

3.0	Revision D 2021/04/09			S Number: 597-00018	Date of last issue: 2020/10/16 Date of first issue: 2014/10/21
1. PROI	DUCT AND CO	MPANY IDE	NT	IFICATION	
Pro	oduct name		:	Mometasone	Suspension Formulation
Ма	nufacturer or s	upplier's de	etai	ils	
Co	mpany		:	Organon & Co).
Ade	dress		:	JL Raya Pano Pandaan, Jaw	laan KM. 48 /a Timur - Indonesia
Tel	lephone		:	551-430-6000	
Em	nergency telepho	one number	:	215-631-6999	1
E-r	nail address		:	EHSSTEWAR	D@organon.com
Re	commended us	se of the ch	em	ical and restri	ctions on use
Re	commended use	Ð	:	Pharmaceutic	al
	commended use		:	Pharmaceutic	al
2. HAZ	ARDS IDENTIFI	CATION	:	Pharmaceutic	
2. HAZA GH Lor		CATION n	:	Pharmaceutic Category 2	al
2. HAZA GH Lor haz	ARDS IDENTIFI	CATION n :) aquatic	:		al
2. HAZA GH Lor haz GH	ARDS IDENTIFI IS Classification ng-term (chronic zard	CATION n aquatic	:		al
2. HAZA GH Lor haz GH Ha: Sig	ARDS IDENTIFI IS Classification ng-term (chronic zard IS label elemen	CATION n aquatic	:	Category 2	al aquatic life with long lasting effects.
2. HAZA GH Lor haz GH Ha: Sig Ha:	ARDS IDENTIFI IS Classification ng-term (chronic zard IS label elemen zard pictograms	CATION n aquatic its	:	Category 2 Category 2 None H411 Toxic to Prevention:	
2. HAZA GH Lor haz GH Ha: Sig Ha:	ARDS IDENTIFI IS Classification ng-term (chronic zard IS label elemen zard pictograms gnal word zard statements	CATION n aquatic its	:	Category 2 Category 2 None H411 Toxic to Prevention: P273 Avoid re Response:	aquatic life with long lasting effects.
2. HAZA GH Lor haz GH Ha: Sig Ha:	ARDS IDENTIFI IS Classification ng-term (chronic zard IS label elemen zard pictograms gnal word zard statements	CATION n aquatic its	:	Category 2 Category 2 None H411 Toxic to Prevention: P273 Avoid re	aquatic life with long lasting effects.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

gency procedures



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Com	ponents				
	nical name			CAS-No.	Concentration (% w/w)
Cellu	lose			9004-34-6	< 10
Mom	etasone			83919-23-7	>= 0.025 -< 0.25
Benz	alkonium chloride			8001-54-5	>= 0.0025 -< 0.025
FIRST	AID MEASURES				
lf inha	aled	:		nove to fresh air. attention if symptoms	s occur.
In ca	se of skin contact	:	Wash with wa	iter and soap as a p ittention if symptoms	recaution.
In ca	se of eye contact	:	Flush eyes wi	th water as a precau	ution.
lf swa	Get medica			DO NOT induce vor ttention if symptoms thoroughly with wate	niting. s occur.
	important symptoms effects, both acute and red	:	None known.		
Prote	ction of first-aiders s to physician	:		ecautions are neces matically and suppo	sary for first aid responders. rtively.
FIREFI	GHTING MEASURES				
Suita	ble extinguishing media	:	Water spray Alcohol-resist Carbon dioxic Dry chemical		
Unsu media	itable extinguishing a	:	None known.		
Spec fightir	ific hazards during fire-	:	Exposure to c	combustion products	may be a hazard to health.
	rdous combustion prod-	:	Carbon oxide	S	
Spec ods	ific extinguishing meth-	:	cumstances a	hing measures that and the surrounding ray to cool unopene	
				amaged containers f	rom fire area if it is safe to do
•	ial protective equipment efighters	:	Wear self-cor essary.		paratus for firefighting if nec- nt.
	ENTAL RELEASE MEAS	SUF	RES		
	onal precautions, protec-			andling advice (see	section 7) and personal pro-
tive e	quipment and emer-	•		nent recommendatio	



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Mot	thods and materials for	barriers). Retain and disp Local authorities cannot be conta	ng over a wide area (e.g. by containment or oil ose of contaminated wash water. s should be advised if significant spillages nined. ert absorbent material.
	tainment and cleaning up	For large spills, ment to keep m be pumped, sto Clean up remain bent. Local or nationa posal of this ma employed in the mine which regu Sections 13 and	provide dyking or other appropriate contain- aterial from spreading. If dyked material can re recovered material in appropriate container. hing materials from spill with suitable absor- al regulations may apply to releases and dis- terial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. I 15 of this SDS provide information regarding hational requirements.
7. HAND	LING AND STORAGE		
Teo	chnical measures		g measures under EXPOSURE RSONAL PROTECTION section.
	al/Total ventilation		dequate ventilation.
Adv	vice on safe handling	practice, based sessment	dance with good industrial hygiene and safety on the results of the workplace exposure as- event spills, waste and minimize release to the
Cor	nditions for safe storage		y labelled containers. ance with the particular national regulations.
Mat	terials to avoid		h the following product types:

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	
Cellulose	9004-34-6	NAB	10 mg/m3	ID OEL
		TWA	10 mg/m3	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m3 (OEB 4)	Internal
	Further inform	ation: Skin		
		Wipe limit	10 µg/100 cm ²	Internal

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.
Use closed processing systems or containment technologies.
If handled in a laboratory, use a properly designed biosafety



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		tial exists fo	he hood, or other containment device if the poten- r aerosolization. If this potential does not exist, lined trays or benchtops.
Perse	onal protective equip	ment	
	iratory protection	sure assess ommended	local exhaust ventilation is not available or expo- ment demonstrates exposures outside the rec- guidelines, use respiratory protection. Particulates and organic vapour type
	I protection	. Combined p	
M	aterial	: Chemical-re	sistant gloves
	emarks protection	: Wear safety If the work e mists or aer Wear a face	puble gloving. glasses with side shields or goggles. environment or activity involves dusty conditions, osols, wear the appropriate goggles. eshield or other full face protection if there is a direct contact to the face with dusts, mists, or
Skin	and body protection	: Work uniforı Additional b task being p posable suit	m or laboratory coat. ody garments should be used based upon the performed (e.g., sleevelets, apron, gauntlets, dis- s) to avoid exposed skin surfaces. riate degowning techniques to remove potentially ed clothing.
Hygie	ene measures	: If exposure eye flushing ing place. When using Wash conta The effective engineering appropriate industrial hy	to chemical is likely during typical use, provide systems and safety showers close to the work- do not eat, drink or smoke. minated clothing before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, giene monitoring, medical surveillance and the nistrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	white to off-white, opaque
Odour	:	odourless
Odour Threshold	:	No data available
рН	:	4.3 - 4.9
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available



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Eva	poration rate		No data available	A
		•		
Flai	mmability (solid, gas)	÷	Not applicable	
Flai	mmability (liquids)	:	No data available	
	per explosion limit / Upper nmability limit	:	No data available)
	ver explosion limit / Lower nmability limit	:	No data available	
Vap	oour pressure	:	No data available	•
Rel	ative vapour density	:	No data available	2
Rel	ative density	:	No data available)
Der	nsity	:	1 g/cm ³	
	ubility(ies) Water solubility	:	soluble	
	tition coefficient: n- anol/water	:	Not applicable	
	o-ignition temperature	:	No data available	9
Dec	composition temperature	:	No data available)
	cosity Viscosity, kinematic	:	No data available	
Exp	losive properties	:	Not explosive	
Ovi	dizing properties		The substance of	mixture is not classified as oxidizing.
		•		
Mo	ecular weight	:	Not applicable	
Par	ticle size	:	Not applicable	

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
	:	Can react with strong oxidizing agents.
tions		
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION



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	mation on likely routes of osure	:	Inhalation Skin contact Ingestion Eye contact	
	te toxicity classified based on availa	ble	information.	
Com	nponents:			
Cell	ulose:			
Acut	e oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
Acut	e inhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere:	h
Acut	e dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
Mon	netasone:			
Acut	e oral toxicity	:	LD50 (Rat): > 2,00	00 mg/kg
			LD50 (Mouse): > 2	2,000 mg/kg
Acut	e inhalation toxicity	:	LC50 (Rat): > 3.3 Exposure time: 4 Test atmosphere: Remarks: No mor	h
			LC50 (Mouse): > 3 Exposure time: 4 Test atmosphere:	h
	e toxicity (other routes of inistration)	:	LD50 (Rat): 300 m Application Route Symptoms: Breath	Subcutaneous
Ben	zalkonium chloride:			
Acut	e oral toxicity	:	LD50 (Rat): 240 m	ng/kg
Acut	e inhalation toxicity	:		h dust/mist
Acut	e dermal toxicity	:	LD50 (Rat, female	e): 704 mg/kg

Skin corrosion/irritation

Not classified based on available information.



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<u>Com</u> p	oonents:			
Mome	etasone:			
Speci		·Ra	bbit	
Resul			skin irritation	
Benza	alkonium chloride:			
Speci Resul			man rrosive after 4	hours or less of exposure
Serio	us eye damage/eye	irritation		
Not cl	assified based on ava	ailable info	rmation.	
<u>Comp</u>	oonents:			
Mome	etasone:			
Speci			bbit	
Resul	t	: No	eye irritation	
Benza	alkonium chloride:			
Speci		: Ra	bbit	
Resul				to on the over
Resul			eversible effec	is on the eye
	iratory or skin sensi		eversidie effec	ts on the eye
Respi	iratory or skin sensi sensitisation	tisation		ts on the eye
Respi	iratory or skin sensi	tisation		is on the eye
Respi Skin s Not cl Respi	iratory or skin sensi sensitisation assified based on ava iratory sensitisation	tisation ailable info	rmation.	is on the eye
Respi Skin s Not cl Respi Not cl	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava	tisation ailable info	rmation.	is on the eye
Respi Skin s Not cl Respi Not cl <u>Comp</u>	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava conents:	tisation ailable info	rmation.	is on the eye
Respi Skin s Not cl Respi Not cl <u>Comp</u>	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava conents: etasone:	tisation ailable info ailable info	rmation. rmation.	
Respi Skin s Not cl Respi Not cl <u>Comp</u> Test 1 Expos	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava ponents: etasone: Type sure routes	tisation ailable info ailable info : Ma	rmation.	
Respi Skin s Not cl Respi Not cl <u>Comp</u> Test 1 Expos Speci	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava <u>conents:</u> etasone: Type sure routes es	tisation ailable info ailable info : Ma : De : Gu	rmation. rmation. aximisation Tea rmal inea pig	st
Respi Skin s Not cl Respi Not cl <u>Comp</u> Test T Expos Speci Asses	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava conents: etasone: Fype sure routes es	tisation ailable info ailable info : Ma : De : Gu : Gu	rmation. rmation. aximisation Tea rmal inea pig es not cause s	
Respi Skin s Not cl Respi Not cl Comp Test T Expos Speci Asses Resul	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava conents: etasone: Fype sure routes es ssment t	tisation ailable info ailable info : Ma : De : Gu : Do : ne	rmation. rmation. aximisation Tea rmal inea pig es not cause s gative	st skin sensitisation.
Respi Skin s Not cl Respi Not cl <u>Comp</u> Test T Expos Speci Asses	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava conents: etasone: Fype sure routes es ssment t	tisation ailable info ailable info : De : De : Cu : Do : ne : Th	rmation. rmation. aximisation Tea rmal inea pig es not cause s gative	st skin sensitisation. est on guinea pigs showed this substance to
Respi Skin s Not cl Respi Not cl Comp Test T Expos Speci Asses Resul Rema	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava conents: etasone: Fype sure routes es ssment t	tisation ailable info ailable info : De : De : Cu : Do : ne : Th	rmation. rmation. rmation Tea rmal inea pig ies not cause s gative e results of a t	st skin sensitisation. est on guinea pigs showed this substance to
Respi Skin s Not cl Respi Not cl Comr Test 7 Expos Speci Asses Resul Rema Benza	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava conents: etasone: Type sure routes es ssment t t irks	tisation ailable info ailable info : Ma : De : De : De : De : Th be	rmation. rmation. rmal inea pig es not cause s gative e results of a t a weak skin s	st skin sensitisation. est on guinea pigs showed this substance to
Respi Skin s Not cl Respi Not cl Comp Test 1 Expos Speci Asses Resul Rema Benza	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava <u>conents:</u> etasone: Type sure routes es ssment t irks alkonium chloride: Type sure routes	tisation ailable info ailable info : Ma : De : De : De : Cu : ne : Th be : Hu : Sk	rmation. rmation. eximisation Tea rmal inea pig es not cause s gative e results of a t a weak skin s man repeat in in contact	st skin sensitisation. est on guinea pigs showed this substance to ensitiser.
Respi Skin s Not cl Respi Not cl Comr Test 7 Expos Speci Asses Resul Rema Benza	iratory or skin sensi sensitisation assified based on ava iratory sensitisation assified based on ava conents: etasone: Type sure routes es ssment t irks alkonium chloride: Type sure routes es	tisation ailable info ailable info : Ma : De : Cu : De : Cu : De : Th be : Hu : Sk : Hu	rmation. rmation. aximisation Tea rmal inea pig ies not cause s gative e results of a t a weak skin s man repeat in	st skin sensitisation. est on guinea pigs showed this substance to ensitiser.

Germ cell mutagenicity

Not classified based on available information.



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Com	ponents:		
Cellu	llose:		
Genc	otoxicity in vitro	Result: nega	
		Test Type: Ir Result: nega	n vitro mammalian cell gene mutation test tive
Genc	otoxicity in vivo	cytogenetic a Species: Mor	use Route: Ingestion
Mom	etasone:		
<u></u>	otoxicity in vitro	: Test Type: B Result: nega	acterial reverse mutation assay (AMES) tive
			hromosomal aberration Chinese hamster lung cells tive
			hromosomal aberration Chinese hamster ovary cells ive
		Test Type: M Result: nega	louse Lymphoma tive
Genc	otoxicity in vivo	: Test Type: M Species: Mon Application R Result: nega	Route: Oral
		Test Type: C Species: Rat Cell type: Bo Result: nega	ne marrow
		Test Type: u Species: Rat Cell type: Liv Result: nega	ver cells
	n cell mutagenicity - ssment	: Weight of evi cell mutagen	idence does not support classification as a germ
Benz	alkonium chloride:		
	otoxicity in vitro	: Test Type: B Result: nega	acterial reverse mutation assay (AMES) tive
			n vitro mammalian cell gene mutation test CD Test Guideline 476



ersion 0	Revision Date: 2021/04/09	SDS Number: 23597-00018	Date of last issue: 2020/10/16 Date of first issue: 2014/10/21
		Result: negativ Remarks: Base	e ed on data from similar materials
		Remains. Dasc	
			omosome aberration test in vitro
			Test Guideline 473
		Result: negativ	e ed on data from similar materials
		Remarks. Dase	
Geno	toxicity in vivo		mmalian erythrocyte micronucleus test (in vivo
		cytogenetic as	
		Species: Mous	
		Application Ro	Test Guideline 474
		Result: negativ	
			ed on data from similar materials
II Carci	nogenicity		
	lassified based on ava	ailable information.	
Com	oonents:		
Cellu			
Speci		: Rat	
	cation Route	: Ingestion	
Expos	sure time	: 72 weeks : negative	
itesu	it.	. negative	
Mom	etasone:		
Speci	es	: Rat	
	cation Route	: Inhalation	
	sure time	: 2 Years	
Dose		: 0.067 mg/kg bo	ody weight
Resu	It	: negative	
Speci		: Mouse	
	cation Route	: Inhalation	
	sure time	: 19 Months	
Dose Resul		: 0.160 mg/kg bo : negative	ody weight
	it.	. negative	
<u>UL</u>	alkonium chloride:		
Speci		: Rat	
	cation Route	: Ingestion	
	sure time	: 2 Years	idaliaa 152
Metho Resul		: OECD Test Gu : negative	
Rema			from similar materials
	es	: Mouse	
Speci			
Speci Applic	cation Route	: Skin contact	
Applic	cation Route sure time	: Skin contact : 80 weeks : negative	



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	cation Route sure time	: :	Rabbit Skin contact 90 weeks negative	
Not c	oductive toxicity lassified based on avai	lable	information.	
11	ponents:			
Effect	lose: ts on fertility	:	Test Type: One-g Species: Rat Application Route Result: negative	eneration reproduction toxicity study : Ingestion
Effect ment	ts on foetal develop-	:	Test Type: Fertilit Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion
Mom	etasone:			
Effect	ts on fertility	:	Symptoms: Redu weight	-
Effect ment	ts on foetal develop-	:	Species: Mouse Application Route Embryo-foetal tox	vo-foetal development e: Subcutaneous cicity: LOAEL: 0.06 mg/kg body weight xic effects., Teratogenicity and developmen-
			Species: Rat Application Route	ticity: LOAEL: 0.3 mg/kg body weight
			Species: Rabbit Application Route Embryo-foetal tox	vo-foetal development e: Dermal cicity: LOAEL: 0.15 mg/kg body weight betal toxicity, Malformations were observed.
			Species: Rat Application Route	cicity: LOAEL: 0.15 mg/kg body weight



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			Species: Rabbit Application Rou Embryo-foetal to	
Repro sessr	oductive toxicity - As- nent	:	animal experime	of adverse effects on development, based on ents., Some evidence of adverse effects on and fertility, based on animal experiments.
 _{Benz}	alkonium chloride:			
UL.	ts on fertility	:	Species: Rat Application Rou Method: OECD Result: negative	Test Guideline 416
Effect ment	ts on foetal develop-	:	Species: Rabbit Application Rou Method: OECD Result: negative	te: Ingestion Test Guideline 414
Not c	F - single exposure lassified based on avail ponents:	able	information.	
Mom Rema	etasone: arks	:	Based on availa	able data, the classification criteria are not met.
	F - repeated exposure lassified based on avail	able	information.	
Com	ponents:			
11	etasone:			
Expo Targe	sure routes et Organs ssment	:		/mist/fume) n, Liver, Kidney, Skin lage to organs through prolonged or repeated
_{Barr} -				
W .	alkonium chloride: ssment	:	No significant h tions of 100 mg	ealth effects observed in animals at concentra- /kg bw or less.



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-	ated dose toxicity		
11	<u>oonents:</u>		
Cellu Speci NOAE	es EL	: Rat : >= 9,000 mg/kg	
	cation Route sure time	: Ingestion : 90 Days	
Mom	etasone:		
Speci NOAE LOAE Applic Expos	es EL	: Rat : 0.005 mg/kg : 0.3 mg/kg : Oral : 30 d : Lymph nodes, L	iver, Adrenal gland, Skin, thymus gland.
Expos		: Dog : 0.5 mg/kg : Oral : 30 d : Lymph nodes, L	iver, Adrenal gland, Skin, thymus gland
Expos		: Rat : 0.00013 mg/l : inhalation (dust/ : 90 d : Adrenal gland, l Kidney, Liver, th	Lungs, Lymph nodes, spleen, Bone marrow,
Expos		: Dog : 0.0005 mg/l : inhalation (dust/ : 90 d : Adrenal gland, l Kidney, thymus	Lungs, Lymph nodes, spleen, Bone marrow,
Benz	alkonium chloride:		
		: Rat : >= 100 mg/kg : Ingestion : 12 Weeks	
-	a tion toxicity lassified based on avai	lable information.	

Components:

Mometasone:

Not applicable



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Expe	rience with human e	xposure		
Com	ponents:			
Mom	etasone:			
Inhala	ation	pirat	ory tract infe	gic rhinitis, Headache, pharyngitis, upper res- ction, sinusitis, oral candidiasis, Back pain, pain, immune system effects, indigestion
Skin o	contact			natitis, Itching
Furth	er information			
Com	ponents:			
Mom	etasone:			
Rema	arks	: Derr	nal absorptic	on possible
Ecoto	OGICAL INFORMAT oxicity ponents:			
Cellu	lose:			
	ity to fish	Expo	osure time: 4	tipes (Japanese medaka)): > 100 mg/l 8 h on data from similar materials
Mom	etasone:			
Toxic	ity to fish	Expo	osure time: 9	eryllina (Silverside)): 0.11 mg/l 6 h icity at the limit of solubility
		Expo	osure time: 7	on variegatus (sheepshead minnow)): > 5 mg/l d icity 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 fish (Chronic tox-	:	NOEC (Pimephales promelas (fathead minnow)): 0.00014		



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icity)			mg/l Exposure time: 32 Method: OECD Te			
	ty to daphnia and other c invertebrates (Chron- city)	:	Exposure time: 21 Method: OECD Te			
	tor (Chronic aquatic	:	100			
	toxicity) Toxicity to microorganisms		 EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility 			
			NOEC: 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility			
Benza	alkonium chloride:					
Toxici	ty to fish	:	LC50 (Pimephales Exposure time: 96	s promelas (fathead minnow)): 0.28 mg/l s h		
	ty to daphnia and other c invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): 0.0056 mg/l 3 h		
Toxici plants	ty to algae/aquatic	:	ErC50 (Chlorella p Exposure time: 72	oyrenoidosa (aglae)): 0.09 mg/l 2 h		
	tor (Acute aquatic tox-	:	100			
icity) Toxici icity)	ty to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 34	es promelas (fathead minnow)): 0.032 mg/l l d		
Persis	stence and degradabili	ity				
Comp	oonents:					
Cellul Biode	ose: gradability	:	Result: Readily bi	odegradable.		
Н				•		
u	etasone: gradability	:	Result: Not readily Biodegradation: 5 Exposure time: 28 Method: OECD Te	50 % 3 d		
Stabili	ty in water	:	Hydrolysis: 50 %(Method: OECD Te			



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<u> </u>	Benzalkonium chlorid Biodegradability	de: :	Method: OEC	ily biodegradable. D Test Guideline 301D sed on data from similar materials
E	Bioaccumulative pote	ential		
<u> </u>	Components:			
Ν	Mometasone:			
	Bioaccumulation	:	Bioconcentra	omis macrochirus (Bluegill sunfish) tion factor (BCF): 107.1 D Test Guideline 305
	Partition coefficient: n- octanol/water	:	log Pow: 4.68	3
	Benzalkonium chlorid	de:		
	Bioaccumulation	:	Bioconcentra	omis macrochirus (Bluegill sunfish) tion factor (BCF): < 500 sed on data from similar materials
	Partition coefficient: n- octanol/water	:	log Pow: 1.69 Remarks: Ca	
Ν	Mobility in soil			
<u>c</u>	Components:			
Π	Mometasone: Distribution among env nental compartments	viron- :	log Koc: 4.02	
	Other adverse effects No data available	6		
13. D	ISPOSAL CONSIDER	RATIONS		
r	Disposal methods			
V	Waste from residues Contaminated packagi	: ng :	Empty contai dling site for	accordance with local regulations. ners should be taken to an approved waste han- recycling or disposal. se specified: Dispose of as unused product.
14. TI	RANSPORT INFORM	ATION		
li li	nternational Regulat	ions		
	_			
ι	JNRTDG JN number Proper shipping name	:	UN 3082 ENVIRONME N.O.S.	NTALLY HAZARDOUS SUBSTANCE, LIQUID,



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Class Packing group Labels		:	(Mometasone, Be 9 III 9	enzalkonium chloride)
IATA-DGR UN/ID No. Proper shipping name		:		azardous substance, liquid, n.o.s. enzalkonium chloride)
Labels Packing aircraft	/	:	9 III Miscellaneous 964	
ger airc	g instruction (passen- craft) nmentally hazardous	:	964 yes	
IMDG- UN nur Proper		:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
Labels EmS C	g group ode pollutant	:	(Mometasone, Be 9 III 9 F-A, S-F yes	nzalkonium chloride)

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

Not applicable for product as supplied.

Special precautions for user

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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No.	74 of 2001 or	the Management	of Hazardous and	Toxic Sub-
stances				

Glycerine

Hazardous substances approved for use :



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Prohil	pited substances		: Not applicable		
Restri	cted substances		: Not applicable		
Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials					
	of Hazardous Materials oution and Supervision	Restricted to Import,	: Not applicable		
The c AICS	omponents of this pro	oduct are reported in : not determined	the following inventories:		
DSL		: not determined			
IECS	C	: not determined			

16. OTHER INFORMATION

Further information

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format	:	yyyy/mm/dd
Full text of other abbreviatio	ns	
ACGIH ID OEL		USA. ACGIH Threshold Limit Values (TLV) Indonesia. Occupational Exposure Limits
ACGIH / TWA ID OEL / NAB		8-hour, time-weighted average Long term exposure limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships;



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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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