

Versi 4.1	on	Revision Date: 30.09.2023		9S Number: 2646-00018	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
SEC		I: Identification of	the	substance/mixt	ure and of the company/undertaking
1.1 P	roduct	identifier			
-	Trade name		:	Olmesartan / Hyd	rochlorothiazide Formulation
1.2 R	elevan	t identified uses of t	he s	ubstance or mixtu	ure and uses advised against
I		he Sub-	:	Pharmaceutical	
	Recomi on use	mended restrictions	:	Not applicable	
1.3 D	etails o	of the supplier of the	saf	ety data sheet	
(Compa	ny	:	Organon & Co. 30 Hudson Street 07302 Jersey Cit	, 33nd floor y, New Jersey, U.S.A
-	Telepho	one	:	+1-551-430-6000	
		address of person sible for the SDS	:	EHSSTEWARD@	organon.com
	•	n cy telephone numb 631-6999	er		

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1A Specific target organ toxicity - repeated exposure, Category 2 H360D: May damage the unborn child. 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	:	Danger
Hazard statements	:	H360D May damage the unborn child. H373 May cause damage to organs through prolonged or repeated exposure.



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Preca	utionary statements	P260 Do not b	pecial instructions before use. reathe dust. otective gloves/ protective clothing/ eye protec- ion.
		Response: P308 + P313 I attention.	F exposed or concerned: Get medical advice/
		Storage: P405 Store loc	sked up.
Haza	rdous components whi	ch must be listed on th	ne label:

Olmesartan

Hydrochlorothiazide

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.

Dust contact with the eyes can lead to mechanical irritation.

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. Registration number	Classification	Concentration (% w/w)
Olmesartan	144689-63-4	Acute Tox. 4; H302 Eye Irrit. 2; H319 Repr. 1A; H360D	>= 1 - < 10
Hydrochlorothiazide	58-93-5 200-403-3	STOT RE 1; H372 (Kidney, Parathy- roid gland)	>= 1 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

Protection of first-aiders : First Aid responders should pay attention to self-protection,



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				mmended personal protective equipment al for exposure exists (see section 8).
lf inha	aled	:	If inhaled, remov Get medical atte	
In cas	se of skin contact	:	of water. Remove contami Get medical atter Wash clothing be	
In cas	se of eye contact	:	If in eyes, rinse v Get medical atte	vell with water. ntion if irritation develops and persists.
If swallowed			Get medical atte	NOT induce vomiting. ntion. roughly with water.
1.2 Most i	mportant symptoms ar	nd e	effects, both acut	e and delayed
Risks		:	May damage the May cause dama exposure.	unborn child. Ige to organs through prolonged or repeated
			the skin.	t can cause mechanical irritation or drying of the eyes can lead to mechanical irritation.
4.3 Indica	tion of any immediate	mec	lical attention an	d special treatment needed
Treat	ment	:	Treat symptomat	ically and supportively.
SECTION	V 5: Firefighting meas	sur	es	
5.1 Exting	uishing media			
_			14/	
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical	
	itable extinguishing	:	Alcohol-resistant Carbon dioxide (
Unsu media	itable extinguishing	:	Alcohol-resistant Carbon dioxide (Dry chemical None known.	CO2)
Unsu media 5.2 Specia	itable extinguishing a al hazards arising from ific hazards during fire-	:	Alcohol-resistant Carbon dioxide (Dry chemical None known.	CO2) i xture dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a



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			Chlorine compou Sulphur oxides	nds
Sp	vice for firefighters	:		e, wear self-contained breathing apparatus.
fo	firefighters		Use personal pro	tective equipment.
Sr oc	ecific extinguishing meth- s	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do

SECTION 6: Accidental release measures

	 ve equipment and emergency procedures Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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 conta	inment and cleaning up
Methods for 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.

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.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

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Local/Total ventilation Advice on safe handling			and bonding, or in If sufficient ventila ventilation. Do not get on skii Do not breathe du Do not breathe du Do not swallow. Avoid contact with Wash skin thorout Handle in accord practice, based of sessment Keep container the Minimize dust get Keep container cl Keep away from Take precautiona Do not eat, drink Take care to prevent environment. If exposure to che flushing systems place. When usin nated clothing be The effective ope engineering contr appropriate dego	ust. h eyes. ighly after handling. ance with good industrial hygiene and safety n the results of the workplace exposure as- ghtly closed. neration and accumulation. losed when not in use. heat and sources of ignition. ary measures against static discharges. or smoke when using this product. vent spills, waste and minimize release to the emical is likely during typical use, provide eye and safety showers close to the working ig do not eat, drink or smoke. Wash contami- fore re-use. tration of a facility should include review of rols, proper personal protective equipment, wning and decontamination procedures, e monitoring, medical surveillance and the	
7.2 Co	onditi	ons for safe storage,	inc	luding any incom	patibilities
R	Require	ements for storage and containers	:	Keep in properly	labelled containers. Store locked up. Keep ore in accordance with the particular national
A	Advice	on common storage	:	Strong oxidizing a	stances and mixtures
7.3 Sp	pecific	c end use(s)			
S	Specifi	c use(s)	:	No data available)

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Olmesartan	144689-63-	TWA	30 µg/m3 (OEB 3)	Internal



Olmesartan / Hydrochlorothiazide Formulation

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		Wipe limit	300 µg/100 cm²	Internal				
Cellulose	9004-34-6	OEL-RL	10 mg/m3	ZA OEL				
		Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents						
Hydrochlorothia- zide	58-93-5	TWA	100 μg/m3 (OEB 2)	Internal				

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipr	nent	
Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Additional body garments should be used based upon the task
		being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	:	powder white to off-white No data available No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available



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range Flash	point	:	Not applicable	
Evap	oration rate	:	Not applicable	
Flam	mability (solid, gas)	:	May form explos dling or other me	ive dust-air mixture during processing, han- eans.
	r explosion limit / Upper nability limit	:	No data available	e
	r explosion limit / Lower nability limit	:	No data available	e
Vapo	ur pressure	:	Not applicable	
Relat	ive vapour density	:	Not applicable	
Relat	ive density	:	No data available	e
Dens	ity	:	No data available	e
W Partit octan	ility(ies) ater solubility ion coefficient: n- ol/water ignition temperature	::	No data available Not applicable No data available	
Deco	mposition temperature	:	No data available	e
	scosity, kinematic	:	Not applicable	
	sive properties	:	Not explosive	
Oxidi	zing properties	:	The substance o	r mixture is not classified as oxidizing.
	information mability (liquids)	:	No data available	e
Moleo	cular weight	:	Not applicable	
Partic	ele size	:	No data available	e

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.



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10.3 Possi	bility of hazardous rea	ctic	ons	
Hazar	dous reactions	:	dling or other r	osive dust-air mixture during processing, han- neans. strong oxidizing agents.
10.4 Cond	itions to avoid			
Condi	tions to avoid	:	Heat, flames a Avoid dust forr	
10.5 Incon	npatible materials			
Materi	als to avoid	:	Oxidizing ager	nts
	dous decomposition p			
SECTION	11: Toxicological in	for	mation	
	nation on toxicological			
expos	ation on likely routes of ure	•	Inhalation Skin contact Ingestion Eye contact	
Acute	toxicity			
	assified based on availa	ble	information.	
<u>Produ</u> Acute	ict: oral toxicity	:	Acute toxicity e Method: Calcul	stimate: > 2.000 mg/kg ation method
Comp	onents:			
Olme	sartan:			
Acute	oral toxicity	:	LD50 (Rat): > 2	2.000 mg/kg
			LD50 (Mouse):	> 2.000 mg/kg
			LD50 (Dog): >	1.500 mg/kg
Acute	inhalation toxicity	:	Remarks: No d	ata available
Acute	dermal toxicity	:	Remarks: No d	ata available
Hydro	ochlorothiazide:			
-	oral toxicity	:	LD50 (Rat): > 2	2.750 mg/kg
			LD50 (Mouse):	> 2.830 mg/kg
	toxicity (other routes of istration)	:	LD50 (Rat): 990 Application Rot	0 mg/kg ute: Intravenous



Application Route: Intravenous Skin corrosion/initiation Not classified based on available information. Components: Offersor Status Remarks Not data available Hydrochlorothiazide: Species Rabbit Result So okin initiation Serious eye damage/eye irritation Not classified based on available information. Serious eye damage/eye irritation Not classified based on available information. Species Rabbit Species Rabbit Species Rabbit Method Drize Test Result Moderate eye irritation Hydrochlorothiazide: Moderate eye irritation Result Moderate eye irritation Result Moderate eye irritation Rost classified based on available information. Represormation Rost classified based on available information. Represormation Mot classified based on available information. Represormation Components: Moderate available Mot classified based on available information. Represormation Components: <td< th=""><th>ersion 1</th><th>Revision Date: 30.09.2023</th><th></th><th>OS Number: 2646-00018</th><th>Date of last issue: 04.04.2023 Date of first issue: 07.01.2016</th></td<>	ersion 1	Revision Date: 30.09.2023		OS Number: 2646-00018	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
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	Geno	toxicity in vitro	:		
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				omosome aberration test in vitro hinese hamster lung cells
			Test Type: Mou Result: negative	
Geno	toxicity in vivo	:	Test Type: Mich Species: Mouse Cell type: Bone Application Rou Result: negative	e marrow ute: Oral
Germ sessr	n cell mutagenicity- As- nent	:	Weight of evide cell mutagen.	ence does not support classification as a germ
Hvdr	ochlorothiazide:			
-	toxicity in vitro	:	Test Type: Bac Result: negative	terial reverse mutation assay (AMES) e
				omosomal aberration hinese hamster ovary cells e
				er chromatid exchange assay hinese hamster ovary cells
			Test Type: in vi Test system: m Result: positive	ouse lymphoma cells
Geno	toxicity in vivo	:	Test Type: Chro Species: Chine Cell type: Bone Result: negative	marrow
			Test Type: in vi Species: Mouse Cell type: Bone Result: negative	e marrow
Germ sessr	n cell mutagenicity- As- ment	:	Weight of evide cell mutagen.	ence does not support classification as a germ
	i nogenicity lassified based on availa	able	information.	
Com	ponents:			
Olme	esartan:			
Spec Appli	ies cation Route	:	Rat Oral	



rsion	Revision Date: 30.09.2023	SDS Number:Date of last issue: 04.04.2023402646-00018Date of first issue: 07.01.2016	
Expos	sure time	: 2 Years	
Resul		: negative	
11000	·	. hogaavo	
Speci	es	: Mouse	
	cation Route	: Oral	
	sure time	: 6 Months	
Resul		: negative	
i vesui	t i	. negative	
Hydro	ochlorothiazide:		
Speci	es	: Mouse, female	
•	cation Route	: Oral	
	sure time	: 2 Years	
Resul		: negative	
Speci	99	: Mouse, male	
	cation Route	: Oral	
	sure time	: 2 Years	
Resul		: equivocal	
Resu	L	. equivocal	
Speci	es	: Rat, male and female	
	cation Route	: Oral	
	sure time	: 2 Years	
Resul		: negative	
Repro	oductive toxicity lamage the unborn ch		
Repro May o <u>Com</u> p	damage the unborn ch ponents:		
Repro May o <u>Comp</u> Olme	damage the unborn ch ponents: sartan:	ld.	
Repro May o <u>Comp</u> Olme	damage the unborn ch ponents:	ld. : Test Type: Fertility	
Repro May o <u>Comp</u> Olme	damage the unborn ch ponents: sartan:	ld. : Test Type: Fertility Species: Rat	
Repro May c <u>Com</u> r Olme	damage the unborn ch ponents: sartan:	ld. : Test Type: Fertility Species: Rat Application Route: Oral	
Repro May c <u>Com</u> r Olme	damage the unborn ch ponents: sartan:	ld. : Test Type: Fertility Species: Rat	
Repro May c <u>Com</u> r Olme	damage the unborn ch ponents: sartan:	ld. : Test Type: Fertility Species: Rat Application Route: Oral	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan:	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	 Id. Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects 	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	Id. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	Id. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	Id. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram Result: No teratogenic effects	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram Result: No teratogenic effects Test Type: Development	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rat I Dose: 1 milligram per kilogram Result: No teratogenic effects	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram Result: No teratogenic effects	b t
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	 Id. Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: >= 1,6 mg/kg body weig 	
Repro May o <u>Comp</u> Olme Effect	damage the unborn ch ponents: sartan: is on fertility	ld. : Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility : Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram Result: No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Dose: 1 milligram per kilogram Result: No teratogenic effects	



Vers 4.1	sion	Revision Date: 30.09.2023		0S Number: 2646-00018	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
				Result: Effects on	postnatal development
	Reprod sessme	luctive toxicity - As- ent	:	Positive evidence human epidemiolo	of adverse effects on development from ogical studies.
	-	chlorothiazide: on fertility	:	Result: Effects on Test Type: Fertilit Species: Mouse, Application Route	e and female : oral (feed) 4 mg/kg body weight fertility y male and female : oral (feed) 100 mg/kg body weight
	Effects ment	on foetal develop-	:	Result: No teratog Test Type: Develo Species: Rat Application Route	: Oral oxicity: NOAEL: 3.000 mg/kg body weight genic effects opment : Oral oxicity: NOAEL: 1.000 mg/kg body weight
	STOT -	single exposure			

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Hydrochlorothiazide:

Target Organs	:	Kidney, Parathyroid gland
Assessment	:	Causes damage to organs through prolonged or repeated
		exposure.

Repeated dose toxicity

Components:

Olmesartan:

Species :	Rat
NOAEL :	2.000 mg/kg
Application Route :	Oral
Exposure time :	24 Months
Remarks :	No significant adverse effects were reported



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Sp LO Ap Ex Ta Sp NC Ap Ex	drochlorothiazide: ecies AEL plication Route posure time rget Organs ecies DAEL plication Route posure time marks	: 10 m : Oral : 2 yr : Kidne : Mouse : 300 - : Oral : 2 yr	y, Parathyr e, male anc 550 mg/kg	oid gland
Ap Ex	ecies plication Route posure time rget Organs	: Oral : 9 Mor	00 mg/kg hths hyroid gland	d
No	piration toxicity t classified based on avail mponents:	able informa	ation.	
-	drochlorothiazide: aspiration toxicity classifie	cation		
Ex	perience with human ex	oosure		

Components:

Olmesartan:		
Eye contact Ingestion	:	Symptoms: Eye irritation Symptoms: hypotension Remarks: May cause harm to the unborn child. Based on Human Evidence
Hydrochlorothiazide:		
Eye contact Ingestion	:	Symptoms: Eye irritation Symptoms: Dizziness, Headache, Fatigue, Nausea, Ab- dominal pain, hypotension, dry mouth, electrolyte imbalance, eye pain

SECTION 12: Ecological information

12.1 Toxicity			
Components:			
Hydrochlorothiazide: Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l Exposure time: 96 h	
Toxicity to daphnia and other	:	EC50 (Daphnia magna (Water flea)): > 500 mg/l	
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aqua	atic invertebrates		Exposure time: 48 h		
12.2 Pers	sistence and degradabi	lity			
Com	nponents:				
-	rochlorothiazide: bility in water	:	Hydrolysis: 46,2	%(96 h)	
	accumulative potential data available				
	bility in soil data available				
12.5 Res	ults of PBT and vPvB a	sse	ssment		
	<u>duct:</u> essment	:	to be either persi	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of	
12.6 Oth	er adverse effects				
Proc	duct:				
Endo tial	ocrine disrupting poten-	:	ered to have end REACH Article 5	hixture does not contain components consid- ocrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.	
SECTIO	N 13: Disposal consi	der			

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

SECTION 14: Transport information

14.1 UN number

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

SAFETY DATA SHEET



Olmesartan / Hydrochlorothiazide Formulation

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RID		: Not regulated as a dangerous good		
IMD	-	: Not regulated as a dangerous good		
IAT		: Not regulated as a dangerous good		
14.2 UN	proper shipping name			
AD	N	: Not regulated as a dangerous good		
AD	R	: Not regulated as a dangerous good		
RID	•	: Not regulated as a dangerous good		
IMC	G	: Not regulated as a dangerous good		
IAT	Α	: Not regulated as a dangerous good		
14.3 Tra	nsport hazard class(es)			
AD	N	: Not regulated as a dangerous good		
AD	R	: Not regulated as a dangerous good		
RID	1	: Not regulated as a dangerous good		
IMD	G	: Not regulated as a dangerous good		
ΙΑΤ	Α	: Not regulated as a dangerous good		
14.4 Pac	king group			
AD	N	: Not regulated as a dangerous good		
AD	R	: Not regulated as a dangerous good		
RID		: Not regulated as a dangerous good		
IMC	G	: Not regulated as a dangerous good		
ΙΑΤ	A (Cargo)	: Not regulated as a dangerous good		
ΙΑΤ	A (Passenger)	: Not regulated as a dangerous good		
14.5 Environmental hazards Not regulated as a dangerous good				
14.6 Special precautions for user Not applicable				
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code				
Rer	narks	: Not applicable for product as supplied.		
SECTION 15: Regulatory information				

15.1 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	



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IECS	6C	: not determine	ed			
	15.2 Chemical safety assessment A Chemical Safety Assessment has not been carried out.					
SECTIO	SECTION 16: Other information					
Othe	er information		changes have been made to the previous version ad in the body of this document by two vertical			
Full	text of H-Statements					
H302 H319 H360 H372	9 DD	: Causes serio : May damage	Harmful if swallowed. Causes serious eye irritation. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.			
Full	Full text of other abbreviations					
Eye Repi STO ZA C	r. T RE	: South Africa. Agents, Occu : Occupational				
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 Re-



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striction 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	:	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data		eChem Portal search results and European Chemicals Agen-
Sheet		cy, http://echa.europa.eu/

Classification of the mixtur	Classification procedure:	
Repr. 1A	H360D	Calculation method
STOT RE 2	H373	Calculation method

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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