

according to Regulation (EC) No. 1907/2006

# **Olmesartan / Hydrochlorothiazide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	443567-00013	Date of first issue: 07.01.2016

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

### 1.1 Product identifier

Trade name : Olmesartan / Hydrochlorothiazide Formulation

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Pharmaceutical stance/Mixture

### 1.3 Details of the supplier of the safety data sheet

Company	:	Organon & Co. 30 Hudson Street, 33nd floor 07302 Jersey City, New Jersey, U.S.A
Telephone	:	551-430-6000
E-mail address of person responsible for the SDS	:	EHSSTEWARD@organon.com

### 1.4 Emergency telephone number

215-631-6999

## **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

Signal word

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

Hazard pictograms



2

2

Hazard statements	:	H360D May damage the unborn child. H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

## Prevention:

- P201 Obtain special instructions before use.
- P260 Do not breathe dust.
- P280 Wear protective gloves/ protective clothing/ eye protec-



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tion/ face protection.

### Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the 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.

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.

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 advice immediately.

## **SAFETY DATA SHEET** according to Regulation (EC) No. 1907/2006



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			When symptom advice.	ns persist or in all cases of doubt seek medical	
Protection of first-aiders		:	and use the red	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).	
lf inha	aled	:	If inhaled, remo Get medical att		
In case of skin contact		:	of water. Remove contar Get medical att Wash clothing	In case of contact, immediately flush skin with soap and pler of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.	
In cas	se of eye contact	:		well with water. ention if irritation develops and persists.	
If swallowed		:	Get medical att	O NOT induce vomiting. ention. oroughly with water.	
I.2 Most i	mportant symptom	s and o	effects, both ac	ute and delayed	
Risks		:		ne unborn child. nage to organs through prolonged or repeated	
			the skin.	ust can cause mechanical irritation or drying of it the eyes can lead to mechanical irritation.	
			Dust contact w	an the eyes can lead to mechanical initiation.	
	-	ate me		ind special treatment needed	
Treatment		:	Treat symptom	atically and supportively.	

5.1 Extinguishing media		
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.

## 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-	:	Avoid generating dust; fine dust dispersed in air in sufficient
fighting		concentrations, and in the presence of an ignition source is a



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Hazardous combustion prod- ucts		:	potential dust explosion hazard. Exposure to combustion products may be a hazard to hea Carbon oxides Nitrogen oxides (NOx) Chlorine compounds Sulphur oxides		
5.3 Advice for firefighters					
	Special for firef	protective equipment ighters	:		e, wear self-contained breathing apparatus. ective equipment.
	Specific ods	c extinguishing meth-	:	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

### 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).
6.2 Environmental precautions	
Environmental 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 spillages cannot be contained.</li> </ul>

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

	Methods for cleaning up	:	Sweep up or vacuum up spillage and collect in suitable con- tainer 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 surfac- es, as these may form an explosive mixture if they are re- leased 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 deter- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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### 6.4 Reference to other sections

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

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### **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 Do not get on skin or clothing. 1 Do not breathe dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment. If exposure to chemical is likely during typical use, provide eye Hygiene measures flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. 7.2 Conditions for safe storage, including 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	:	Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases
7.3 Specific end use(s)		
Specific use(s)	:	No data available

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## **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- 4	TWA	30 µg/m3 (OEB 3)	Internal
		Wipe limit	300 µg/100 cm²	Internal
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 equipment

Eye protection Hand 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.
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. Work uniform or laboratory coat. 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 Filter type	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to NS EN 143 Particulates type (P)

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

#### 9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	white to off-white

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	Odour Odour <sup>-</sup>	Threshold	:	No data available No data available	
	Melting	point/freezing point	:	No data available	)
		oiling point and boiling	:	No data available	9
	range Flamma	ability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.
	Flamma	ability (liquids)	:	No data available	)
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Flash p	oint	:	Not applicable	
	Auto-ig	nition temperature	:	No data available	)
		position temperature omposition tempera-	:	No data available	)
	рН		:	No data available	)
	Viscosi <sup>.</sup> Visc	ty osity, kinematic	:	Not applicable	
	Solubili Wat	ty(ies) er solubility	:	No data available	
	Partition octanol	n coefficient: n- /water	:	Not applicable	
		pressure	:	Not applicable	
	Relative	e density	:	No data available	
	Density	,	:	No data available	
	Relative	e vapour density	:	Not applicable	
		characteristics icle size	:	No data available	
		formation			
	Explosi		:	Not explosive	
	Oxidizir	ng properties	:	The substance or	r mixture is not classified as oxidizing.
	Evapor	ation rate	:	Not applicable	

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Molecular weight		:	Not applicable	9		
SECTION	10: Stability and	reactivi	ty			
<b>10.1 Reac</b> Not c	<b>tivity</b> lassified as a reactivit <sup>,</sup>	y hazard				
	nical stability e under normal condit	ions.				
10.3 Poss	ibility of hazardous	reaction	S			
	rdous reactions	:	May form exp dling or other	losive dust-air mixture during processing, han- means. n strong oxidizing agents.		
10.4 Cond	litions to avoid					
Cond	itions to avoid		Heat, flames a Avoid dust for			
	mpatible materials					
Mate	rials to avoid	:	Oxidizing agents			
10.6 Haza	rdous decompositio			nis		
No ha SECTION 11.1 Infor	Azardous decomposition 11: Toxicological mation on hazard cla nation on likely routes	n produ on produ inform asses as of : I	cts icts are known ation			
No ha SECTION 11.1 Infor Inforr expos	Azardous decomposition 11: Toxicological mation on hazard cla nation on likely routes	n produ on produ inform asses as of : I	cts acts are known ation s defined in F nhalation Skin contact ngestion	٦.		
No ha SECTION 11.1 Infor Inforr expose Acute	Azardous decomposition 11: Toxicological mation on hazard cla nation on likely routes sure	n produ on produ inform asses as of : li S li E	cts acts are known ation s defined in F nhalation Skin contact ngestion Eye contact	٦.		
No ha SECTION 11.1 Infor Inforr expose Acute Not c <u>Prod</u>	Azardous decomposition A 11: Toxicological mation on hazard cla nation on likely routes sure e toxicity lassified based on ava	in produ on produ inform asses as of : li S il E ailable in : A	cts acts are known ation s defined in F nhalation Skin contact ngestion Eye contact formation.	٦.		
No ha SECTION 11.1 Infor Inforr expose Acute Not c Prod Acute	Azardous decomposition N 11: Toxicological mation on hazard cla nation on likely routes sure e toxicity lassified based on ava uct:	in produ on produ inform asses as of : li S il E ailable in : A	cts acts are known ation s defined in F nhalation Skin contact ngestion Eye contact formation.	n. Regulation (EC) No 1272/2008 estimate: > 2.000 mg/kg		
No ha SECTION 11.1 Infor Inforr expose Acute Not c Prod Acute	Azardous decomposition N 11: Toxicological mation on hazard cla nation on likely routes sure e toxicity lassified based on ava uct: e oral toxicity	in produ on produ inform asses as of : li S il E ailable in : A	cts acts are known ation s defined in F nhalation Skin contact ngestion Eye contact formation.	n. Regulation (EC) No 1272/2008 estimate: > 2.000 mg/kg		
No ha SECTION 11.1 Infor Inforr expose Acute Not c Prod Acute Olme	Azardous decomposition A 11: Toxicological mation on hazard cla nation on likely routes sure e toxicity lassified based on avain uct: e oral toxicity ponents:	n produ on produ <b>inform</b> asses as of : II S ili E ailable in : <i>A</i>	cts acts are known ation s defined in F nhalation Skin contact ngestion Eye contact formation.	estimate: > 2.000 mg/kg lation method		
No ha SECTION 11.1 Infor Inforr expose Acute Not c Prod Acute Olme	Azardous decomposition A 11: Toxicological mation on hazard cla nation on likely routes sure e toxicity lassified based on ava uct: e oral toxicity ponents: esartan:	n produ on produ inform asses as of : II S ailable in : A N	cts icts are known ation s defined in R nhalation Skin contact ngestion Eye contact formation. Acute toxicity e Acute toxicity e Acute toxicity e	estimate: > 2.000 mg/kg lation method		
No ha SECTION 11.1 Infor Inforr expose Acute Not c Prod Acute Olme	Azardous decomposition A 11: Toxicological mation on hazard cla nation on likely routes sure e toxicity lassified based on ava uct: e oral toxicity ponents: esartan:	in produ on produ inform asses as of : I E ailable in : A M	cts icts are known ation s defined in R nhalation Skin contact ngestion Eye contact formation. Acute toxicity e Acute toxicity e Acute toxicity e	n. Regulation (EC) No 1272/2008 estimate: > 2.000 mg/kg lation method 2.000 mg/kg : > 2.000 mg/kg		

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Acut	e dermal toxicity	:	Remarks: No data	a available
Hydı	rochlorothiazide:			
Acut	e oral toxicity	:	LD50 (Rat): > 2.7	50 mg/kg
			LD50 (Mouse): > 2	2.830 mg/kg
	e toxicity (other routes of inistration)	:	LD50 (Rat): 990 n Application Route	
			LD50 (Mouse): 59 Application Route	
-	corrosion/irritation	ble	information.	
Com	ponents:			
Olm	esartan:			
Rem	arks	:	No data available	
Hydı	rochlorothiazide:			
Spec		:	Rabbit	
Resu	ılt	:	No skin irritation	
	ous eye damage/eye irri			
Not o	classified based on availa	ble	information.	
<u>Com</u>	ponents:			
Olm	esartan:			
Spec		:	Rabbit	
Meth		:	Draize Test	- 41 - 11
Resu	lit	:	Moderate eye irrit	ation
Hydı	rochlorothiazide:			
Spec		:	Rabbit	
Resu	ılt	:	Mild eye irritation	
Resp	piratory or skin sensitis	atic	n	
Skin	sensitisation			
Not o	classified based on availa	ble	information.	
-	<b>biratory sensitisation</b> classified based on availa	ble	information.	
<u>Com</u>	ponents:			
	esartan:			
	osure routes	:	Skin contact	

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ersion 5	Revision Date: 09.04.2021		OS Number: 3567-00013	Date of last issue: 10.10.2020 Date of first issue: 07.01.2016					
Rema	Remarks		: No data available						
Not cla	cell mutagenicity assified based on availa	able	information.						
Olmor	sartan:								
	oxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)					
			Test Type: Mutag Result: negative	enicity (in vitro mammalian cytogenetic test					
				nosome aberration test in vitro nese hamster lung cells					
			Test Type: Mouse Result: negative	e Lymphoma					
Genot	oxicity in vivo	:	Test Type: Micror Species: Mouse Cell type: Bone m Application Route Result: negative	arrow					
Germ sessm	cell mutagenicity- As- nent	:	Weight of evidend cell mutagen.	ce does not support classification as a gern					
Hvdro	ochlorothiazide:								
-	oxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)					
				nosomal aberration nese hamster ovary cells					
				chromatid exchange assay nese hamster ovary cells					
			Test Type: in vitro Test system: mou Result: positive	o assay ise lymphoma cells					
Genot	oxicity in vivo	:	Test Type: Chron Species: Chinese Cell type: Bone m Result: negative						
			Test Type: in vivo Species: Mouse	assay					



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			Cell type: Bone Result: negative	
Germ sessr	n cell mutagenicity- As- nent	:	Weight of evide cell mutagen.	ence does not support classification as a germ
	<b>inogenicity</b> lassified based on avai	lable	information.	
Com	ponents:			
Olme	esartan:			
	cation Route sure time	: : :	Rat Oral 2 Years negative	
	cation Route sure time	:	Mouse Oral 6 Months negative	
Hydr	ochlorothiazide:			
	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 f Oral 2 Years negative	emale
Repr	oductive toxicity			
-	damage the unborn chil	ld.		
<u>Com</u>	ponents:			
	esartan: ts on fertility	:	Test Type: Fert Species: Rat Application Rou Fertility: NOAEI Result: No effect	ite: Oral L: 1.000 mg/kg body weight
Effect ment	ts on foetal develop-	:	Test Type: Dev Species: Rat Application Rou	

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				Dose: 1000 milligi Result: No teratog	
				Test Type: Develo Species: Rabbit Application Route Dose: 1 milligram Result: No teratog	: Oral per kilogram
				Symptoms: Malfor weight	
	Reprod sessme	luctive toxicity - As- ent	:	Positive evidence human epidemiolo	of adverse effects on development from ogical studies.
	Hydroc	chlorothiazide:			
	-	on fertility	:	Test Type: Fertility Species: Rat, mai Application Route Fertility: NOAEL: A Result: Effects on	e and female : oral (feed) 4 mg/kg body weight
				Test Type: Fertility Species: Mouse, I Application Route Fertility: NOAEL: Result: Effects on	male and female : oral (feed) 100 mg/kg body weight
	Effects ment	on foetal develop-	:	Test Type: Develor Species: Mouse Application Route Developmental To Result: No teratog	: Oral pxicity: NOAEL: 3.000 mg/kg body weight
				Test Type: Develo Species: Rat Application Route Developmental To Result: No teratoo	: Oral oxicity: NOAEL: 1.000 mg/kg body weight

## STOT - single exposure

Not classified based on available information.

## STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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<u>(</u>	Compo	onents:			
I	Hydrod	chlorothiazide:			
	Target Assess	Organs ment	:	Kidney, Parathyro Causes damage t exposure.	oid gland to organs through prolonged or repeated
F	Repeat	ted dose toxicity			
<u>(</u>	Compo	onents:			
(	Olmes	artan:			
1 / E		- ition Route ire time		Rat 2.000 mg/kg Oral 24 Months No significant adv	verse effects were reported
I	Hydrod	chlorothiazide:			
L F 	Exposu Target Specie NOAEL Applica	tion Route re time Organs s - ition Route ure time		Rat, male and fer 10 mg/kg Oral 2 yr Kidney, Parathyro Mouse, male and 300 - 550 mg/kg Oral 2 yr No significant adv	pid gland
S	Specie	S	:	Dog 50 - 200 mg/kg	
E	Exposi	ition Route ire time Organs	:	Oral 9 Months Parathyroid glanc	l
	-	<b>tion toxicity</b> ssified based on availa	ble	information	
			adie	information.	
<u>-</u>		onents:			

### Hydrochlorothiazide:

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



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				7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.
Exp	erience with human exp	osi	ıre	
<u>Com</u>	ponents:			
Olm	esartan:			
	contact stion	:	Symptoms: Eye in Symptoms: hypot Remarks: May ca Based on Human	ension use harm to the unborn child.
Hyd	rochlorothiazide:			
	contact stion	:	Symptoms: Eye irritation Symptoms: Dizziness, Headache, Fatigue, Nausea, Ab- dominal pain, hypotension, dry mouth, electrolyte imbalance eye pain	
SECTIO	N 12: Ecological infor	rma	ntion	
12.1 Tox	icity			
	iponents:			
-	rochlorothiazide: city to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): > 500 mg/l 5 h
	city to daphnia and other atic invertebrates	:	EC50 (Daphnia m Exposure time: 48	nagna (Water flea)): > 500 mg/l 3 h
12.2 Pers	sistence and degradabil	ity		
Con	ponents:			
Hyd	rochlorothiazide:			
Stab	ility in water	:	Hydrolysis: 46,2 9	%(96 h)
	accumulative potential lata available			
	<b>ility in soil</b> lata available			
12.5 Res	ults of PBT and vPvB as	sse	ssment	
Proc	luct:			
Asse	essment	:	to be either persis	ixture contains no components considered stent, bioaccumulative and toxic (PBT), or id very bioaccumulative (vPvB) at levels of
			14/40	

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### 12.6 Other adverse effects

### Product:

<u>I Toudot:</u>		
Endocrine disrupting poten- tial	:	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	:	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.
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 or ID number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

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 Maritime transport in bulk according to IMO instruments

Remarks

: Not applicable 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 : Not applicable the market and use of certain dangerous substances, preparations and articles (Annex XVII)



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	H - Candidate List of S ern for Authorisation (A	•	igh	:	Not applicable
	H - List of substances	subject to authorisati	on	:	Not applicable
```	x XIV) ation (EC) No 1005/20	00 on aubstances the	t do		Notappliashla
0	he ozone layer		ii de-	•	Not applicable
Regula	ation (EU) 2019/1021 recast)	on persistent organic	pollu-	:	Not applicable
Regula ment a	ation (ÉC) No 649/201 and the Council conce gerous chemicals	•		:	Not applicable
Seves	o III: Directive 2012/1	R/ELL of the European	Parliame	ant	and of the Council on the control of

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:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

### 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	:	Harmful if swallowed.

H302	: Harmful if swallowed.
H319	: Causes serious eye irritation.
H360D	: May damage the unborn child.
H372	: Causes damage to organs through prolonged or repeated
	exposure.

### Full text of other abbreviations

Acute Tox. :	Acute toxicity
Eye Irrit. :	Eye irritation
Repr. :	Reproductive toxicity
STOT RE :	Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for



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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; 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	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/	
Classification of the mixture	<b>e</b> :		Classification procedure:
Repr. 1A	H3(	60D	Calculation method
STOT RE 2	H3	73	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.

NO / EN

according to Regulation (EC) No. 1907/2006



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