

Version 2.15	Revision Date: 09.04.2021		DS Number: 615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
SECTION	1: Identification of	the	substance/mixt	ure and of the company/undertaking
1.1 Produc Trade		:	Mometasone Sus	pension Formulation
1.2 Releva	nt identified uses of t	he s	substance or mixtu	ure and uses advised against
	the Sub- /Mixture	:	Pharmaceutical	
1.3 Details	of the supplier of the	saf	ety data sheet	
Compa	any	:	Organon & Co. 30 Hudson Street 07302 Jersey Cit	, 33nd floor y, New Jersey, U.S.A
Teleph	none	:	551-430-6000	
	address of person asible for the SDS	:	EHSSTEWARD@	organon.com
1.4 Emerge	ency telephone numb	er		

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Long-term (chronic) aquatic hazard, Category 2 H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

		10 1212/2000)
Hazard pictograms	:	¥2
Hazard statements	:	H411 Toxic to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P273 Avoid release to the environment.
		Response:

Response:

P391 Collect spillage.

2.3 Other hazards

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



Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.15	09.04.2021	23615-00018	Date of first issue: 21.10.2014

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Mometasone	83919-23-7	Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity):	>= 0,025 - < 0,1
Benzalkonium chloride	8001-54-5	100Acute Tox. 3; H301Acute Tox. 2; H330Acute Tox. 3; H311Skin Corr. 1; H314Eye Dam. 1; H318Aquatic Acute 1;H400Aquatic Chronic 2;H411M-Factor (Acute aquatic toxicity):100	>= 0,0025 - < 0,025

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

Protection of first-aiders	: No special precautions are necessary for first aid responders.
If inhaled	: If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	: Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.



Version 2.15	Revision Date: 09.04.2021		OS Number: 615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
	t important symptoms a ne known.	nd e	effects, both act	ute and delayed
4.3 Indie	cation of any immediate	med	dical attention a	nd special treatment needed
Tre	atment	:	Treat symptom	atically and supportively.
SECTIO	ON 5: Firefighting mea	sur	es	
5.1 Exti	nguishing media			
Sui	table extinguishing media	:	Water spray Alcohol-resistar Carbon dioxide Dry chemical	
Uns	suitable extinguishing dia	:	None known.	
5.2 Spe	cial hazards arising from	n the	e substance or i	nixture
•	ecific hazards during fire- ting	:	Exposure to co	mbustion products may be a hazard to health.
Haz	zardous combustion prod- s	:	Carbon oxides	
5.3 Adv	ice for firefighters			
	ecial protective equipment firefighters	:		ained breathing apparatus for firefighting if nec- rsonal protective equipment.
Spe ods	ecific extinguishing meth-	:	cumstances an Use water spra	ng measures that are appropriate to local cir- d the surrounding environment. y to cool unopened containers. naged containers from fire area if it is safe to do

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	: Follow safe handling advice (see section 7) and personal pro- tective 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. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
	3 / 20



Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.15	09.04.2021	23615-00018	Date of first issue: 21.10.2014

6.3 Methods and material for containment and cleaning up

I	Methods for cleaning up	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contain- ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor- bent. 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.
			certain local or national requirements.

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

7.1 Precautions for sale handling	J	
Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami- nated 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, i	inc	luding any incompatibilities
Requirements for storage areas and containers	:	Keep in properly labelled containers. Store in accordance with the particular national regulations.
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents
7.3 Specific end use(s)		
Specific use(s)	:	No data available



Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.15	09.04.2021	23615-00018	Date of first issue: 21.10.2014

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis		
Glycerine	56-81-5	TWA OEL-RL (Mist)	10 mg/m3	ZA OEL		
	Further inform	nation: Recommende	ed Limit			
Cellulose	9004-34-6 TWA OEL-R (Respirable of		5 mg/m3	ZA OEL		
	Further inform	Further information: Recommended Limit				
		TWA OEL-RL 10 mg/m3 ZA OEL (inhalable dust)				
	Further inform	Further information: Recommended Limit				
		STEL OEL-RL 20 mg/m3 ZA OEL (Dust)				
	Further information: Recommended Limit					
Mometasone	83919-23-7	TWA	1 µg/m3 (OEB 4)	Internal		
	Further information: Skin					
		Wipe limit	10 µg/100 cm²	Internal		

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health ef-	Value
			fects	
Glycerine	Workers	Inhalation	Long-term local ef-	56 mg/m3
-			fects	
	Consumers	Ingestion	Long-term systemic	229 mg/kg
			effects	bw/day
	Consumers	Inhalation	Long-term local ef-	33 mg/m3
			fects	-

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Glycerine	Fresh water	0,885 mg/l
	Marine water	0,0885 mg/l
	Intermittent use/release	8,85 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	3,3 mg/kg dry weight (d.w.)
	Marine sediment	0,33 mg/kg dry weight (d.w.)
	Soil	0,141 mg/kg dry weight (d.w.)

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. Essentially no open handling permitted.



Version 2.15	Revision Date: 09.04.2021		OS Number: 615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
lf har tainm		e a p al ex	roperly designed b	nologies. iosafety cabinet, fume hood, or other con- ion. If this potential does not exist, handle
Pers	onal protective equipn	nent		
Eye	protection	:	If the work enviro mists or aerosols Wear a faceshiel	ses with side shields or goggles. nment or activity involves dusty conditions, , wear the appropriate goggles. d or other full face protection if there is a et contact to the face with dusts, mists, or
Hand	d protection			
М	aterial	:	Chemical-resistar	nt gloves
	emarks and body protection	:	being performed suits) to avoid exp	aboratory coat. arments should be used based upon the task (e.g., sleevelets, apron, gauntlets, disposable bosed skin surfaces. legowning techniques to remove potentially
Resp	iratory protection	:	If adequate local sure assessment	exhaust ventilation is not available or expo- demonstrates exposures outside the rec- lines, use respiratory protection.
Fi	lter type	:		lates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

information on basic physical	rand chemical properties
Appearance Colour Odour Odour Threshold	 liquid white to off-white, opaque odourless No data available
рН	: 4,3 - 4,9
Melting point/freezing point	: No data available
Initial boiling point and boiling	: No data available
range Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available

SAFETY DATA SHEET



Mometasone Suspension Formulation

Version 2.15	Revision Date: 09.04.2021	SDS Number: 23615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
Rel	ative vapour density	: No data av	ailable
Relative density		: No data av	ailable
Density		: 1 g/cm ³	
Par octa Aut Dec Viso	ubility(ies) Water solubility tition coefficient: n- anol/water o-ignition temperature composition temperature cosity Viscosity, kinematic losive properties dizing properties	 soluble Not applica No data av No data av No data av No data av Not data av Not explos The substa 	ailable ailable ailable
9.2 Othe	er information		
Flai	nmability (liquids)	: No data av	ailable
Mol	ecular weight	: Not applica	ble
Par	ticle size	: Not applica	ble

SECTION 10: Stability and reactivity

10.1	Reactivity Not classified as a reactivity haz	zaro	d.	
10.2	Chemical stability Stable under normal conditions.			
10.3	Possibility of hazardous reac	tio	ns	
	Hazardous reactions	:	Can react with strong oxidizing agents.	
10.4	Conditions to avoid			
	Conditions to avoid	:	None known.	
10.5	i Incompatible materials			
	Materials to avoid	:	Oxidizing agents	

10.6 Hazardous decomposition products

No hazardous decomposition products are known.



ersion 15	Revision Date: 09.04.2021		0S Number: 615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
	I 11: Toxicological in	for	mation	
1 Infor	nation on toxicologica	ا م	facts	
	nation on likely routes of			
	e toxicity assified based on availa	ble	information.	
Comp	oonents:			
	etasone: oral toxicity	:	LD50 (Rat): > 2	.000 mg/kg
			LD50 (Mouse):	> 2.000 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 3 Exposure time: Test atmospher Remarks: No m	4 h
			LC50 (Mouse): Exposure time: Test atmospher	4 h
	toxicity (other routes of istration)	:) mg/kg ite: Subcutaneous athing difficulties
Benza	alkonium chloride:			
Acute	oral toxicity	:	LD50 (Rat): 240) mg/kg
Acute	inhalation toxicity	:	Exposure time: Test atmospher Method: OECD Assessment: C	
Acute	dermal toxicity	:	LD50 (Rat, fem	ale): 704 mg/kg
	corrosion/irritation assified based on availa	ble	information.	
<u>Comp</u>	oonents:			
_	etasone:		D.11.1	
Speci Resul		:	Rabbit No skin irritatior	n

Benzalkonium chloride:

Revision Date:

09.04.2021

Version

2.15



Date of last issue: 16.10.2020 Date of first issue: 21.10.2014

Mometasone Suspension Formulation

SDS Number:

23615-00018

Species: HumanResult: Corrosive after 4 hours or less of exposure				
Serious eye damage/ey	e irritation			
Not classified based on a	vailable information.			
<u>Components:</u>				
Mometasone:				
Species	: Rabbit			
Result	: No eye irritation			
Benzalkonium chloride				
Species	: Rabbit			
Result	: Irreversible effects on the eye			
Respiratory or skin sen	sitisation			
Skin sensitisation				
Not classified based on a	vailable information.			
Respiratory sensitisation	n			
Not classified based on a	vailable information.			
Components:				
Mometasone:				
Test Type	: Maximisation Test			
Exposure routes	: Dermal			
Species Assessment	: Guinea pig : Does not cause skin sensitisation.			
Result	: negative			
Remarks	: The results of a test on guinea pigs showed this substance			
	be a weak skin sensitiser.			
Benzalkonium chloride				
Test Type	: Human repeat insult patch test (HRIPT)			
Exposure routes	: Skin contact			
Species	: Humans			
Result	: negative			
Germ cell mutagenicity				
Not classified based on a	vailable information.			
Components:				
Mometasone:				
Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative			
	Test Type: Chromosomal aberration			
	Test system: Chinese hamster lung cells			
	Result: negative			



Version 2.15	Revision Date: 09.04.2021	SDS Number: 23615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
		Test system Result: posit	Iouse Lymphoma
Genotoxicity in vivo		C C	/licronucleus test use Route: Oral
		Test Type: 0 Species: Ra Cell type: Bo Result: nega	one marrow
		Test Type: u Species: Ra Cell type: Liv Result: nega	ver cells
Germ sessr	n cell mutagenicity- As- ment	: Weight of ev cell mutager	ridence does not support classification as a germ
Benz	alkonium chloride:		
	otoxicity in vitro	: Test Type: E Result: nega	Bacterial reverse mutation assay (AMES)
		Method: OE Result: nega	n vitro mammalian cell gene mutation test CD Test Guideline 476 ttive ased on data from similar materials
		Method: OE Result: nega	Chromosome aberration test in vitro CD Test Guideline 473 ative ased on data from similar materials
Genc	otoxicity in vivo	cytogenetic Species: Mo Application I Method: OE Result: nega	use Route: Ingestion CD Test Guideline 474

Carcinogenicity

Not classified based on available information.



sion 5	Revision Date: 09.04.2021	SDS Number: 23615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
<u>Comp</u>	onents:		
Mome	etasone:		
Specie	29	: Rat	
•	ation Route	: Inhalation	
	sure time	: 2 Years	
Dose		: 0.067 mg/kg b	ody weight
Result	t	: negative	body weight
Specie	29	: Mouse	
	ation Route	: Inhalation	
	ure time	: 19 Months	
Dose		: 0.160 mg/kg b	body weight
Result	t	: negative	
Benza	alkonium chloride:		
Specie	es	: Rat	
•	ation Route	: Ingestion	
	ure time	: 2 Years	
Metho		: OECD Test G	uideline 453
Result		: negative	
Remai		-	a from similar materials
Specie	29	: Mouse	
	ation Route	: Skin contact	
	sure time	: 80 weeks	
Result		: negative	
Specie	<u>-</u>	: Rabbit	
•	ation Route	: Skin contact	
	sure time	: 90 weeks	
Result		: negative	
Repro	oductive toxicity		
Not cla	assified based on ava	ilable information.	
Not cla <u>Comp</u>	assified based on ava ponents:	ilable information.	
Not cla <u>Comp</u>	assified based on ava	ilable information.	
Not cla <u>Comp</u> Mome	assified based on ava ponents:	ilable information. : Test Type: Fe	rtility
Not cla <u>Comp</u> Mome	assified based on ava ponents: etasone:	: Test Type: Fe	rtility
Not cla <u>Comp</u> Mome	assified based on ava ponents: etasone:	: Test Type: Fe Species: Rat	
Not cla <u>Comp</u> Mome	assified based on ava ponents: etasone:	: Test Type: Fe Species: Rat Application Ro	oute: Subcutaneous
Not cla <u>Comp</u> Mome	assified based on ava ponents: etasone:	: Test Type: Fe Species: Rat Application Ro Fertility: NOAl	bute: Subcutaneous EL: 0,015 mg/kg body weight
Not cla <u>Comp</u> Mome	assified based on ava ponents: etasone:	: Test Type: Fe Species: Rat Application Ro Fertility: NOAI Symptoms: Ro	oute: Subcutaneous
Not cla <u>Comp</u> Mome	assified based on ava ponents: etasone:	: Test Type: Fe Species: Rat Application Ro Fertility: NOAI Symptoms: Ro weight	oute: Subcutaneous EL: 0,015 mg/kg body weight educed embryonic survival, Reduced foetal
Not cla <u>Comp</u> Mome Effects	assified based on ava ponents: etasone: s on fertility	: Test Type: Fe Species: Rat Application Ro Fertility: NOAI Symptoms: Ro weight Result: No eff	oute: Subcutaneous EL: 0,015 mg/kg body weight educed embryonic survival, Reduced foetal ects on fertility, Effect on reproduction capac
Not cla <u>Comp</u> Mome Effects	assified based on ava ponents: etasone:	: Test Type: Fe Species: Rat Application Ro Fertility: NOAI Symptoms: Ro weight Result: No eff : Test Type: En	bute: Subcutaneous EL: 0,015 mg/kg body weight educed embryonic survival, Reduced foetal ects on fertility, Effect on reproduction capac nbryo-foetal development
Not cla <u>Comp</u> Mome Effects	assified based on ava ponents: etasone: s on fertility	 Test Type: Fe Species: Rat Application Ro Fertility: NOAI Symptoms: Ro weight Result: No eff Test Type: En Species: Mou 	oute: Subcutaneous EL: 0,015 mg/kg body weight educed embryonic survival, Reduced foetal ects on fertility, Effect on reproduction capac nbryo-foetal development se
Not cla <u>Comp</u> Mome Effects	assified based on ava ponents: etasone: s on fertility	 Test Type: Fe Species: Rat Application Ro Fertility: NOAI Symptoms: Ro weight Result: No eff Test Type: En Species: Mou Application Ro 	bute: Subcutaneous EL: 0,015 mg/kg body weight educed embryonic survival, Reduced foetal ects on fertility, Effect on reproduction capac nbryo-foetal development se bute: Subcutaneous
Not cla <u>Comp</u> Mome Effects	assified based on ava ponents: etasone: s on fertility	 Test Type: Fe Species: Rat Application Ro Fertility: NOAI Symptoms: Ro weight Result: No eff Test Type: En Species: Mou Application Ro Embryo-foetal 	oute: Subcutaneous EL: 0,015 mg/kg body weight educed embryonic survival, Reduced foetal ects on fertility, Effect on reproduction capac nbryo-foetal development se



Version 2.15	Revision Date: 09.04.2021	SDS Number: 23615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
		Species: Ra Application F Embryo-foet	Embryo-foetal development t Route: Dermal al toxicity: LOAEL: 0,3 mg/kg body weight ryo-foetal toxicity
		Species: Ra Application F Embryo-foet	Embryo-foetal development bbit Route: Dermal al toxicity: LOAEL: 0,15 mg/kg body weight ryo-foetal toxicity, Malformations were observed.
		Species: Ra Application F Embryo-foet	Embryo-foetal development t Route: Subcutaneous al toxicity: LOAEL: 0,15 mg/kg body weight cts on newborn
		Species: Ra Application F Embryo-foet	
Repro sessr	oductive toxicity - As- nent	animal expe	nce of adverse effects on development, based on riments., Some evidence of adverse effects on ion and fertility, based on animal experiments.
Benz	alkonium chloride:		
Effec	ts on fertility	Species: Ra Application F Method: OE Result: nega	Route: Ingestion CD Test Guideline 416
Effec ment	ts on foetal develop-	Species: Ra Application F Method: OE Result: nega	Route: Ingestion CD Test Guideline 414
	Γ - single exposure lassified based on avail	able information.	
Com	ponents:		
Mom	etasone:		
_			

Remarks

: Based on available data, the classification criteria are not met.

STOT - repeated exposure

Not classified based on available information.



sion	Revision Date: 09.04.2021	SDS Number: 23615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
<u>Comp</u>	onents:		
Mome	etasone:		
Expos	ure routes	: inhalation (dus	t/mist/fume)
Target Organs			n, Liver, Kidney, Skin
Asses	sment	: May cause dar exposure.	nage to organs through prolonged or repea
Benza	alkonium chloride:		
Assessment		: No significant h tions of 100 mg	health effects observed in animals at conce /kg bw or less.
Repea	ated dose toxicity		
<u>Comp</u>	onents:		
	etasone:		
Specie		: Rat	
NOAE		: 0,005 mg/kg	
	L ation Route	: 0,3 mg/kg : Oral	
	ure time	: 30 d	
	t Organs		Liver, Adrenal gland, Skin, thymus gland
Specie		: Dog	
LOAE		: 0,5 mg/kg	
	ation Route	: Oral : 30 d	
	ure time t Organs		Liver, Adrenal gland, Skin, thymus gland
-	-		
Specie		: Rat	
NOAE		: 0,00013 mg/l	
	ation Route ure time	: inhalation (dus	/mist/iume)
	t Organs		Lungs, Lymph nodes, spleen, Bone marrow
3-		Kidney, Liver, t	
Specie		: Dog	
NOAE		: 0,0005 mg/l	(mint/fuma)
	ation Route ure time	: inhalation (dus : 90 d	//IIIS/IUIIIE)
	t Organs		Lungs, Lymph nodes, spleen, Bone marrow
raige	ergano	Kidney, thymus	
Benza	alkonium chloride:		
Specie	es	: Rat	
NOAE		: >= 100 mg/kg	
	ation Route	: Ingestion	
Expos	ure time	: 12 Weeks	

Not classified based on available information.



Version 2.15	Revision Date: 09.04.2021	SDS Number: 23615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014				
<u>Com</u>	ponents:						
Mom	Mometasone:						
Not a	pplicable						
Expe	rience with human ex	posure					
<u>Com</u>	ponents:						
Mom	etasone:						
Inhal	ation	piratory tra	allergic rhinitis, Headache, pharyngitis, upper res- tot infection, sinusitis, oral candidiasis, Back pain, eletal pain, immune system effects, indigestion				
Skin	contact		: Dermatitis, Itching				
Furth	ner information						
<u>Com</u>	ponents:						
Mom Rema	etasone:	: Dermal ab	sorption possible				
T C I I C		. Dennarab					

SECTION 12: Ecological information

12.1 Toxicity

Components:		
Mometasone:		
Toxicity to fish	:	LC50 (Menidia beryllina (Silverside)): 0,11 mg/l Exposure time: 96 h Remarks: No toxicity at the limit of solubility
		LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l Exposure time: 7 d Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
		EC50 (Americamysis): > 5 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 3,2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to microorganisms	:	EC50 : > 1.000 mg/l



Vers 2.15		Revision Date: 09.04.2021		9S Number: 615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
				Exposure time: 3 Test Type: Respir Method: OECD To Remarks: No toxid	ration inhibition
				NOEC : 1.000 mg Exposure time: 3 Test Type: Respir Method: OECD To Remarks: No toxic	h ration inhibition
	Toxicity icity)	to fish (Chronic tox-	:	NOEC: 0,00014 n Exposure time: 32 Species: Pimepha Method: OECD Te	2 d ales promelas (fathead minnow)
		to daphnia and other invertebrates (Chron- ty)	:	Method: OECD To	magna (Water flea)
	M-Facto toxicity)	or (Chronic aquatic	:	100	
	Benzal Toxicity	konium chloride: ^r to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): 0,28 mg/l 5 h
		r to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48	nagna (Water flea)): 0,0056 mg/l 3 h
	Toxicity plants	to algae/aquatic	:	ErC50 (Chlorella Exposure time: 72	pyrenoidosa (aglae)): 0,09 mg/l 2 h
	M-Facto icity)	or (Acute aquatic tox-	:	100	
	Toxicity icity)	to fish (Chronic tox-	:	NOEC: 0,032 mg/ Exposure time: 34 Species: Pimepha	
12.2	Persist	ence and degradabil	ity		
	<u>Compo</u>	onents:			
	Momet a Biodegr	asone: radability	:	Result: Not readily Biodegradation: 5 Exposure time: 28 Method: OECD To	50 % 3 d
	Stability	in water	:	Hydrolysis: 50 %(Method: OECD Te	



09.04.2021	23	615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
I konium chloride: gradability	:		biodegradable. Fest Guideline 301D I on data from similar materials
cumulative potential			
onents:			
tasone:			
cumulation	:	Bioconcentration	is macrochirus (Bluegill sunfish) i factor (BCF): 107,1 Fest Guideline 305
on coefficient: n- l/water	:	log Pow: 4,68	
Ikonium chloride:			
cumulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): < 500 on data from similar materials
on coefficient: n- I/water	:	log Pow: 1,692 Remarks: Calcul	ation
ity in soil			
onents:			
tasone:			
ution among environ- l compartments	:	log Koc: 4,02	
ts of PBT and vPvB a	sse	ssment	
<u>ct:</u> sment	:	to be either persi	nixture contains no components considered istent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
adverse effects			
<u>ct:</u>			
rine disrupting poten-	:	ered to have end REACH Article 5	hixture does not contain components consid- locrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.
	cumulative potential onents: tasone: cumulation on coefficient: n- l/water lkonium chloride: cumulation on coefficient: n- l/water ity in soil onents: tasone: ution among environ- l compartments ts of PBT and vPvB as ct: sment adverse effects ct:	gradability : cumulative potential onents: tasone: cumulation cumu	gradability : Result: Readily b Method: OECD T Remarks: Based cumulative potential onents: tasone: sumulation : Species: Lepomi Bioconcentration Method: OECD T on coefficient: n- il/water ilkonium chloride: sumulation : Species: Lepomi Bioconcentration Remarks: Based on coefficient: n- ilywater : log Pow: 4,68 ibioconcentration Remarks: Based on coefficient: n- ilywater : log Pow: 1,692 Remarks: Calcul ity in soil onents: tasone: ution among environ- compartments : ts of PBT and vPvB assessment ct: sment : This substance/r to be either pers very persistent a 0.1% or higher. adverse effects ct: rine disrupting poten- : The substance/n ered to have end REACH Article 5 (EU) 2017/2100

SECTION 13: Disposal considerations

13.1 Waste treatment methods



Version 2.15	Revision Date: 09.04.2021		OS Number: 615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
Product Contaminated packaging		:	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. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	
SECTION	I 14: Transport infor	mat	,	· · ·
14.1 UN n	umber			
ADN			UN 3082	
ADR			UN 3082	
RID		÷	UN 3082	
IMDG	i		UN 3082	
IATA			UN 3082	
	roper shipping name	•	0110002	
ADN	1 11 0	:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
ADR		:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
RID		:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
IMDG	i	:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
ΙΑΤΑ		:	Environmentally h	nazardous substance, liquid, n.o.s. enzalkonium chloride)
14.3 Trans	sport hazard class(es)			
ADN		:	9	
ADR		:	9	
RID		:	9	
IMDG	i	:	9	
ΙΑΤΑ		:	9	
14.4 Pack	ing group			
Class	ng group ification Code rd Identification Number s	:	III M6 90 9	



Versi 2.15		Revision Date: 09.04.2021		9S Number: 615-00018	Date of last issue: 16.10.2020 Date of first issue: 21.10.2014
	Hazard Labels	g group cation Code Identification Number restriction code		III M6 90 9 (-)	
		g group cation Code Identification Number	: : :	III M6 90 9	
	IMDG Packing Labels EmS Co		:	III 9 F-A, S-F	
	aircraft)	instruction (cargo	:	964 Y964 III Miscellaneous	
	Packing ger airc	instruction (LQ)	:	964 Y964 III Miscellaneous	
14.5	Enviro	nmental hazards			
	ADN Environ ADR	mentally hazardous	:	yes	
	RID	mentally hazardous mentally hazardous	:	yes	
	IMDG Marine	pollutant	:	yes	
	IATA (F	Passenger) mentally hazardous	:	yes	
	ΙΑΤΑ (Ο	-	:	yes	
14.6	Specia	I precautions for use	r		

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks

: Not applicable for product as supplied.



Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.15	09.04.2021	23615-00018	Date of first issue: 21.10.2014

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
IECSC	:	not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SEC	CTION 16: Other information	n	
	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		
	H301	:	Toxic if swallowed.
	H311	:	Toxic in contact with skin.
	H314	:	Causes severe skin burns and eye damage.
	H318	:	Causes serious eye damage.
	H330	:	Fatal if inhaled.
	H360Df	:	May damage the unborn child. Suspected of damaging fertili-
			ty.
	H373	:	May cause damage to organs through prolonged or repeated
	11400		exposure if inhaled.
	H400	:	Very toxic to aquatic life.
	H410	÷	Very toxic to aquatic life with long lasting effects.
	H411	÷	Toxic to aquatic life with long lasting effects.
	EUH071	÷	Corrosive to the respiratory tract.
	Full text of other abbreviation	าร	
	Acute Tox.	:	Acute toxicity
	Aquatic Acute	:	Short-term (acute) aquatic hazard
	Aquatic Chronic	:	Long-term (chronic) aquatic hazard
	Eye Dam.	:	Serious eye damage
	Repr.	:	Reproductive toxicity
	Skin Corr.	:	Skin corrosion
	STOT RE	:	Specific target organ toxicity - repeated exposure
	ZA OEL	:	South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
	ZA OEL / TWA OEL-RL	:	Long term occupational exposure limits - recommended limit
	ZA OEL / STEL OEL-RL	:	Short term occupational exposure limits - recommended limit
			· · ·

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 the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation;



Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.15	09.04.2021	23615-00018	Date of first issue: 21.10.2014

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

Classification of the mixture:

Aquatic Chronic 2 H411

Classification procedure: 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.

ZA / EN