

Vers	sion	Revision Date:		S Number:	Date of last issue: 23.03.2020
3.1		16.10.2020	236	800-00017	Date of first issue: 21.10.2014
1. PI	RODUC	T AND COMPANY IDE	ENT	IFICATION	
	Product	t name	:	Mometasone Su	spension Formulation
	Manufa	acturer or supplier's d	etai	ils	
	Compa	ny	:	Organon & Co.	
	Addres	S	:	30 Hudson Stree Jersey City, New	et, 33nd floor 9 Jersey, U.S.A 07302
	Telepho	one	:	551-430-6000	
	Emerge	ency telephone number	:	215-631-6999	
	E-mail a	address	:	EHSSTEWARD	@organon.com
	Recom	mended use of the ch	nem	ical and restriction	ons on use
	Recom	mended use	:	Pharmaceutical	
2. H	AZARD	S IDENTIFICATION			
	Manufa	acture, Storage and In	npol	rt of Hazardous C	Chemicals Rules 1989
	Classif Not clas		cor	ding to criteria laid	down in Part I of Schedule-1.
		lassification erm (acute) aquatic	:	Category 3	
	Long-te	erm (chronic) aquatic	:	Category 2	

GHS label elements

Hazard pictograms

hazard

Signal word Hazard statements



None
 H402 Harmful to aquatic life.
 H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention: P273 Avoid release to the environment.

Response:

2

P391 Collect spillage.

Disposal:



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			P501 Dispose disposal plant	of contents/ container	to an approved waste
Other	hazards which do not	res	ult in classifica	ation	
None	known.				
	SITION/INFORMATION			S	
				-	
Subst	ance / Mixture	:	Mixture		
	oonents				
Chem	ical name			CAS-No.	Concentration (%
Cellul	ose			9004-34-6	
	etasone			83919-23-7	>= 0.025 - < 0.1
Benza	alkonium chloride			8001-54-5	>= 0.0025 - < 0.02
lf inha	lled	:	If inhaled, rem	ove to fresh air.	
				tention if symptoms occ	
In cas	e of skin contact	:		er and soap as a preca	
In cas	e of eye contact			tention if symptoms occ h water as a precaution	
in ouo		•		tention if irritation devel	
lf swa	llowed	:	If swallowed, D	O NOT induce vomiting	g.
				tention if symptoms occ	cur.
Most i	mportant symptoms		None known.	noroughly with water.	
	ffects, both acute and	•			
delaye					
	ction of first-aiders	÷			for first aid responders.
Notes	to physician		I reat symptom	natically and supportive	y.
FIREFIG	BHTING MEASURES				
Suitab	ble extinguishing media		Water spray		
Ounac		•	Alcohol-resista	int foam	
			Carbon dioxide		
			Dry chemical		
Unsui media	table extinguishing		None known.		
	fic hazards during fire-	:	Exposure to co	ombustion products may	y be a hazard to health.
	dous combustion prod-	:	Carbon oxides		
Specif ods	fic extinguishing meth-	:	cumstances ar Use water spra Remove undar	ing measures that are and the surrounding envi ay to cool unopened con maged containers from	ronment.
	al protective equipment fighters	:	so. Evacuate area Wear self-cont essary.		tus for firefighting if nec-



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			Use personal pro	otective equipment.
6. ACCID	ENTAL RELEASE MEA	SUI	RES	
tive e	onal precautions, protec- equipment and emer- cy procedures	:		lling advice (see section 7) and personal pro- t recommendations (see section 8).
Envi	ronmental precautions	:	Prevent spreadin barriers). Retain and dispo	eakage or spillage if safe to do so. Ig over a wide area (e.g. by containment or oil se of contaminated wash water. should be advised if significant spillages
	nods and materials for ainment and cleaning up	:	For large spills, p ment to keep ma be pumped, store Clean up remain bent. Local or national posal of this mate employed in the mine which regul Sections 13 and	rt absorbent material. provide dyking or other appropriate contain- terial from spreading. If dyked material can e recovered material in appropriate container. ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding ational requirements.
7. HAND	LING AND STORAGE			
Tech	nnical measures	:		measures under EXPOSURE

Local/Total ventilation Advice on safe handling	 CONTROLS/PERSONAL PROTECTION section. Use only with adequate ventilation. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
	Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m3 (OEB 4)	Internal



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			Further information: Skin
			Wipe limit 10 µg/100 cm ² Internal
Engi	neering 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 cabinet, fume hood, or other containment device if the poten- tial exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.
Pers	onal protective equip	ment	
Resp	iratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
	lter type protection	:	Combined particulates and organic vapour type
Μ	aterial	:	Chemical-resistant gloves
	emarks protection	:	Consider double gloving. 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.
Skin	and body protection	:	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.
Hygie	ene 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 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: white to off-white, opaque
Odour	: odourless
Odour Threshold	: No data available



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	рН		:	4.3 - 4.9	
	Melting	point/freezing point	:	No data available	
	Initial bo range	oiling point and boiling	:	No data available	
	Flash p	oint	:	No data available	9
	Evapora	ation rate	:	No data available)
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	9
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	No data available)
	Relative	e vapour density	:	No data available	9
	Relative	e density	:	No data available)
	Density		:	1 g/cm3	
	Solubili Wate	ty(ies) er solubility	:	soluble	
		n coefficient: n-	:	Not applicable	
	octanol/ Auto-igi	nition temperature	:	No data available	•
	Decom	position temperature	:	No data available)
	Viscosit Visc	ty osity, kinematic	:	No data available)
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance or	mixture is not classified as oxidizing.
	Molecu	lar weight	:	Not applicable	
	Particle	size	:	Not applicable	

10. STABILITY AND REACTIVITY

Reactivity

: Not classified as a reactivity hazard.



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	Possibil tions Conditio Incompa	al stability ity of hazardous reac- ons to avoid atible materials ous decomposition s	:	None known. Oxidizing agents	mal conditions. rong oxidizing agents. composition products are known.
11. T	ΓΟΧΙCΟ	LOGICAL INFORMAT		1	
	exposu		:	Inhalation Skin contact Ingestion Eye contact	
	Acute t Not clas	oxicity ssified based on availa	ble	information.	
	Compo				
	Cellulo	se:			
	Acute o	ral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
	Acute ir	nhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere:	h
	Acute d	ermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
	Mometa	asone:			
		ral toxicity	:	LD50 (Rat): > 2,00	00 mg/kg
				LD50 (Mouse): > 2	2,000 mg/kg
	Acute ir	nhalation toxicity	:	LC50 (Rat): > 3.3 Exposure time: 4 Test atmosphere: Remarks: No mor	h
				LC50 (Mouse): > 3 Exposure time: 4 Test atmosphere:	h
	Acute to adminis	oxicity (other routes of tration)	:	LD50 (Rat): 300 m Application Route Symptoms: Breath	Subcutaneous
	Benzall	konium chloride:			
	Acute o	ral toxicity	:	LD50 (Rat): 240 m	ng/kg
	Acute ir	nhalation toxicity	:	LC50 (Rat, male): Exposure time: 4 I Test atmosphere: Method: OECD Te	h dust/mist



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		Assessment: Corrosive to Remarks: Based on data	o the respiratory tract. from similar materials
Acute	dermal toxicity	: LD50 (Rat, female): 704 i	mg/kg
	corrosion/irritation		
	assified based on av	lable information.	
Comp	oonents:		
	etasone:		
Specie Resul		: Rabbit : No skin irritation	
Benza	alkonium chloride:		
Specie Resul		: Human : Corrosive after 4 hours of	r less of exposure
	us eye damage/eye assified based on av		
<u>Comp</u>	oonents:		
Mome	etasone:		
Specie Resul		: Rabbit : No eye irritation	
Benza	alkonium chloride:		
Specie Resul		: Rabbit : Irreversible effects on the	eye
Respi	iratory or skin sens	isation	
	sensitisation assified based on av	lable information.	
-	iratory sensitisatior assified based on av	lable information.	
<u>Comp</u>	oonents:		
Mome	etasone:		
Specie	sure routes es ssment t	 Maximisation Test Dermal Guinea pig Does not cause skin sens negative The results of a test on group be a weak skin sensitiser 	uinea pigs showed this substance to
Benz:	alkonium chloride:		



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Expo Spec Resu			Skin contact Humans negative	
Not c	n cell mutagenicity lassified based on ava	ailable	information.	
Com	ponents:			
Cellu Geno	lose: toxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
			Test Type: In vitro Result: negative	o mammalian cell gene mutation test
Geno	toxicity in vivo	:	Test Type: Mamn cytogenetic assay Species: Mouse Application Route Result: negative	
Mom	etasone:			
Geno	toxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
				nosomal aberration nese hamster lung cells
				nosomal aberration nese hamster ovary cells
			Test Type: Mouse Result: negative	e Lymphoma
Geno	toxicity in vivo	:	Test Type: Micror Species: Mouse Application Route Result: negative	
			Test Type: Chron Species: Rat Cell type: Bone m Result: negative	nosomal aberration narrow
			Test Type: unsch Species: Rat Cell type: Liver ce Result: negative	eduled DNA synthesis assay
	a cell mutagenicity - ssment	:	Weight of evidend cell mutagen.	ce does not support classification as a germ



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Benza	lkonium chloride:		
Genoto	oxicity in vitro	: Test Type: Ba Result: negati	acterial reverse mutation assay (AMES)
		Method: OEC	vitro mammalian cell gene mutation test D Test Guideline 476
		Result: negati Remarks: Bas	sed on data from similar materials
			nromosome aberration test in vitro D Test Guideline 473 ve
			sed on data from similar materials
Genoto	oxicity in vivo	cytogenetic as	
			oute: Ingestion
		Result: negati	D Test Guideline 474 ive sed on data from similar materials
		Remarks: Bac	
Not cla	ogenicity Issified based on ava	ailable information.	
Not cla <u>Compo</u> Cellulo Specie	assified based on ava onents: ose: s	: Rat	
Not cla <u>Compo</u> Cellulo Specie Applica	assified based on ava onents: ose: s ation Route	: Rat : Ingestion	
Not cla <u>Compo</u> Cellulo Specie Applica	assified based on ava onents: ose: s	: Rat	
Not cla Compo Cellulo Specie Applica Exposu Result	assified based on ava onents: ose: s ation Route	: Rat : Ingestion : 72 weeks	
Not cla <u>Compo</u> <u>Cellula</u> Specie Applica Exposu Result <u>Momet</u> Specie	assified based on ava onents: ose: as ation Route ure time tasone: s	: Rat : Ingestion : 72 weeks : negative : Rat	
Not cla <u>Compo</u> <u>Cellula</u> Specie Applica Exposu Result <u>Momet</u> Specie Applica	assified based on ava onents: ose: s ation Route ure time tasone: s ation Route	: Rat : Ingestion : 72 weeks : negative : Rat : Inhalation	
Not cla Compo Cellulo Specie Applica Exposu Result Momet Specie Applica Exposu	assified based on ava onents: ose: as ation Route ure time tasone: s	: Rat : Ingestion : 72 weeks : negative : Rat : Inhalation : 2 Years	oody weight
Not cla <u>Compo</u> <u>Cellula</u> Specie Applica Exposu Result <u>Momet</u> Specie Applica	assified based on ava onents: ose: s ation Route ure time tasone: s ation Route	: Rat : Ingestion : 72 weeks : negative : Rat : Inhalation	oody weight
Not cla Compo Cellula Specie Applica Exposu Result Momen Specie Applica Exposu Dose Result Specie	assified based on ava <u>onents:</u> ose: s ation Route ure time s ation Route ure time s ation Route ure time	 Rat Ingestion 72 weeks negative Rat Inhalation 2 Years 0.067 mg/kg b negative Mouse 	oody weight
Not cla Compo Cellulo Specie Applica Exposu Result Momet Specie Applica Exposu Dose Result Specie Applica	assified based on ava <u>onents:</u> ose: as ation Route ure time tasone: ation Route ure time s ation Route ure time	 Rat Ingestion 72 weeks negative Rat Inhalation 2 Years 0.067 mg/kg b negative Mouse Inhalation 	oody weight
Not cla Compo Specie Applica Exposu Result Momet Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result	assified based on ava <u>onents:</u> ose: s ation Route ure time s ation Route ure time s ation Route ure time	 Rat Ingestion 72 weeks negative Rat Inhalation 2 Years 0.067 mg/kg b negative Mouse Inhalation 19 Months 	
Not cla Compo Cellulo Specie Applica Exposu Result Momet Specie Applica Exposu Dose Result Specie Applica	assified based on ava <u>onents:</u> ose: as ation Route ure time tasone: ation Route ure time s ation Route ure time	 Rat Ingestion 72 weeks negative Rat Inhalation 2 Years 0.067 mg/kg b negative Mouse Inhalation 	
Not cla Compo Specie Applica Exposu Result Momet Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result	assified based on ava <u>onents:</u> ose: as ation Route ure time tasone: ation Route ure time s ation Route ure time	 Rat Ingestion 72 weeks negative Rat Inhalation 2 Years 0.067 mg/kg b negative Mouse Inhalation 19 Months 0.160 mg/kg b 	
Not cla Compo Specie Applica Exposu Result Momet Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result	issified based on avaination Route ation Route	 Rat Ingestion 72 weeks negative Rat Inhalation 2 Years 0.067 mg/kg b negative Mouse Inhalation 19 Months 0.160 mg/kg b 	
Not cla Compo Cellula Specie Applica Exposu Result Momen Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result	issified based on ava <u>onents:</u> ose: s ation Route ure time tasone: s ation Route ure time tasone: s ation Route ure time Ikonium chloride: s ation Route	 Rat Ingestion 72 weeks negative Rat Inhalation 2 Years 0.067 mg/kg k negative Mouse Inhalation 19 Months 0.160 mg/kg k negative Rat Rat Ingestion 	
Not cla Compo Cellula Specie Applica Exposu Result Momen Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result Specie Applica Exposu Dose Result	issified based on avaination Route ation Route	 Rat Ingestion 72 weeks negative Rat Inhalation 2 Years 0.067 mg/kg k negative Mouse Inhalation 19 Months 0.160 mg/kg k negative Rat	body weight



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Resi Rem		: negative : Based on dat	negativeBased on data from similar materials				
	ication Route osure time	: Mouse : Skin contact : 80 weeks : negative					
	ication Route osure time	: Rabbit : Skin contact : 90 weeks : negative	: Rabbit : Skin contact : 90 weeks				
•	roductive toxicity classified based on ava	ilable information.					
Com	ponents:						
	ulose: ets on fertility	Species: Rat	ne-generation reproduction toxicity study oute: Ingestion ive				
Effec ment	ets on foetal develop-	Species: Rat	ertility/early embryonic development oute: Ingestion ive				
Mom	netasone:						
	ets on fertility	Fertility: NOA Symptoms: F weight					
Effec ment	ets on foetal develop-	Species: Mou Application R Embryo-foeta Result: Embr tal toxicity Test Type: E	mbryo-foetal development use oute: Subcutaneous al toxicity: LOAEL: 0.06 mg/kg body weight yotoxic effects., Teratogenicity and developmen mbryo-foetal development				
		Embryo-foeta Result: Embr	oute: Dermal al toxicity: LOAEL: 0.3 mg/kg body weight yo-foetal toxicity mbryo-foetal development obit				



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				e: Dermal xicity: LOAEL: 0.15 mg/kg body weight oetal toxicity, Malformations were observed.
			Species: Rat Application Route	xicity: LOAEL: 0.15 mg/kg body weight
			Species: Rabbit Application Route Embryo-foetal to	yo-foetal development e: Oral xicity: LOAEL: 0.7 mg/kg body weight oetal toxicity, Malformations were observed.
Repro sessm	oductive toxicity - As- nent	:	animal experime	f adverse effects on development, based on nts., Some evidence of adverse effects on nd fertility, based on animal experiments.
Benza	alkonium chloride:			
Effect	s on fertility	:	Species: Rat Application Route Method: OECD T Result: negative	generation reproduction toxicity study e: Ingestion Test Guideline 416 on data from similar materials
Effect ment	s on foetal develop-	:	Species: Rabbit Application Route Method: OECD T Result: negative	yo-foetal development e: Ingestion ⁻ est Guideline 414 on data from similar materials
стот	- single exposure			
Not cl	assified based on avail	lable	information.	
<u>Comp</u>	oonents:			
Mome Rema	e tasone: rks	:	Based on availab	ble data, the classification criteria are not me
	- repeated exposure assified based on avail		information.	
<u>Comp</u>	oonents:			
Mome	etasone:			
Targe	sure routes t Organs ssment	:		nist/fume) Liver, Kidney, Skin age to organs through prolonged or repeated



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	Benzalkonium chloride: Assessment		:	No significant heations of 100 mg/k	alth effects observed in animals at concentra- g bw or less.
	Repea	ted dose toxicity			
	Comp	onents:			
	Cellulo	ose:			
			: :	Rat >= 9,000 mg/kg Ingestion 90 Days	
	Mome	tasone:			
	Exposi	L		Rat 0.005 mg/kg 0.3 mg/kg Oral 30 d Lymph nodes, Liv	ver, Adrenal gland, Skin, thymus gland
	Exposi		: : : : : : : : : : : : : : : : : : : :	Dog 0.5 mg/kg Oral 30 d Lymph nodes, Liv	ver, Adrenal gland, Skin, thymus gland
	Exposi				nist/fume) ungs, Lymph nodes, spleen, Bone marrow, mus gland
	Exposi			Dog 0.0005 mg/l inhalation (dust/n 90 d Adrenal gland, Lu Kidney, thymus g	ungs, Lymph nodes, spleen, Bone marrow,
	Benza	Ikonium chloride:			
			: :	Rat >= 100 mg/kg Ingestion 12 Weeks	

Aspiration toxicity

Not classified based on available information.



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<u>Comp</u>	onents:		
	e tasone: oplicable		
Exper	ience with human e	exposure	
Comp	onents:		
Mome	etasone:		
Inhala	tion	piratory tract	Illergic rhinitis, Headache, pharyngitis, upper re infection, sinusitis, oral candidiasis, Back pain, etal pain, immune system effects, indigestion
Skin c	ontact		Dermatitis, Itching
Furth	er information		
<u>Comp</u>	onents:		
Mome	etasone:		
Rema	rks	: Dermal abso	rption possible
ECOL(Ecoto	DGICAL INFORMAT	ION	
Ecoto		ION	
Ecoto <u>Comp</u> Cellul	xicity onents: ose:		
Ecoto <u>Comp</u> Cellul	xicity ponents:	: LC50 (Oryzia Exposure tim	as latipes (Japanese medaka)): > 100 mg/l le: 48 h lsed on data from similar materials
Ecoto Comp Cellul Toxici	xicity onents: ose:	: LC50 (Oryzia Exposure tim	ne: 48 h
Ecoto <u>Comp</u> Cellul Toxici	xicity ponents: ose: ty to fish	: LC50 (Oryzia Exposure tim Remarks: Ba : LC50 (Menid	ia beryllina (Silverside)): 0.11 mg/l
Ecoto <u>Comp</u> Cellul Toxici	exicity ponents: ose: ty to fish etasone:	: LC50 (Oryzia Exposure tim Remarks: Ba : LC50 (Menid Exposure tim	ia beryllina (Silverside)): 0.11 mg/l
Ecoto <u>Comp</u> Cellul Toxici	exicity ponents: ose: ty to fish etasone:	 : LC50 (Oryzia Exposure tim Remarks: Ba : LC50 (Menid Exposure tim Remarks: No LC50 (Cyprin Exposure tim 	ne: 48 h lised on data from similar materials hia beryllina (Silverside)): 0.11 mg/l he: 96 h o toxicity at the limit of solubility hodon variegatus (sheepshead minnow)): > 5 n
Ecoto Comp Cellul Toxici Mome Toxici	exicity ponents: ose: ty to fish etasone:	 : LC50 (Oryzia Exposure tim Remarks: Ba : LC50 (Menid Exposure tim Remarks: No LC50 (Cyprir Exposure tim Remarks: No 	ne: 48 h lised on data from similar materials ne: 96 h o toxicity at the limit of solubility nodon variegatus (sheepshead minnow)): > 5 n ne: 7 d
Ecoto Comp Cellul Toxici Mome Toxici	exicity ponents: ose: ty to fish etasone: ty to fish	 : LC50 (Oryzia Exposure tim Remarks: Ba : LC50 (Menid Exposure tim Remarks: No LC50 (Cyprir Exposure tim Remarks: No ner : EC50 (Daphi Exposure tim 	he: 48 h he: 48 h he: 48 h he: 96 h he: 96 h he toxicity at the limit of solubility hodon variegatus (sheepshead minnow)): > 5 n he: 7 d he: 7 d hia magna (Water flea)): > 5 mg/l he: 48 h
Ecoto Comp Cellul Toxici Mome Toxici	exicity onents: ose: ty to fish etasone: ty to fish ty to fish	 : LC50 (Oryzia Exposure tim Remarks: Ba : LC50 (Menid Exposure tim Remarks: No LC50 (Cyprin Exposure tim Remarks: No her : EC50 (Daphin Exposure tim Method: OEC 	he: 48 h lised on data from similar materials his beryllina (Silverside)): 0.11 mg/l he: 96 h o toxicity at the limit of solubility hodon variegatus (sheepshead minnow)): > 5 n he: 7 d o toxicity at the limit of solubility hia magna (Water flea)): > 5 mg/l
Ecoto Comp Cellul Toxici Mome Toxici	exicity onents: ose: ty to fish etasone: ty to fish ty to fish	 : LC50 (Oryzia Exposure tim Remarks: Ba : LC50 (Menid Exposure tim Remarks: No LC50 (Cyprin Exposure tim Remarks: No her : EC50 (Daphin Exposure tim Method: OEC Remarks: No 	he: 48 h he: 48 h he: 96 h he: 96 h ho toxicity at the limit of solubility hodon variegatus (sheepshead minnow)): > 5 n he: 7 d he: 7 d he: 48 h CD Test Guideline 202 ho toxicity at the limit of solubility
Ecoto Comp Cellul Toxici Mome Toxici	exicity onents: ose: ty to fish etasone: ty to fish ty to fish	 : LC50 (Oryzia Exposure tim Remarks: Ba : LC50 (Menid Exposure tim Remarks: No LC50 (Cyprin Exposure tim Remarks: No her : EC50 (Daphi Exposure tim Method: OEC Remarks: No 	he: 48 h he: 48 h he: 96 h he: 96 h hotoxicity at the limit of solubility hodon variegatus (sheepshead minnow)): > 5 n he: 7 d hotoxicity at the limit of solubility hia magna (Water flea)): > 5 mg/l he: 48 h CD Test Guideline 202 hotoxicity at the limit of solubility hia solubility hia magna (Water flea)): > 5 mg/l he: 48 h



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Toxicity plants	to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD To	
Toxicity	to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Test Type: Respin Method: OECD To Remarks: No toxid	h ation inhibition
			NOEC: 1,000 mg/ Exposure time: 3 Test Type: Respir Method: OECD To Remarks: No toxic	h ation inhibition
Toxicity icity)	to fish (Chronic tox-	:	NOEC: 0.00014 n Exposure time: 32 Species: Pimepha Method: OECD To	2 d ales promelas (fathead minnow)
	to daphnia and other invertebrates (Chron- ty)	:	Method: OECD T	magna (Water flea)
M-Facto toxicity)	or (Chronic aquatic	:	100	
Benzal	konium chloride:			
Toxicity	to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): 0.28 mg/l S h
	to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (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	

Components:

Cellulose:



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Biode	gradability	:	Result: Readily	biodegradable.
Mome	etasone:			
	gradability	:	Biodegradation Exposure time:	
Stabili	ty in water	:	Hydrolysis: 50 9 Method: OECD	%(12 d) Test Guideline 111
Benza	alkonium chloride:			
Biode	gradability	:		biodegradable. Test Guideline 301D d on data from similar materials
Bioac	cumulative potential			
<u>Comp</u>	onents:			
Mome	etasone:			
Bioaco	cumulation	:	Bioconcentratio	nis macrochirus (Bluegill sunfish) n factor (BCF): 107.1 Test Guideline 305
	on coefficient: n- bl/water	:	log Pow: 4.68	
Benza	alkonium chloride:			
Bioaco	cumulation	:	Bioconcentratio	nis macrochirus (Bluegill sunfish) n factor (BCF): < 500 d on data from similar materials
	on coefficient: n- bl/water	:	log Pow: 1.692 Remarks: Calcu	ulation
Mobil	ity in soil			
<u>Comp</u>	onents:			
Distrib	etasone: oution among environ- Il compartments	:	log Koc: 4.02	
	adverse effects ta available			
3. DISPO	SAL CONSIDERATION	NS		
Diene	sal methods			
-	e from residues	:	Dispose of in a	ccordance with local regulations.



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C	Contaminated packaging		dling site for recyc	should be taken to an approved waste han- cling or disposal. becified: Dispose of as unused product.
14. TF	RANSPORT INFORMATION			
Ir	nternational Regulations			
U	INRTDG JN number Proper shipping name	:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID, enzalkonium chloride)
Р	Class Packing group abels	:	9 III 9	
U P	ATA-DGR JN/ID No. Proper shipping name	:	(Mometasone, B	nazardous substance, liquid, n.o.s. enzalkonium chloride)
P L P	Class Packing group abels Packing instruction (cargo ircraft)	:	9 III Miscellaneous 964	
P g	Packing instruction (passen- er aircraft) Environmentally hazardous	:	964 yes	
ir U	MDG-Code JN number Proper shipping name	:	UN 3082 ENVIRONMENTA N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
P L E	Class Packing group abels EmS Code Marine pollutant	:	(Mometasone, Be 9 III 9 F-A, S-F yes	nzalkonium chloride)

Transport in bulk according to IMO instruments

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



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The o			eported in t	he following inventories:
DSL		: not de	etermined	
IECS	с	: not de	etermined	

16. OTHER INFORMATION

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 Agen- cy, http://echa.europa.eu/
Date format :		dd.mm.yyyy
Full text of other abbreviation	ons	
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA	:	8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized 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; 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



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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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