date of first issue: 07.10.2014

#### Serious eye damage/eye irritation

Causes serious eye damage.

#### Components:

Losartan:	
Species	

Result

: Rabbit : Severe 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

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

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

#### Carcinogenicity

Not classified based on available information.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version 4.2	Revision Date: 06.04.2024	SDS Number: 19361-00023	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
<u>Cor</u>	nponents:		
	artan:	: Mouse	
App		: Oral : 92 weeks : 200 mg/kg k : negative	oody weight
App		: Rat : Oral : 105 weeks : 270 mg/kg b : negative	oody weight
May	oroductive toxicity and damage the unborn ch and cause harm to breast-f		
<u>Cor</u>	nponents:		
	a <b>rtan:</b> acts on fertility	Result: fema	it, female
Effe mer	ects on foetal develop- nt	Species: Ra Application General To Developmen Result: Emb	Route: Oral kicity Maternal: NOAEL: 10 mg/kg body weight ntal Toxicity: NOAEL F1: 20 mg/kg body weight pryotoxic effects and adverse effects on the off- detected only at high maternally toxic doses, No
		Species: Ra Application Development	
-	productive toxicity - As- sment	: Clear evider animal expe	nce of adverse effects on development, based on priments.
		Studies indi od	cating a hazard to babies during the lactation peri-

#### STOT - single exposure

Not classified based on available information.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

ersion 2	Revision Date: 06.04.2024	SDS Number: 19361-00023	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
	- repeated exposur		
-	onents:	ins through proionged	or repeated exposure.
Losa			
Expos Targe	sure routes t Organs ssment		vascular system, Stomach, Kidney mage to organs through prolonged or repeated
Repe	ated dose toxicity		
<u>Comp</u>	oonents:		
Losai	rtan:		
Expos Numb		: Rat : 15 mg/kg : Oral : 309 d : daily : Blood, Kidney,	Cardio-vascular system, Stomach
	EL cation Route sure time	: Dog : 5 mg/kg : Oral : 1 Months : Salivation, Vor	niting
Expos Numb		: Dog : 25 mg/kg : Oral : 53 Weeks : daily : Salivation, Vor	niting
-	ation toxicity assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
Losai	·tan·		

No aspiration toxicity classification

#### 11.2 Information on other hazards

#### Endocrine disrupting properties

#### Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023	
4.2	06.04.2024	19361-00023	Date of first issue: 07.10.2014	

(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### Experience with human exposure

#### Components:

Losartan:
-----------

Logartan	
	Symptoms: Eye irritation Symptoms: hypotension, tachycardia

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### Components:

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

#### 12.2 Persistence and degradability

#### Components:

#### Losartan:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	19361-00023	Date of first issue: 07.10.2014

#### 12.3 Bioaccumulative potential

#### **Components:**

Losartan:

Partition coefficient: n-	:	log Pow: 1,2
octanol/water		

:

#### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

#### 12.6 Endocrine disrupting properties

#### Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### **SECTION 13: Disposal considerations**

13.1 Waste treatment methods	
Product :	<ul> <li>Dispose of in accordance with local regulations.</li> <li>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.</li> <li>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.</li> <li>Do not dispose of waste into sewer.</li> </ul>
Contaminated packaging	<ul> <li>Empty containers should be taken to an approved waste han- dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>

#### **SECTION 14: Transport information**

14.1 UN	l number	or ID	number
---------	----------	-------	--------

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version 4.2	Revision Date: 06.04.2024	SDS Number: 19361-00023	Date of last issue: 26.09.2023 Date of first issue: 07.10.2014
ΙΑΤΑ		: Not regulate	ed as a dangerous good
14.2 UN p	roper shipping name		
ADN		: Not regulate	ed as a dangerous good
ADR		: Not regulate	ed as a dangerous good
RID		: Not regulate	ed as a dangerous good
IMDG	3	: Not regulate	ed as a dangerous good
ΙΑΤΑ		: Not regulate	ed as a dangerous good
14.3 Tran	sport hazard class(es		
ADN		: Not regulate	ed as a dangerous good
ADR		: Not regulate	ed as a dangerous good
RID		: Not regulate	ed as a dangerous good
IMDG	3	: Not regulate	ed as a dangerous good
ΙΑΤΑ		: Not regulate	ed as a dangerous good
14.4 Pack	ing group		
ADN		: Not regulate	ed as a dangerous good
ADR		: Not regulate	ed as a dangerous good
RID		: Not regulate	ed as a dangerous good
IMDG	3	: Not regulate	ed as a dangerous good
ΙΑΤΑ	(Cargo)	: Not regulate	ed as a dangerous good
ΙΑΤΑ	(Passenger)	: Not regulate	ed as a dangerous good
14.5 Envi	ronmental hazards		
Not re	egulated as a dangero	s good	
•	ial precautions for us pplicable	er	
14.7 Marit	time transport in bulk	according to IMC	) instruments
Rema	arks	: Not applicat	ble for product as supplied.

### **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	: Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	: Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	: Not applicable
Regulation (EC) No 1005/2009 on substances that de-	: Not applicable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	19361-00023	Date of first issue: 07.10.2014
	the ozone layer lation (EU) 2019/1021	on persistent organic	pollu- : Not applicable

tants (recast) Regulation (EU) No 649/2012 of the European Parlia- : Not applicable ment and the Council concerning the export and import of dangerous chemicals Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Not applicable

#### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.		
Full text of H-Statements				
H302 H317 H318 H360D H362 H373		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.		
Full text of other abbreviations				
Acute Tox. Eye Dam. Lact.	:	Acute toxicity Serious eye damage Effects on or via lactation		

Lact.	: Effects on or via lactation
Repr.	: Reproductive toxicity
Skin Sens.	: Skin sensitisation
STOT RE	: Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358	: Norway. Occupational Exposure limits
FOR-2011-12-06-1358 /	: Long term exposure limit

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	19361-00023	Date of first issue: 07.10.2014

#### TWA

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

#### Further information

Sources of key data used to compile the Safety Data Sheet		data from raw material SDSs, OECD esults and European Chemicals Agen- eu/
Classification of the mixtur	e:	Classification procedure:
Acute Tox. 4	H302	Calculation method
Eye Dam. 1	H318	Calculation method
Skin Sens. 1	H317	Calculation method
Repr. 1B	H360D	Calculation method
Lact.	H362	Calculation method
STOT RE 2	H373	Calculation method

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	19361-00023	Date of first issue: 07.10.2014

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.

NO / EN