

Version 3.1	Revision Date: 2020/10/16		S Number: 603-00017	Date of last issue: 2020/03/23 Date of first issue: 2014/10/21
1. PRODL	JCT AND COMPANY IDE	ENT	IFICATION	
Chen	nical product name	:	Mometasone	Suspension Formulation
Supp	olier's company name, a	ıddr	ess and phon	e number
Com	pany name of supplier	:	Organon & C	0.
Addre	ess	:		treet, 33nd floor New Jersey, U.S.A 07302
Telep	bhone	:	551-430-600	)
E-ma	il address	:	EHSSTEWA	RD@organon.com
Emer	gency telephone number	• :	215-631-699	9
Reco	ommended use of the ch	nem	ical and restri	ctions on use
Reco	mmended use	:	Pharmaceution	cal
hazai	t-term (acute) aquatic rd -term (chronic) aquatic	:		
hazai		•		
GHS	label elements			
Haza	rd pictograms	:	*	
Signa	al word	:	None	
Haza	rd statements	:		I to aquatic life. aquatic life with long lasting effects.
Preca	autionary statements	:	Prevention: P273 Avoid r	elease to the environment.
			Response: P391 Collect	spillage.
			Disposal:	e of contents/ container to an approved was

Other hazards which do not result in classification None known.

disposal plant.



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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

: Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cellulose	9004-34-6	>= 1 - < 10	
Mometasone	83919-23-7	>= 0.025 - < 0.1	
Benzalkonium chloride	8001-54-5	>= 0.0025 - < 0.025	

## 4. FIRST AID MEASURES

	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.
	Most important symptoms and effects, both acute and delayed	:	None known.
	Protection of first-aiders		No special precautions are necessary for first aid responders.
	Notes to physician	÷	Treat symptomatically and supportively.
5. F	IREFIGHTING MEASURES		
	Suitable extinguishing media	:	Water spray
			Alcohol-resistant foam
			Carbon dioxide (CO2)
			Dry chemical
	Unsuitable extinguishing media	:	None known.
	Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
	Hazardous combustion prod- ucts	:	Carbon oxides
	Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so.

Special protective equipmentEvacuate area.for firefightersWear self-contained breathing apparatus for firefighting if nec-<br/>essary.<br/>Use personal protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :	Follow safe handling advice (see section 7) and personal pro-
tive equipment and emer-	tective equipment recommendations (see section 8).



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ç	gency p	procedures			
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 or barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.		
-	Methods and materials for containment and cleaning up		:	For large spills, p ment to keep mat be pumped, store Clean up remaining bent. Local or national posal of this mate employed in the of mine which regula Sections 13 and	t absorbent material. rovide dyking or other appropriate contain- erial from spreading. If dyked material can recovered material in appropriate container. ng materials from spill with suitable absor- regulations may apply to releases and dis- rial, as well as those materials and items leanup of releases. You will need to deter- ations are applicable. 5 of this SDS provide information regarding tional requirements.
7. HA	NDLIN	IG AND STORAGE			
F	Handlii	ng			
Т	Technic	cal measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.	
L	ocal/T	otal ventilation		Use only with adequate ventilation.	

Local/Total ventilation Advice on safe handling Avoidance of contact Hygiene measures		Use only with adequate ventilation. 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. Oxidizing agents 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.
Storage		
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
Packaging material	:	Unsuitable material: None known.



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#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm <sup>2</sup>	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 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.
Personal protective equipment	t
Respiratory protection :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Combined particulates and organic vapour type
Filter type : Hand protection	Combined particulates and organic vapour type
Material :	Chemical-resistant gloves
Remarks :	Consider double gloving.
Eye protection :	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
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, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: liquid
Colour	: white to off-white, opaque
Odour	: odourless

## SAFETY DATA SHEET



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	Odour <sup>-</sup>	Threshold	:	No data available	9
	Melting	point/freezing point	:	No data available	)
		point, initial boiling nd boiling range	:	No data available	
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	
	Upper e	explosion limit and upp explosion limit / Upper bility limit			
		explosion limit / Lower bility limit	:	No data available	
	Flash p	oint	:	No data available	)
	Decom	position temperature	:	No data available	)
	рН		:	4.3 - 4.9	
	Evapor	ation rate	:	No data available	
	Auto-ig	nition temperature	:	No data available	
	Viscosi Visc	ty cosity, kinematic	:	No data available	
	Solubili Wat	ty(ies) er solubility	:	soluble	
	Partitio octanol	n coefficient: n- /water	:	Not applicable	
	Vapour	pressure	:	No data available	)
		and / or relative densi e density	ty :	No data available	)
	Density	,	:	1 g/cm3	
	Relative	e vapour density	:	No data available	)
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance or	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	Not applicable	
	Particle Particle	e characteristics e size	:	Not applicable	



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## **10. STABILITY AND REACTIVITY**

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

## **11. TOXICOLOGICAL INFORMATION**

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion
		Eye contact

## Acute toxicity

Not classified based on available information.

## Components:

Cellulose:		
Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg
Mometasone:		
Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
		LD50 (Mouse): > 2,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 3.3 mg/l Exposure time: 4 h Test atmosphere: dust/mist Remarks: No mortality observed at this dose.
		LC50 (Mouse): > 3.2 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute toxicity (other routes of administration)	:	LD50 (Rat): 300 mg/kg Application Route: Subcutaneous Symptoms: Breathing difficulties
Benzalkonium chloride:		
Acute oral toxicity	:	LD50 (Rat): 240 mg/kg

## SAFETY DATA SHEET



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Acute	inhalation toxicity	Exposure Test atmo Method: C Assessme	t, male): > 0.05 - 0.5 mg/l time: 4 h sphere: dust/mist DECD Test Guideline 403 ent: Corrosive to the respiratory tract. Based on data from similar materials
Acute	dermal toxicity	: LD50 (Rat	t, female): 704 mg/kg
Not cla	corrosion/irritation assified based on ava	ilable information	
	<u>onents:</u>		
Mome Specie Result		: Rabbit : No skin irr	itation
Benza	Ikonium chloride:		
Specie Result		: Human : Corrosive	after 4 hours or less of exposure
Not cla <u>Comp</u>	us eye damage/eye assified based on ava onents:		ı.
	tasone:		
Specie Result		: Rabbit : No eye irri	itation
Benza	Ikonium chloride:		
Specie Result		: Rabbit : Irreversibl	e effects on the eye
Respi	ratory or skin sensi	tisation	
	ensitisation assified based on ava	ilable information	
Respi	ratory sensitisation		
	onents:		
	tasone:		
Test T		: Maximisat	ion Test
	ure routes	: Dermal	
Specie	es	: Guinea pig	
Asses			cause skin sensitisation.
Result Remar		: negative · The result	s of a test on guinea pigs showed this substance



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				be a weak skin se	nsitiser.
	Test T	ure routes es	: : :	Human repeat ins Skin contact Humans negative	ult patch test (HRIPT)
		<b>cell mutagenicity</b> assified based on availa	able	information.	
	Comp	onents:			
	<b>Cellulo</b> Genoto	ose: oxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
				Test Type: In vitro Result: negative	mammalian cell gene mutation test
	Genoto	oxicity in vivo	:	Test Type: Mamm cytogenetic assay Species: Mouse Application Route Result: negative	
	Mome	tasone:			
		oxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
					osomal aberration lese hamster lung cells
					osomal aberration lese hamster ovary cells
				Test Type: Mouse Result: negative	Lymphoma
	Genoto	oxicity in vivo	:	Test Type: Micror Species: Mouse Application Route Result: negative	
				Test Type: Chrom Species: Rat Cell type: Bone m Result: negative	osomal aberration arrow
				Test Type: unscho Species: Rat	eduled DNA synthesis assay



rsion	Revision Date: 2020/10/16	SDS Number: 23603-00017	Date of last issue: 2020/03/23 Date of first issue: 2014/10/21
		Cell type: Liv Result: nega	
	cell mutagenicity - ssment	: Weight of ev cell mutagen	idence does not support classification as a gerr
Benza	alkonium chloride:		
Geno	toxicity in vitro	: Test Type: B Result: nega	acterial reverse mutation assay (AMES) tive
		Method: OE0 Result: nega	n vitro mammalian cell gene mutation test CD Test Guideline 476 tive ased on data from similar materials
		Method: OE0 Result: nega	Promosome aberration test in vitro CD Test Guideline 473 tive ased on data from similar materials
Geno	toxicity in vivo	cytogenetic a Species: Mo Application F Method: OE0 Result: nega	use Route: Ingestion CD Test Guideline 474
	nogenicity assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
Cellu	lose:		
	cation Route sure time	: Rat : Ingestion : 72 weeks : negative	
Mom	etasone:		
	cation Route sure time	: Rat : Inhalation : 2 Years : 0.067 mg/kg : negative	body weight
	cation Route sure time	: Mouse : Inhalation : 19 Months : 0.160 mg/kg : negative	body weight



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Benz	alkonium chloride:		
Spec	ies	: Rat	
•	cation Route	: Ingestion	
	sure time	: 2 Years	
Meth			Guideline 453
Resu		: negative	
Rema			ata from similar materials
Spec	ies	: Mouse	
	cation Route	: Skin contact	
	sure time	: 80 weeks	
Resu		: negative	
Spec	ies	: Rabbit	
	cation Route	: Skin contact	
	sure time	: 90 weeks	
Resu		: negative	
-	oductive toxicity lassified based on ava	ilable information.	
	ponents:		
	lose:		
		Test Test of	
Ellec	ts on fertility	Species: Ra	Route: Ingestion
Effec	ts on foetal develop-		ertility/early embryonic development
ment		Species: Ra	
		Application I	Route: Ingestion
		Result: nega	ative
Mom	etasone:		
-	ts on fertility	: Test Type: F	- Artility
Liico	is off fertility	Species: Ra	
			Route: Subcutaneous
			AEL: 0.015 mg/kg body weight
			Reduced embryonic survival, Reduced foetal
			Reduced emplyonic survival, Reduced Ideial
		weight Result: No e	ffects on fertility, Effect on reproduction capacity
Fffor	ts on foetal develop-	· Test Type: F	Embryo-foetal development
ment	•	Species: Mc	
mont		•	Route: Subcutaneous
			al toxicity: LOAEL: 0.06 mg/kg body weight
			ryotoxic effects., Teratogenicity and developmen
		Test Type: E	Embryo-foetal development
		Species: Ra	t
			Route: Dermal
			al toxicity: LOAEL: 0.3 mg/kg body weight
		<b>,</b> -	



Result: Embryo-foetal toxicity         Test Type: Embryo-foetal development         Species: Rabbit         Application Route: Dermal         Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight         Result: Embryo-foetal development         Species: Rat         Application Route: Subcutaneous         Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight         Result: Effects on newborn         Test Type: Embryo-foetal development         Species: Rabbit         Application Route: Oral         Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight         Result: Effects on newborn         Species: Rabbit         Application Route: Oral         Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight         Result: Embryo-foetal toxicity, Malformations were observed         Seessment         Elfects on fertility         Elfects on fertility         Effects on fertility         Effects on foetal developer         ment         Species: Rabbit         Application Route: Ingestion         Method: OECD Test Guideline 416         Result: negative         Remarks: Based on data from similar materials         Effects on foetal developer         Effects on foetal develop	ersion 1	Revision Date: 2020/10/16	SDS Number: 23603-00017	Date of last issue: 2020/03/23 Date of first issue: 2014/10/21					
Species: Rabbit         Application Route: Dermal         Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight         Result: Embryo-foetal toxicity, Malformations were observed         Test Type: Embryo-foetal development         Species: Rat         Application Route: Subcutaneous         Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight         Result: Effects on newborn         Test Type: Embryo-foetal development         Species: Rabbit         Application Route: Subcutaneous         Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight         Result: Effects on newborn         Sessment         Effects on fertility         Effects on fertility         Effects on foetal development         Species: Rat         Application and fertility, based on animal experiments.         Stort - single exposure         Not classified based on available information.         Components:         Mometasone:         Remarks       E Based on available data, the classification criteria are not me			Result: Embi	ryo-foetal toxicity					
Species: Rat Application Route: Subcutaneous Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight Result: Effects on newborn Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight Result: Embryo-foetal toxicity. Malformations were observed sessment Effects on feetility Effects on fertility Effects on foetal develop- ment Effects on foet		Species: Rabbit Application Route: Dermal							
Species: Rabbit       Application Route: Oral         Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight       Result: Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight         Reproductive toxicity - Assessment       :       Clear evidence of adverse effects on development, based or animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments.         Benzalkonium chloride:       :       Clear evidence of adverse effects on development, based or animal experiments.         Benzalkonium chloride:       :       Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials         Effects on foetal develop- ment       :       Test Type: Embryo-foetal development Species: Ratbbit Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative Remarks: Based on data from similar materials         STOT - single exposure       Not classified based on available information.         Components:       Mometasone: Remarks         Remarks       :       Based on available data, the classification criteria are not me         STOT - repeated exposure Not classified based on available information.       Components:         Components:       :       Based on available data, the classification criteria are not me		Species: Rat Application Route: Subcutaneous Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight							
sessment       animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments.         Benzalkonium chloride:       Effects on fertility       Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials         Effects on foetal development       Test Type: Embryo-foetal development Species: Rabbit Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative Remarks: Based on data from similar materials         STOT - single exposure       Remarks: Based on data from similar materials         STOT - single exposure       Remarks: Based on data from similar materials         Mometasone:       Remarks: Based on available information.         Components:       Mometasone:         Not classified based on available information.       Eased on available data, the classification criteria are not method: STOT - repeated exposure         Not classified based on available information.       Components:         Monetasone:       Based on available data, the classification criteria are not method: Classified based on available information.         Components:       Not classified based on available information.			Species: Rat Application F Embryo-foeta	obit Route: Oral al toxicity: LOAEL: 0.7 mg/kg body weight					
Effects on fertility       : Test Type: Two-generation reproduction toxicity study         Species: Rat       Application Route: Ingestion         Method: OECD Test Guideline 416       Result: negative         Remarks: Based on data from similar materials       Effects on foetal develop-         Effects on foetal develop-       : Test Type: Embryo-foetal development         Species: Rabbit       Application Route: Ingestion         Method: OECD Test Guideline 414       Result: negative         Remarks: Based on data from similar materials       Method: OECD Test Guideline 414         Result: negative       Remarks: Based on data from similar materials         STOT - single exposure       Not classified based on available information.         Components:       Mometasone:         Remarks       : Based on available data, the classification criteria are not method:         STOT - repeated exposure       Not classified based on available information.         Components:       Not classified based on available information.	•	-	animal exper	iments., Some evidence of adverse effects on					
Species: Rat         Application Route: Ingestion         Method: OECD Test Guideline 416         Result: negative         Remarks: Based on data from similar materials         Effects on foetal develop-         image: method:         Effects on foetal develop-         image: method:         Species: Rabbit         Application Route: Ingestion         Method: OECD Test Guideline 414         Result: negative         Remarks: Based on data from similar materials         STOT - single exposure         Not classified based on available information.         Components:         Mometasone:         Remarks       :         Based on available data, the classification criteria are not method:         STOT - repeated exposure         Not classified based on available information.         Components:         Monetasone:         Remarks       :         Based on available data, the classification criteria are not method:         STOT - repeated exposure         Not classified based on available information.         Components:	Benza	alkonium chloride:							
ment       Species: Rabbit Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative Remarks: Based on data from similar materials         STOT - single exposure Not classified based on available information.         Components: Remarks         Mometasone: Remarks         Remarks         STOT - repeated exposure Not classified based on available information.         STOT - repeated exposure Not classified based on available information.         Components: Remarks         Mometasone: Remarks         Remarks         :         Based on available data, the classification criteria are not method         STOT - repeated exposure Not classified based on available information.         Components:	Effect	s on fertility	Species: Rat Application F Method: OEC Result: nega	Route: Ingestion CD Test Guideline 416 tive					
Not classified based on available information.         Components:         Mometasone:         Remarks       :         Based on available data, the classification criteria are not me         STOT - repeated exposure         Not classified based on available information.         Components:		s on foetal develop-	Species: Rat Application F Method: OE0 Result: nega	obit Route: Ingestion CD Test Guideline 414 tive					
Mometasone:         Remarks       : Based on available data, the classification criteria are not me         STOT - repeated exposure         Not classified based on available information.         Components:		• •	able information.						
Remarks       : Based on available data, the classification criteria are not me         STOT - repeated exposure         Not classified based on available information.         Components:	<u>Com</u>	oonents:							
Not classified based on available information.			: Based on av	ailable data, the classification criteria are not me					
Mometasone:	<u>Com</u> r	oonents:							
Exposure routes : inhalation (dust/mist/fume)			: inhalation (du	ust/mist/fume)					



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	et Organs ssment		ause dama	Liver, Kidney, Skin ge to organs through prolonged or repeated
Benza	alkonium chloride:			
Asses	ssment			alth effects observed in animals at concentra g bw or less.
Repe	ated dose toxicity			
Comp	oonents:			
Cellu	lose:			
		: Rat : >= 9,0 : Ingest : 90 Da		
Mome	etasone:			
Expos	EL	: 0.3 m : Oral : 30 d		ver, Adrenal gland, Skin, thymus gland
Expos		: Dog : 0.5 mg : Oral : 30 d : Lympł		ver, Adrenal gland, Skin, thymus gland
Expos		: inhala : 90 d : Adren	13 mg/l tion (dust/m al gland, Lu y, Liver, thy	ings, Lymph nodes, spleen, Bone marrow,
Expos		: 90 d : Adren	tion (dust/m	ings, Lymph nodes, spleen, Bone marrow,
Benza	alkonium chloride:			
		: Rat : >= 10 : Ingest : 12 We		



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-	iration toxicity classified based on av	ailable inforn	nation.	
Con	nponents:			
	netasone: applicable			
Exp	erience with human e	exposure		
<u>Con</u>	<u>iponents:</u>			
Mon	netasone:			
Inha	lation	pirat	ory tract in	ergic rhinitis, Headache, pharyngitis, upper res- nfection, sinusitis, oral candidiasis, Back pain, al pain, immune system effects, indigestion
Skin	contact	: Sym	ptoms: De	ermatitis, Itching
Furt	her information			
<u>Con</u>	ponents:			
	netasone: narks	: Derr	nal absorp	otion possible

## 12. ECOLOGICAL INFORMATION

Ecotoxicity	
Components:	
Cellulose:	
Toxicity to fish :	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Mometasone:	
	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



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				OPPTS 850.1035 city at the limit of solubility
Toxic plants	ity to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD Te	
Toxic icity)	ity to fish (Chronic tox-	:	NOEC (Pimephale mg/l Exposure time: 32 Method: OECD Te	
	ity to daphnia and other tic invertebrates (Chron- icity)	:	Exposure time: 21 Method: OECD Te	
M-Fa	ctor (Chronic aquatic	:	100	
	ity to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Test Type: Respir Method: OECD Te Remarks: No toxid	h ration inhibition
			NOEC: 1,000 mg/ Exposure time: 3 Test Type: Respir Method: OECD Te Remarks: No toxic	h ration inhibition
Benz	alkonium chloride:			
Toxic	ity to fish	:	LC50 (Pimephales Exposure time: 96	s promelas (fathead minnow)): 0.28 mg/l S h
	ity to daphnia and other tic invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): 0.0056 mg/l 3 h
Toxic plants	ity to algae/aquatic	:	ErC50 (Chlorella   Exposure time: 72	pyrenoidosa (aglae)): 0.09 mg/l 2 h
	ctor (Acute aquatic tox-	:	100	
icity) Toxic icity)	Toxicity to fish (Chronic tox-		NOEC (Pimephale Exposure time: 34	es promelas (fathead minnow)): 0.032 mg/l 1 d
Persi	stence and degradabil	ity		
<u>Com</u>	ponents:			
<b>Cellu</b> Biode	<b>lose:</b> egradability	:	Result: Readily bi	odegradable.



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Mom	etasone:						
Biodegradability		:	<ul> <li>Result: Not readily biodegradable.</li> <li>Biodegradation: 50 %</li> <li>Exposure time: 28 d</li> <li>Method: OECD Test Guideline 314</li> </ul>				
Stability in water		:	Hydrolysis: 50 %(12 d) Method: OECD Test Guideline 111				
Benz	alkonium chloride:						
Biode	egradability	:	Method: OECC	/ biodegradable. ) Test Guideline 301D ed on data from similar materials			
Bioa	ccumulative potential						
Com	ponents:						
-	etasone: ccumulation	:	Bioconcentratio	mis macrochirus (Bluegill sunfish) on factor (BCF): 107.1 ) Test Guideline 305			
	ion coefficient: n- ol/water	:	log Pow: 4.68				
Benz	alkonium chloride:						
Bioac	cumulation	:	Bioconcentratio	mis macrochirus (Bluegill sunfish) on factor (BCF): < 500 ed on data from similar materials			
	ion coefficient: n- ol/water	:	log Pow: 1.692 Remarks: Calc				
Mobi	lity in soil						
Com	ponents:						
Distri	etasone: bution among environ- al compartments	:	log Koc: 4.02				
	rdous to the ozone lay	er					
	r adverse effects ata available						

**Disposal methods** Waste from residues

: Dispose of in accordance with local regulations.



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Contaminated packaging		:	dling site for recyc	should be taken to an approved waste han- cling or disposal. becified: Dispose of as unused product.	
14. TRANSPORT INFORMATION					
	Interna	tional Regulations			
	UNRTI UN nur Proper	-	:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID, enzalkonium chloride)
Class Packing group Labels		:	9 III 9		
	IATA-DGR UN/ID No. Proper shipping name Class Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft) Environmentally hazardous		:		azardous substance, liquid, n.o.s. enzalkonium chloride)
			:	9 III Miscellaneous	
			:	964	
			:	964	
			:	yes	
	IMDG-( UN nur Proper		:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
	Labels EmS C	g group ode pollutant	:	9 III 9 F-A, S-F yes	

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

Not applicable for product as supplied.

## **National Regulations**

Refer to section 15 for specific national regulation.

### 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.



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## Mometasone Suspension Formulation

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

#### **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

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

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

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

## Harmful Substances Required Permission for Manufacture

Not applicable

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

Not applicable

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

Not applicable

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

Not applicable

## Substances Subject to be Notified Names

Not applicable

## Substances Subject to be Indicated Names

Not applicable

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

Not applicable

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

Not applicable

## Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

# Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

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

Not applicable

# Poisonous and Deleterious Substances Control Law

Not applicable

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



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-	Pressure Gas Safety	Act	
-	osive Control Law		
Misce	el Safety Law Ilaneous dangerous su f dangerous goods and		es (Article 2 and 3 of rules on shipping and stor- 1)
Misce	<b>ion Law</b> Ilaneous dangerous su aw and its Attached Ta		es (Article 194 of The Enforcement Rules of Avia
Marin	e Pollution and Sea	Disaster Preventior	n etc Law
Bulk t	ransportation	: Noxious liquid	substance(Category Z)
Pack	transportation	: Classified as	marine pollutant
Narco	otics and Psychotropi atic or Psychotropic Ray oplicable		Import Permission)
	fic Narcotic or Psychot oplicable	ropic Raw Material (	Export / Import permission)
	e Disposal and Public trial waste	Cleansing Law	
The c	omponents of this pr	oduct are reported	in the following inventories:
AICS		: not determine	d
DSL		: not determine	d
IECS	C	: not determine	d
6. OTHE	R INFORMATION		
Furth	er information		
	es of key data used to ile the Safety Data		ical data, data from raw material SDSs, OECD search results and European Chemicals Agen- a.europa.eu/
Date f	format	: yyyy/mm/dd	
Full t	ext of other abbreviat	ions	

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;



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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

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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