

Version 4.1	Revision Date: 2020/10/10	-	S Number: 2581-00012	Date of last issue: 2020/03/23 Date of first issue: 2016/01/07
1. PRODU	ICT AND COMPANY ID	ENT	IFICATION	
Chem	nical product name	:	Olmesartan / Hy	drochlorothiazide Formulation
	lier's company name, a bany name of supplier		-	umber
Addre	ess	:	30 Hudson Stree Jersey City, New	et, 33nd floor / Jersey, U.S.A 07302
Telep	hone	:	551-430-6000	
E-mai	il address	:	EHSSTEWARD	@organon.com
Emer	gency telephone numbe	r :	215-631-6999	
	mmended use of the c mmended use	hem :	ical and restriction Pharmaceutical	ons on use
2. HAZAR	DS IDENTIFICATION			
0.10				
	classification of chemi oductive toxicity			
Speci	fic target organ toxicity - ted exposure			ney, Parathyroid gland)
GHS	label elements			
	rd pictograms	:		
Signa	l word	:	Danger	
Hazai	rd statements	:	H373 May cause	nage the unborn child. a damage to organs (Kidney, Parathyroid rolonged or repeated exposure.
Preca	utionary statements	:	P202 Do not har and understood. P260 Do not bre P280 Wear protection/ face protect <b>Response:</b>	ective gloves/ protective clothing/ eye protec-



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		<b>Storage:</b> P405 Store loo	cked up.			
		<b>Disposal:</b> P501 Dispose disposal plant	of contents/ container to an approved waste			
Othe	r hazards which do not	t result in classifica	ation			
	rtant symptoms and out- of the emergency as- ed	Contact with d the skin. May form expl	Contact with dust can cause mechanical irritation or drying of			

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture	
Components			
Chemical name		CAS-No.	Concentration (
Olmesartan		144689-63-4	>= 1 - < 10

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Olmesartan	144689-63-4	>= 1 - < 10	
Cellulose	9004-34-6	>= 1 - < 10	
Hydrochlorothiazide	58-93-5	>= 1 - < 10	

#### 4. 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.
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	:	
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	:	May damage the unborn child. May cause damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment



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Not	es to physician	:		I for exposure exists (see section 8). cally and supportively.				
5. FIRE	FIGHTING MEASURES							
Suit	table extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical					
Uns	suitable extinguishing	:	None known.					
Specific hazards during fire- fighting			Avoid generating dust; fine dust dispersed in air in sufficie concentrations, and in the presence of an ignition source potential dust explosion hazard. Exposure to combustion products may be a hazard to he					
Haz ucts	zardous combustion prod- S	:	Carbon oxides Nitrogen oxides (I Chlorine compour Sulphur oxides					
Spe ods	ecific extinguishing meth-	:	cumstances and t Use water spray t Remove undamag so.	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				
	ecial protective equipment firefighters	:	Evacuate area. In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.				
6. ACCI	DENTAL RELEASE MEAS	SUF	RES					
tive	sonal precautions, protec- equipment and emer- cy procedures	:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).				
Env	rironmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages				
	hods and materials for tainment and cleaning up	:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the att Local or national u posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces				



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7. HAN	IDLING AND STORAGE		
H	andling		
	echnical measures	causing an exp Provide adequa	ate precautions, such as electrical grounding
Local/Total ventilation		: If sufficient ven	r inert atmospheres. tilation is unavailable, use with local exhaust
Αν	dvice on safe handling voidance of contact vgiene measures	<ul> <li>Handle in acco practice, based sessment</li> <li>Keep container</li> <li>Minimize dust g</li> <li>Keep container</li> <li>Keep away fror</li> <li>Take precautio</li> <li>Do not eat, drin</li> <li>Take care to pr</li> <li>environment.</li> <li>Oxidizing agen</li> <li>If exposure to or</li> <li>flushing system</li> <li>place.</li> <li>When using do</li> <li>Wash contamir</li> <li>The effective or</li> </ul>	dust. with eyes. oughly after handling. rdance with good industrial hygiene and safety on the results of the workplace exposure as- tightly closed. generation and accumulation. closed when not in use. n heat and sources of ignition. nary measures against static discharges. k or smoke when using this product. event spills, waste and minimize release to the
			gowning and decontamination procedures, ne monitoring, medical surveillance and the rative controls.
St	orage		
C	onditions for safe storage	Store locked up Keep tightly clo	
Μ	aterials to avoid		th the following product types:
Pa	ackaging material	: Unsuitable mat	erial: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Components CAS-No. Value type Control parame- Basis				
	$(\Delta S_{-}N)$	Value type	Control parame-	



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			(Form of exposure)	ters / Permissible concentration				
Olme	sartan	144689-63-4	TWA	30 µg/m3 (OEB 3)	Internal			
	ountum		Wipe limit	300 µg/100 cm <sup>2</sup>	Internal			
Cellu	lose	9004-34-6	TWA	10 mg/m3	ACGIH			
	ochlorothiazide	58-93-5	TWA	100 µg/m3 (OEB 2)	Internal			
Engii	neering measures	design and c protect produ Containment are required	perated in acco ucts, workers, a technologies s to control at sound to uncontrolle rices).	uld be implemented by ordance with GMP princ nd the environment. uitable for controlling c urce and to prevent mig ed areas (e.g., open-fac	ciples to ompounds gration of			
Perso	onal protective equip	ment	:					
Fil	iratory protection Iter type protection	sure assessr ommended g	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type					
M	aterial	: Chemical-res	Chemical-resistant gloves					
Eye p	emarks protection and body protection	If the work en mists or aero Wear a faces potential for aerosols.	glasses with sic nvironment or a osols, wear the a shield or other fu direct contact to	le shields or goggles. ctivity involves dusty co appropriate goggles. ull face protection if the o the face with dusts, m coat.	ere is a			
		Additional bo task being po posable suits Use appropri	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.					

Physical state	:	powder
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available



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F	-lamma	ability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.			
F	-lamma	ability (liquids)	:	No data available				
ι	Jpper e	explosion limit and uppe explosion limit / Upper bility limit		·				
		explosion limit / Lower bility limit	:	No data available				
F	-lash p	oint	:	Not applicable				
0	Decomp	position temperature	:	No data available				
p	ъH		:	No data available				
E	Evapora	ation rate	:	Not applicable				
A	Auto-igr	nition temperature	:	No data available				
١	∕iscosit Visc	y osity, kinematic	:	Not applicable				
S	Solubilit Wate	ty(ies) er solubility	:	No data available				
	Partitior	n coefficient: n- /water	:	Not applicable				
١	√apour	pressure	:	Not applicable				
		and / or relative densit e density	у :	No data available				
0	Density		:	No data available				
F	Relative	e vapour density	:	Not applicable				
E	Explosiv	ve properties	:	Not explosive				
C	Oxidizin	ng properties	:	The substance or	mixture is not classified as oxidizing.			
Ν	Molecul	ar weight	:	Not applicable				
	Particle Particle	characteristics size	:	No data available				

### 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.



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	Possibility of hazardous reac- tions		:	: May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.				
	Conditions to avoid Incompatible materials Hazardous decomposition products			Heat, flames and sparks. Avoid dust formation. Oxidizing agents No hazardous decomposition products are known.				
11.	τοχις	OLOGICAL INFORMAT	101	1				
	Inform expos	nation on likely routes of ure	:	Inhalation Skin contact Ingestion Eye contact				
	Not cla	e <b>toxicity</b> assified based on availal	ble	information.				
	<u>Produ</u> Acute	<u>ict:</u> oral toxicity	:	Acute toxicity estine Method: Calculation	mate: > 2,000 mg/kg on method			
	<u>Comp</u>	oonents:						
	Olme	sartan:						
	Acute	oral toxicity	:	LD50 (Rat): > 2,00	00 mg/kg			
				LD50 (Mouse): > 2	2,000 mg/kg			
				LD50 (Dog): > 1,5	00 mg/kg			
	Acute	inhalation toxicity	:	Remarks: No data	available			
	Acute	dermal toxicity	:	Remarks: No data	available			
	Cellul	ose:						
	Acute	oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg			
	Acute	inhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere:	h			
	Acute	dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg			
	Hydro	ochlorothiazide:						
	-	oral toxicity	:	LD50 (Rat): > 2,7	50 mg/kg			
				LD50 (Mouse): > 2	2,830 mg/kg			
		toxicity (other routes of istration)	:	LD50 (Rat): 990 n Application Route				



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				//
			LD50 (Mouse): Application Ro	590 mg/kg ute: Intravenous
Skin	corrosion/irritation			
Not cl	assified based on av	ailable	information.	
Comp	oonents:			
Olme	sartan:			
Rema	arks	:	No data availal	ble
Hydro	ochlorothiazide:			
Speci		:	Rabbit	
Resul	lt	:	No skin irritatio	n
	us eye damage/eye			
Not cl	assified based on av	ailable	information.	
<u>Comp</u>	oonents:			
Olme	sartan:			
Speci		:	Rabbit	
Resul Metho		:	Moderate eye i Draize Test	rritation
Metho	Ju	•	Dialze Test	
Hydro	ochlorothiazide:			
Speci		:	Rabbit	
Resul	lt	:	Mild eye irritati	on
Resp	iratory or skin sens	itisatic	n	
Skin	sensitisation			
Not cl	assified based on av	ailable	information.	
Resp	iratory sensitisation	1		
Not cl	assified based on av	ailable	information.	
<u>Comp</u>	oonents:			
Olme	sartan:			
	sure routes	:	Skin contact	
Rema	arks	:	No data availal	ble
Germ	cell mutagenicity			
Not cl	assified based on av	ailable	information.	
<u>Comp</u>	oonents:			
Olme	sartan:			
Geno	toxicity in vitro	:		cterial reverse mutation assay (AMES)
			Result: negativ	e



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		Test Type: Mutagenicity (in vitro mammalian cytogenetic tes Result: negative
		Test Type: Chromosome aberration test in vitro Test system: Chinese hamster lung cells Result: positive
		Test Type: Mouse Lymphoma Result: negative
Geno	toxicity in vivo	: Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: negative
	cell mutagenicity - ssment	: Weight of evidence does not support classification as a gerr cell mutagen.
Cellu	lose:	
Geno	toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: In vitro mammalian cell gene mutation test Result: negative
Geno	toxicity in vivo	<ul> <li>Test Type: Mammalian erythrocyte micronucleus test (in viv cytogenetic assay)</li> <li>Species: Mouse</li> <li>Application Route: Ingestion</li> <li>Result: negative</li> </ul>
Hydro	ochlorothiazide:	
•	toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative
		Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: positive
		Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive
Geno	toxicity in vivo	: Test Type: Chromosomal aberration Species: Chinese hamster Cell type: Bone marrow Result: negative
		Test Type: in vivo assay

Test Type: in vivo assay



ersion 1	Revision Date: 2020/10/10		S Number: 2581-00012	Date of last issue: 2020/03/23 Date of first issue: 2016/01/07
			Species: Mous Cell type: Bone Result: negativ	e marrow
	cell mutagenicity - ssment	:	Weight of evide cell mutagen.	ence does not support classification as a germ
	nogenicity	labla	information	
	assified based on avai ponents:	lable	information.	
Olme	sartan:			
Speci		:	Rat	
	ation Route	:	Oral	
	sure time	:	2 Years	
Resul	t	:	negative	
Speci	es	:	Mouse	
Applic	ation Route	:	Oral	
	sure time	:	6 Months	
Resul	t	:	negative	
Cellu	lose:			
Speci		:	Rat	
	ation Route	:	Ingestion	
Expos Resul	sure time	:	72 weeks	
Resul	L	•	negative	
Hydro	ochlorothiazide:			
Speci		:	Mouse, female	
	ation Route	:	Oral	
Expos Resul	sure time t	:	2 Years negative	
		•	Ū	
Speci		:	Mouse, male	
	cation Route sure time	:	Oral 2 Years	
Resul		:	equivocal	
Speci	es	:	Rat, male and	female
Applic	ation Route	:	Oral	
	sure time	:	2 Years	
Resul	t	:	negative	
Repro	oductive toxicity			
May c	lamage the unborn chi	ld.		
<u>Comp</u>	oonents:			
Olme	sartan:			
Effect	s on fertility	:	Test Type: Fer	tility
			Species: Rat	



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				oute: Oral EL: 1,000 mg/kg body weight ects on fertility
	Effects on foetal develop- ment			
				pit
			Symptoms: M weight	
	eproductive toxicity - As ssment	- :		nce of adverse effects on development from niological studies.
Ce	ellulose:			
Ef	fects on fertility	:	Species: Rat	e-generation reproduction toxicity study oute: Ingestion ve
	fects on foetal develop- ent	· :	Species: Rat	rtility/early embryonic development oute: Ingestion ve
H	/drochlorothiazide:			
-	fects on fertility	:	Application Ro	male and female oute: oral (feed) EL: 4 mg/kg body weight
			Application Ro	se, male and female oute: oral (feed) EL: 100 mg/kg body weight
	fects on foetal develop- ent	:	Test Type: De Species: Mous Application Ro	se



	Revision Date: 2020/10/10		Number: 31-00012	Date of last issue: 2020/03/23 Date of first issue: 2016/01/07
				I Toxicity: NOAEL: 3,000 mg/kg body weight togenic effects
		S  A  D		
	- single exposure			
Not cl	assified based on av	ailable info	ormation.	
	- repeated exposu			
May o sure.	cause damage to org	ans (Kidne	ey, Parathyro	id gland) through prolonged or repeated expo
<u>Com</u>	oonents:			
Hydro	ochlorothiazide:			
•	et Organs ssment	: C	idney, Parath auses damag oposure.	yroid gland ge to organs through prolonged or repeated
Repe	ated dose toxicity			
Com	oonents:			
	corton.			
Oime	sartan:			
Speci	es	: R		
Speci NOAE	es EL	: 2,	000 mg/kg	
Speci NOAE Applic	es EL cation Route	: 2, : O	000 mg/kg ral	
Speci NOAE Applic	es EL cation Route sure time	: 2, : O : 24	000 mg/kg ral 4 Months	adverse effects were reported
Speci NOAE Applic Expos	es EL cation Route sure time arks	: 2, : O : 24	000 mg/kg ral 4 Months	adverse effects were reported
Speci NOAE Applic Expos Rema <b>Cellu</b> Speci	es EL cation Route sure time arks <b>Iose:</b> es	: 2, : O : 24	000 mg/kg ral 4 Months o significant a	adverse effects were reported
Speci NOAE Applic Expos Rema <b>Cellu</b> Speci NOAE	es EL cation Route sure time arks <b>Iose:</b> es EL	: 2, : O : 2 <sup>2</sup> : N : R : R	000 mg/kg ral 4 Months o significant a at = 9,000 mg/k	
Speci NOAE Applic Expos Rema <b>Cellu</b> Speci NOAE Applic	es EL cation Route sure time arks <b>Iose:</b> es	: 2, : O : 2 <sup>2</sup> : N : R : >= : In	000 mg/kg ral 4 Months o significant a at	
Speci NOAE Applic Expos Rema <b>Cellu</b> Speci NOAE Applic Expos	es EL cation Route sure time arks <b>lose:</b> es EL cation Route sure time	: 2, : O : 2 <sup>2</sup> : N : R : >= : In	000 mg/kg ral 4 Months o significant a at = 9,000 mg/k gestion	
Speci NOAE Applic Expos Rema <b>Cellu</b> Speci NOAE Applic Expos <b>Hydro</b> Speci	es EL cation Route sure time arks <b>lose:</b> es EL cation Route sure time <b>ochlorothiazide:</b> es	: 2, : O : 24 : N : N : R : >= : In : 90	000 mg/kg ral 4 Months o significant a at = 9,000 mg/k gestion	g
Speci NOAE Applic Expos Rema Speci NOAE Applic Expos Hydro Speci LOAE	es EL cation Route sure time arks <b>lose:</b> es EL cation Route sure time <b>ochlorothiazide:</b> es EL	: 2, : O : 2 <sup>2</sup> : N : R : P : In : 90 : R : 10	000 mg/kg ral 4 Months o significant a at = 9,000 mg/k gestion 0 Days at, male and 0 mg/kg	g
Speci NOAE Applic Expos Rema Speci NOAE Applic Expos Hydro Speci LOAE Applic	es EL cation Route sure time arks <b>lose:</b> es EL cation Route sure time <b>ochlorothiazide:</b> es EL cation Route	: 2, : O : 2 <sup>4</sup> : N : N : R : N : 90 : R : 10 : 0	000 mg/kg ral 4 Months o significant a at = 9,000 mg/k gestion ) Days at, male and ) mg/kg ral	g
Speci NOAE Applic Expos Rema Speci NOAE Applic Expos Speci LOAE Applic Expos	es EL cation Route sure time arks <b>lose:</b> es EL cation Route sure time <b>ochlorothiazide:</b> es EL	: 2, : O : 2 <sup>4</sup> : N : N : R : N : 90 : R : 10 : 0 : 2	000 mg/kg ral 4 Months o significant a at = 9,000 mg/k gestion ) Days at, male and ) mg/kg ral	g female
Speci NOAE Applic Expos Rema Speci NOAE Applic Expos Hydro Speci LOAE Applic Expos Targe	es EL cation Route sure time arks <b>lose:</b> es EL cation Route sure time <b>ochlorothiazide:</b> es EL cation Route sure time es ture time es to Organs es	: 2, : O : 2 <sup>4</sup> : N : N : R : N : 90 : 90 : 0 : 2 : Ki : M	000 mg/kg ral 4 Months o significant a at = 9,000 mg/k gestion 0 Days at, male and 0 mg/kg ral yr idney, Parath ouse, male a	g female yroid gland nd female
Speci NOAE Applic Expos Rema Speci NOAE Applic Expos Speci LOAE Applic Expos Targe	es EL cation Route sure time arks <b>lose:</b> es EL cation Route sure time <b>ochlorothiazide:</b> es EL cation Route sure time et Organs es EL	: 2, : O : 2 <sup>4</sup> : N : N : N : N : N : 90 : 2 : Ki : 0 : 2 : Ki : M : 30	000 mg/kg ral 4 Months o significant a at = 9,000 mg/k gestion 0 Days at, male and 0 mg/kg ral yr idney, Parath ouse, male a 00 - 550 mg/k	g female yroid gland nd female
Speci NOAE Applic Expos Rema Speci NOAE Applic Expos Speci LOAE Applic Expos Targe Speci NOAE	es EL cation Route sure time arks <b>lose:</b> es EL cation Route sure time <b>ochlorothiazide:</b> es EL cation Route sure time es ture time es to Organs es	: 2, : O : 2 <sup>2</sup> : N : N : N : N : N : 90 : 10 : 90 : 2 : Ki : 0 : 2 : Ki : 30 : 30 : 0	000 mg/kg ral 4 Months o significant a at = 9,000 mg/k gestion 0 Days at, male and 0 mg/kg ral yr idney, Parath ouse, male a	g female yroid gland nd female



tion Route	:	Dog				
	-	50 - 200 mg/kg				
	:	Oral				
Exposure time		9 Months				
Organs	:	: Parathyroid gland				
ion toxicity						
ssified based on ava	ilable	information.				
onents:						
hlorothiazide:						
ration toxicity classif	fication					
ence with human e	xposı	ıre				
onents:						
artan:						
ntact	:	Symptoms: Eye i	rritation			
n	:	Symptoms: hypot Remarks: May ca Based on Humar	ause harm to the unborn child.			
hlorothiazide:						
ntact	:	Symptoms: Eye i	rritation			
n	:		ness, Headache, Fatigue, Nausea, Ab- potension, dry mouth, electrolyte imbalance			
	ssified based on ava ments: hlorothiazide: ration toxicity classif ence with human en ments: artan: htact on	ssified based on available nents: hlorothiazide: ration toxicity classificatio ence with human exposu nents: artan: htact : hlorothiazide: htact :	ssified based on available information. nents: hlorothiazide: ration toxicity classification ence with human exposure ments: artan: ntact : Symptoms: Eye i on : Symptoms: May ca Based on Human chlorothiazide: ntact : Symptoms: Eye i on : Symptoms: Eye i on : Symptoms: Eye i			

Ecotoxicity

Components:

#### Cellulose:

Toxicity to fish		LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Hydrochlorothiazide:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 500 mg/l Exposure time: 48 h



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Persi	istence and degrada	bility	
<u>Com</u>	ponents:		
	egradability	: Result: Read	dily biodegradable.
Hydr	ochlorothiazide:		
Stabi	lity in water	: Hydrolysis:	46.2 %(96 h)
	<b>ccumulative potentia</b> ata available	I	
	<b>lity in soil</b> ata available		
	rdous to the ozone la pplicable	ayer	
	<b>r adverse effects</b> ata available		

#### **13. DISPOSAL CONSIDERATIONS**

#### **Disposal methods**

Waste from residues Contaminated packaging	:	Dispose of in accordance with local regulations. 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.

### 14. TRANSPORT INFORMATION

#### International Regulations

**UNRTDG** Not regulated as a dangerous good

IATA-DGR Not regulated as a dangerous good

**IMDG-Code** Not regulated as a dangerous good

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

Not applicable for product as supplied.

#### **National Regulations**

Refer to section 15 for specific national regulation.



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

#### **Related Regulations**

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

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

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

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

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

Not applicable

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

Not applicable

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

Not applicable

#### Substances Subject to be Notified Names

Not applicable

#### Substances Subject to be Indicated Names

Not applicable

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

Not applicable

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

Not applicable

#### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

## Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

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

Not applicable

### Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof Not applicable



rsion	Revision Date: 2020/10/10	SDS N 402581	umber: I-00012	Date of last issue: 2020/03/23 Date of first issue: 2016/01/07						
-	Pressure Gas Safety	/ Act								
Explo	Explosive Control Law									
Not a	Not applicable									
Vesse	Vessel Safety Law									
Not re	egulated as a dangero	ous good								
Aviat	ion Law									
Not re	egulated as a dangero	ous good								
Marin	e Pollution and Sea	Disaster I	Prevention	etc Law						
Bulk t	ransportation	: Not	classified a	as noxious liquid substance						
Pack	transportation	: Not	classified a	as marine pollutant						
Narco	otics and Psychotro	pics Contr	ol Act							
	tic or Psychotropic R oplicable	aw Materia	l (Export / lı	nport Permission)						
	fic Narcotic or Psycho oplicable	otropic Raw	/ Material (E	xport / Import permission)						
	e Disposal and Publ trial waste	ic Cleansi	ng Law							
The c	omponents of this p	oroduct are	e reported	in the following inventories:						
AICS	-	: not	determined	-						
DSL		: not	determined	I						
IECS	<b>C</b>	: not	determined	1						

Further in	nformation
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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 Agen- cy, http://echa.europa.eu/	
Date format	:	yyyy/mm/dd	
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 Sys-



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tem; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China: IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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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