according to the Globally Harmonized System



### Losartan / Hydrochlorothiazide Formulation

Version Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1 26.09.2023	17068-00021	Date of first issue: 30.09.2014

#### **1. PRODUCT AND COMPANY IDENTIFICATION**

Product name	:	Losartan / Hydrochlorothiazide Formulation				
Manufacturer or supplier's de	eta	ils				
Company	:	Organon & Co.				
Address	:	30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302				
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 Restrictions on use	:	Pharmaceutical Not applicable				

#### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification	
Agute texicity (Oral)	

Acute toxicity (Oral)	:	Category 5
Serious eye damage/eye irri- tation	:	Category 1
Skin sensitisation	:	Category 1
Reproductive toxicity	:	Category 1B
Effects on or via lactation		
Specific target organ toxicity - repeated exposure	:	Category 2 (Kidney, Parathyroid gland)
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Blood, Cardio-vascular system, Stomach, Kidney)

#### GHS label elements

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Hazar	d pictograms		
Signa	l word	: Danger	$\mathbf{v}$
Hazar	rd statements	H317 May ca H318 Causes H360D May c H362 May ca H373 May ca gland) throug H373 May ca	e harmful if swallowed. use an allergic skin reaction. s serious eye damage. damage the unborn child. use harm to breast-fed children. use damage to organs (Kidney, Parathyroid h prolonged or repeated exposure. use damage to organs (Blood, Cardio-vascular nach, Kidney) through prolonged or repeated ex- llowed.
Preca	utionary statements	Prevention:	
		P260 Do not P263 Avoid c P264 Wash s P270 Do not P272 Contan the workplace	ontact during pregnancy and while nursing. kin thoroughly after handling. eat, drink or smoke when using this product. hinated work clothing should not be allowed out e. rotective gloves/ protective clothing/ eye protec-
		rash occurs: P302 + P352 P305 + P354 with water for sent and eas P318 IF expo	<ul> <li>+ P317 IF SWALLOWED or if skin irritation or Get medical help.</li> <li>IF ON SKIN: Wash with plenty of water.</li> <li>+ P338 + P317 IF IN EYES: Immediately rinse several minutes. Remove contact lenses, if pre y to do. Continue rinsing. Get medical help.</li> <li>ised or concerned, get medical advice.</li> <li>Take off contaminated clothing and wash it before</li> </ul>
		<b>Storage:</b> P405 Store Ic	ocked up.
		<b>Disposal:</b> P501 Dispose disposal plan	e of contents/ container to an approved waste

May form explosive dust-air mixture during processing, handling or other means.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

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#### 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

#### 4. FIRST AID MEASURES

General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	<ul> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>
In case of eye contact	<ul> <li>In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.</li> <li>If easy to do, remove contact lens, if worn.</li> <li>Get medical attention immediately.</li> </ul>
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	<ul> <li>May be 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. Contact with dust can cause mechanical irritation or drying of the skin.</li> </ul>
Protection of first-aiders	<ul> <li>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).</li> </ul>
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

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	Hazard ucts	ous combustion prod-	:	potential dust exp Exposure to com Carbon oxides Chlorine compou Nitrogen oxides ( Chlorine compou Sulphur oxides	bustion products may be a hazard to health. nds NOx)	
	Specific ods	c extinguishing meth-	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so.		
	Special for firef	l protective equipment ighters	:		e, wear self-contained breathing apparatus. tective equipment.	
6. A	CCIDEN	NTAL RELEASE MEAS	SUF	RES		
	tive equ	al precautions, protec- uipment and emer- procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t recommendations (see section 8).	
	Enviror	nmental precautions	<ul> <li>Avoid release to the environment.</li> <li>Prevent further leakage or spillage if safe to do so.</li> <li>Retain and dispose of contaminated wash water.</li> <li>Local authorities should be advised if significant spilla cannot be contained.</li> </ul>		akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages	
		ls and materials for ment and cleaning up	:	<ul> <li>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 dis posal 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 regardi certain local or national requirements.</li> </ul>		
7. H		NG AND STORAGE				
	Technic	cal measures	:	causing an explose Provide adequate	precautions, such as electrical grounding	
	Local/T	otal ventilation	<ul> <li>and bonding, or inert atmospheres.</li> <li>If sufficient ventilation is unavailable, use with local exhaust ventilation.</li> </ul>			
	Advice	on safe handling	:	<ul> <li>Avoid contact during pregnancy and while nursing.</li> <li>Do not get on skin or clothing.</li> </ul>		

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	C C V F S S K M K T C C		e dust. v. eyes. roughly after handling. ordance with good industrial hygiene and safety d on the results of the workplace exposure as- r tightly closed. generation and accumulation. r closed when not in use. m heat and sources of ignition. onary measures against static discharges. nk or smoke when using this product. revent spills, waste and minimize release to the
Cond	ditions for safe storage	: Keep in proper Store locked u Keep tightly cle	•
Mate	erials to avoid	Store in accord	dance with the particular national regulations. ith the following product types:

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
Losartan	124750-99-8	TWA	100 µg/m3 (OEB 2)	Internal
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
Hydrochlorothiazide	58-93-5	TWA	100 µg/m3 (OEB 2)	Internal

#### Components with workplace control parameters

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	t
Filter type :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type
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.

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Skin a	and body protection	potential for d aerosols.	nield or other full face protection if there is a irect contact to the face with dusts, mists, or or laboratory coat.
Hygiene measures		flushing syste place. When using d Contaminated workplace. Wash contam The effective of engineering co appropriate de industrial hygi	chemical is likely during typical use, provide eye ms and safety showers close to the working o not eat, drink or smoke. work clothing should not be allowed out of the inated clothing before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, egowning and decontamination procedures, ene monitoring, medical surveillance and the strative controls.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	yellow
Odour	:	odourless
Odour Threshold	:	No data available
рН	:	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, han- dling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available

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D	Density		:	No data available	9
S	Solubilit Wate	ry(ies) er solubility	:	No data available	9
	Partition	n coefficient: n-	:	Not applicable	
-		nition temperature	:	No data available	9
D	ecom	position temperature	:	No data available	9
V	/iscosit Visc	y osity, kinematic	:	Not applicable	
E	xplosi	ve properties	:	Not explosive	
С	Dxidizir	g properties	:	The substance of	r mixture is not classified as oxidizing.
Р	Particle	size	:	No data available	9

#### **10. STABILITY AND REACTIVITY**

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling 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	:	

#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : exposure	Inhalation Skin contact Ingestion Eye contact
Acute toxicity	
May be harmful if swallowed.	
Product:	
Acute oral toxicity :	Acute toxicity estimate: 2,201 mg/kg Method: Calculation method
Components:	
Cellulose:	

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Acute	e oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere:	h
Acute	e dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
Losa	rtan:			
Acute	e oral toxicity	:	LD50 (Mouse): 1,2	257 - 1,590 mg/kg
			LDLo (Rat): 200 n	ng/kg
			LDLo (Mouse): 40	00 mg/kg
Starc	:h:			
Acute	e oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
Acute	e dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
Hydr	ochlorothiazide:			
Acute	e oral toxicity	:	LD50 (Rat): > 2,7	50 mg/kg
			LD50 (Mouse): > 2	2,830 mg/kg
	e toxicity (other routes of nistration)	:	LD50 (Rat): 990 n Application Route	
			LD50 (Mouse): 59 Application Route	
Not c <u>Com</u> Losa Speci	ies	ble :	Rabbit	
Resu	lt	:	Mild skin irritation	
Hydr	ochlorothiazide:			
			Rabbit	
Speci Resu		:	No skin irritation	
Resu Serio		tati	No skin irritation	
Resu Serio Caus	lt ous eye damage/eye irri	tati	No skin irritation	
Resu Serio Caus	lt <b>ous eye damage/eye irri</b> es serious eye damage. <u>ponents:</u> rtan:	tati	No skin irritation	

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Resu	ılt	: Severe irrita	ation
Stard	ch:		
Spec		: Rabbit	
Resu	ılt	: No eye irrita	ation
Hydr	ochlorothiazide:		
Spec		: Rabbit	
Resu	ılt	: Mild eye irri	tation
Resp	piratory or skin sens	sitisation	
Skin	sensitisation		
May	cause an allergic skir	n reaction.	
Resp	piratory sensitisation	n	
Not c	classified based on av	vailable information.	
<u>Com</u>	ponents:		
Losa	artan:		
	Туре	: Maximisatio	
Expo Spec	sure routes	: Skin contac : Guinea pig	t
•	essment		or evidence of skin sensitisation in humans
Resu		: positive	
Stard	ch:		
	Туре	: Maximisatio	n Test
Expo	sure routes	: Skin contac	
Spec		: Guinea pig	
Resu	lit	: negative	
Gern	n cell mutagenicity		
Not c	classified based on av	vailable information.	
<u>Com</u>	ponents:		
Cellu	lose:		
Geno	otoxicity in vitro	: Test Type: I Result: nega	Bacterial reverse mutation assay (AMES) ative
		Test Type: I Result: neg	n vitro mammalian cell gene mutation test ative
Geno	otoxicity in vivo	cytogenetic Species: Mo	Duse Route: Ingestion

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	artan: notoxicity in vitro	: Test Type Result: ne	in vitro assay gative
			In vitro mammalian cell gene mutation test m: Chinese hamster ovary cells gative
		Test Type Result: ne	Alkaline elution assay gative
		Test Type Result: ne	Chromosomal aberration gative
Ger	notoxicity in vivo	: Test Type Result: ne	Chromosomal aberration gative
Sta	rch:		
Ger	notoxicity in vitro	: Test Type Result: ne	Bacterial reverse mutation assay (AMES) gative
Нус	drochlorothiazide:		
Ger	notoxicity in vitro	: Test Type Result: ne	Bacterial reverse mutation assay (AMES) gative
			Chromosomal aberration m: Chinese hamster ovary cells gative
			sister chromatid exchange assay m: Chinese hamster ovary cells sitive
			in vitro assay m: mouse lymphoma cells sitive
Ger	notoxicity in vivo	Species: C	Chromosomal aberration chinese hamster Bone marrow gative
		Species: N	Bone marrow
	m cell mutagenicity - essment	: Weight of cell mutag	evidence does not support classification as a germ en.

#### Carcinogenicity

Not classified based on available information.

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Cellu Spec Applie Expo Resu Losa	cation Route sure time It <b>rtan:</b>		Rat Ingestion 72 weeks negative	
	cation Route sure time		Mouse Oral 92 weeks 200 mg/kg bod negative	y weight
	cation Route sure time		Rat Oral 105 weeks 270 mg/kg bod negative	y weight
Spec Appli	cation Route sure time	: :	Mouse, female Oral 2 Years negative	
	cation Route sure time	:	Mouse, male Oral 2 Years equivocal	
	cation Route sure time	:	Rat, male and Oral 2 Years negative	female
May	oductive toxicity damage the unborn chil cause harm to breast-fe		ildren.	
Com	ponents:			
	l <b>lose:</b> ts on fertility	:	Test Type: One Species: Rat Application Ro Result: negativ	
Effec ment	ts on foetal develop-	:	Test Type: Fer Species: Rat Application Ro	tility/early embryonic development ute: Ingestion

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Version 5.1	Revision Date: 26.09.2023	-	DS Number: /068-00021	Date of last issue: 20.03.2023 Date of first issue: 30.09.2014		
			Result: negative			
	sartan: ects on fertility	:	Test Type: Fertilit Species: Rat, fem Application Route Fertility: LOAEL: 2 Result: female rep	ale : Oral 200 mg/kg body weight		
	Effects on foetal develop- ment		<ul> <li>Remarks: Maternal toxicity observed.</li> <li>Test Type: Development Species: Rabbit Application Route: Oral General Toxicity Maternal: NOAEL: 10 mg/kg body weig Developmental Toxicity: NOAEL F1: 20 mg/kg body wei Result: Embryotoxic effects and adverse effects on the of spring were detected only at high maternally toxic doses teratogenic effects</li> </ul>			
	productive toxicity - As- sment	animal experiments.		adverse effects on development, based on ts. a hazard to babies during the lactation peri-		
Hv	drochlorothiazide:					
•	ects on fertility	:	Test Type: Fertilit Species: Rat, mal Application Route Fertility: NOAEL: Result: Effects on	e and female : oral (feed) 4 mg/kg body weight		
			Test Type: Fertilit Species: Mouse, Application Route Fertility: NOAEL: Result: Effects on	male and female : oral (feed) 100 mg/kg body weight		
Effe	ects on foetal develop- nt	:	Test Type: Develo Species: Mouse Application Route Developmental To Result: No teratoo	: Oral oxicity: NOAEL: 3,000 mg/kg body weight		
			Test Type: Develo Species: Rat Application Route			

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Developmental Toxicity: NOAEL: 1,000 mg/kg body weight Result: No teratogenic effects

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

May cause damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.

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

#### **Components:**

#### Losartan:

Exposure routes Target Organs Assessment	:	Ingestion Blood, Cardio-vascular system, Stomach, Kidney May cause damage to organs through prolonged or repeated exposure.
<b>Hydrochlorothiazide:</b> Target Organs Assessment	:	Kidney, Parathyroid gland Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity		
Components:		
<b>Cellulose:</b> Species NOAEL Application Route Exposure time	:	Rat >= 9,000 mg/kg Ingestion 90 Days
Losartan: Species LOAEL Application Route Exposure time Number of exposures Target Organs		Rat 15 mg/kg Oral 309 d daily Blood, Kidney, Cardio-vascular system, Stomach
Species NOAEL Application Route Exposure time Symptoms	:	Dog 5 mg/kg Oral 1 Months Salivation, Vomiting
Species LOAEL Application Route	:	Dog 25 mg/kg Oral

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Num	osure time ber of exposures ptoms	: 53 Weeks : daily : Salivation, Vo			
	cies EL ication Route osure time	: Rat : >= 2,000 mg/k : Skin contact : 28 Days : OECD Test G			
Spec LOA Appl Expo		: Rat, male and : 10 mg/kg : Oral : 2 yr : Kidney, Paratl			
Expo	cies EL ication Route osure time arks	: Mouse, male a : 300 - 550 mg/ : Oral : 2 yr : No significant			
Expo	cies ication Route osure time et Organs	: Dog : 50 - 200 mg/k : Oral : 9 Months : Parathyroid gl			
Not	iration toxicity classified based on ava aponents:	ilable information.			
	artan: spiration toxicity classi	fication			
-	rochlorothiazide: spiration toxicity classi	fication			
-	erience with human e	xposure			
<b>Los</b> a Eye Inge	nponents: artan: contact stion	: Symptoms: Ey : Symptoms: hy	ve irritation vpotension, tachycardia		

#### Hydrochlorothiazide:

•		
Eye contact	:	Symptoms: Eye irritation
Ingestion	:	Symptoms: Dizziness, Headache, Fatigue, Nausea, Ab-

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			dominal pain, hyp eye pain	potension, dry mouth, electrolyte imbalance,
2. ECOLO	DGICAL INFORMATION	N		
Ecoto	oxicity			
Comp	onents:			
Cellul	ose:			
Toxici	ty to fish	:	Exposure time: 4	ipes (Japanese medaka)): > 100 mg/l 8 h on data from similar materials
Losar	tan:			
Toxici	ty to fish	:	LC50 (Oncorhynd Exposure time: 9 Method: FDA 4.1	
	ty to daphnia and other c invertebrates	:	Exposure time: 4	nagna (Water flea)): 331 mg/l 8 h est Guideline 202
Toxici plants	ty to algae/aquatic	:	NOEC ( Microcys Exposure time: 1 Method: FDA 4.0	
			NOEC ( Selenast Exposure time: 1 Method: FDA 4.0	
Toxici icity)	ty to fish (Chronic tox-	:		2 d ales promelas (fathead minnow) est Guideline 210
	ty to daphnia and other ic invertebrates (Chron- city)	:		1 d a magna (Water flea) est Guideline 211
Hydro	ochlorothiazide:			
-	ty to fish	:	LC50 (Pimephale Exposure time: 9	s promelas (fathead minnow)): > 500 mg/l 6 h
	ty to daphnia and other c invertebrates	:	EC50 (Daphnia n Exposure time: 4	nagna (Water flea)): > 500 mg/l 8 h
Persis	stence and degradabili	ity		
Comm	oonents:			

#### Cellulose:

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Biode	egradability	:	Result: Readily	biodegradable.	
Losa	rtan:				
	lity in water	:	Hydrolysis: < 10 %(5 d)		
Hydr	ochlorothiazide:				
Stabi	lity in water	:	Hydrolysis: 46.2 %(96 h)		
Bioa	ccumulative potential				
<u>Com</u>	ponents:				
Losa	rtan:				
	ion coefficient: n- ol/water	:	: log Pow: 1.2		
	<b>lity in soil</b> ata available				
	<b>r adverse effects</b> ata available				
13. DISPO	DSAL CONSIDERATIC	ONS			
Disp	osal methods				
-	e from residues	:		of waste into sewer.	
Conta	aminated packaging	:	<ul> <li>Dispose of in accordance with local regulations.</li> <li>Empty containers should be taken to an approved wast dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused production</li> </ul>		
14. TRAN	SPORT INFORMATIO	N			
Inter	national Regulations				
UNR Not re	<b>TDG</b> egulated as a dangerou	us go	od		
	-DGR egulated as a dangerou	us go	od		
IMDO	G-Code egulated as a dangerou				
	sport in bulk accordin	-		c	

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### Special precautions for user

Not applicable

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#### **15. REGULATORY INFORMATION**

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

#### 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	:	26.09.2023	
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	:	dd.mm.yyyy	
Full text of other abbreviations			
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)	
ACGIH / TWA	:	8-hour, time-weighted average	

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, Evalua-

according to the Globally Harmonized System



#### Losartan / Hydrochlorothiazide Formulation

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tion, 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.

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