

Vers 3.12		Revision Date: 16.10.2020		S Number: 610-00016	Date of last issue: 13.09.2019 Date of first issue: 21.10.2014
Sec	tion 1:	dentification			
	Product name		:	Mometasone Su	spension Formulation
	Manufacturer or supplier's d		leta	ils	
	Company		:	Organon & Co.	
	Address		:	30 Hudson Stree Jersey City, New	t, 33nd floor Jersey, U.S.A 07302
	Telephone		:	551-430-6000	
	Emergency telephone number		r :	215-631-6999	
	E-mail address		:	EHSSTEWARD	2 organon.com
		mended use of the cl	-		ons on use
	Recommended use		:	Pharmaceutical	

#### Section 2: Hazard identification

#### **GHS Classification**

Not a hazardous substance or mixture.

#### **GHS** label elements

Not a hazardous substance or mixture.

#### Other hazards which do not result in classification

None known.

### Section 3: Composition/information on ingredients

Substance / Mixture	:	Mixture
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#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Glycerine	56-81-5	< 10
Cellulose	9004-34-6	< 10
Mometasone	83919-23-7	< 0.3

#### Section 4: First-aid measures

If inhaled	: If inhaled, remove to fresh air.	
In some of all in some of	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	s.
If swallowed	: If swallowed, DO NOT induce vomiting.	
	Get medical attention if symptoms occur.	



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and e	Most important symptoms and effects, both acute and delayed Protection of first-aiders Notes to physician		Rinse mouth thor None known.	oughly with water.
Prote				utions are necessary for first aid responders. ically and supportively.
Section 5	: Fire-fighting measure	s		
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (0 Dry chemical	
Unsu medi	iitable extinguishing a	:	None known.	
fighti	Specific hazards during fire- fighting Hazardous combustion prod- ucts Specific extinguishing meth- ods Special protective equipment for firefighters			bustion products may be a hazard to health.
			Carbon oxides	
•			cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do
			essary.	ed breathing apparatus for firefighting if nec-
Hazo	hem Code	:	Use personal pro 3Z	tective equipment.
Section 6	: Accidental release me	eas	ures	
tive e	Personal precautions, protec- tive equipment and emer- gency procedures Environmental precautions			ling advice (see section 7) and personal pro- t recommendations (see section 8).
Envir				the environment. akage or spillage if safe to do so. g over a wide area (e.g. by containment or oil

tive equipment and emer- gency procedures	•	tective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contain- ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor- bent. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable.



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					5 of this SDS provide information regarding tional requirements.
Sectio	on 7: Har	ndling and storage			
Т	echnical	measures	:		neasures under EXPOSURE SONAL PROTECTION section.
L	.ocal/Tota	l ventilation	:	Use only with ade	
Advice on safe handling			:	Handle in accorda practice, based or sessment	ance with good industrial hygiene and safety in the results of the workplace exposure as- ent spills, waste and minimize release to the
Hygiene measures		:	If exposure to chemical is likely during typical use, provide ey 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.		
С	Conditions	s for safe storage	:	Keep in properly I	abelled containers. ce with the particular national regulations.
N	/laterials t	o avoid	:		the following product types:

#### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	cAS-No.		Control parame-	Basis
		(Form of exposure)	ters / Permissible concentration	
Glycerine	56-81-5	WES-TWA (Mist)	10 mg/m3	NZ OEL
Cellulose	9004-34-6	WES-TWA	10 mg/m3	NZ 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 <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 potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

## SAFETY DATA SHEET



# Mometasone Suspension Formulation

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Perso	onal protective equipn	nent		
Fil	iratory protection Iter type protection	<ul> <li>If adequate local exhaust ventilation is not available or exsure assessment demonstrates exposures outside the roommended guidelines, use respiratory protection.</li> <li>Combined particulates and organic vapour type</li> </ul>		demonstrates exposures outside the rec- lines, use respiratory protection.
Material		:	Chemical-resistar	nt gloves
Eye p	emarks protection and body protection	:	Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty condition 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. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, or posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potenti contaminated clothing.	

### Section 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
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available

### SAFETY DATA SHEET



## **Mometasone Suspension Formulation**

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Relative vapour density		: No data available	
Relat	ive density	: No data available	
Dens	ity	: 1 g/cm3	
	ility(ies) ater solubility	: soluble	
	ion coefficient: n-	: Not applicable	
octanol/water Auto-ignition temperature		: No data available	
Deco	mposition temperature	: No data available	
Visco Vi	sity scosity, kinematic	: No data available	
Explo	sive properties	: Not explosive	
Oxidi	zing properties	: The substance or m	nixture is not classified as oxidizing.
Moleo	cular weight	: Not applicable	
Partic	cle size	: Not applicable	

#### Section 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.

### Section 11: Toxicological information

Exposure routes	: Inhalation Skin contact Ingestion Eye contact	
Acute toxicity Not classified based on avai	able information.	
Components:		
Glycerine: Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg	
Acute dermal toxicity	: LD50 (Guinea pig): > 5,000 mg/kg	



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Cellu	lose:			
Acute	oral toxicity	:	LD50 (Rat): > 5,	000 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 5. Exposure time: 4 Test atmosphere	↓h
Acute	dermal toxicity	:	LD50 (Rabbit): >	- 2,000 mg/kg
Mome	etasone:			
Acute	oral toxicity	:	LD50 (Rat): > 2,	000 mg/kg
			LD50 (Mouse): >	> 2,000 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 3. Exposure time: 4 Test atmosphere Remarks: No mo	lh -
			LC50 (Mouse): > Exposure time: 4 Test atmosphere	1 h
	toxicity (other routes of istration)	:		e: Subcutaneous
Skin	corrosion/irritation			
-	assified based on availa	ble	information.	
Comp	oonents:			
Glyce				
Speci			Rabbit	
Resul		:	No skin irritation	
Mome	etasone:			
Speci	es	:	Rabbit	
Resul	t	:	No skin irritation	
Serio	us eye damage/eye irri	tati	on	
Not cl	assified based on availa	ble	information.	
<u>Comp</u>	oonents:			
Glyce	erine:			
	••		Rabbit	
Speci Resul		•	Ναυσιι	



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Mome	etasone:			
Speci			Rabbit	
Resul			No eye irritation	l
Resp	iratory or skin sens	itisatio	n	
-	sensitisation			
Not cl	assified based on av	ailable	information.	
Resp	iratory sensitisatior	า		
Not cl	assified based on av	ailable	information.	
<u>Comp</u>	oonents:			
	etasone:			
Test 7		:	Maximisation T	est
Expos Speci	sure routes	-	Dermal Guinea pig	
	es ssment	:		e skin sensitisation.
Resul			negative	
Rema	irks	:		a test on guinea pigs showed this substance to
			be a weak skin	sensitiser.
Chroi	nic toxicity			
	-			
	cell mutagenicity			
Not cl	assified based on av	ailable	information.	
<u>Comp</u>	oonents:			
Glyce	erine:			
-	erine: toxicity in vitro	:	Test Type: In v	itro mammalian cell gene mutation test
-		:	Test Type: In v Result: negativ	
-		:	Result: negativ	e
-		:	Result: negativ Test Type: Bac	e terial reverse mutation assay (AMES)
-		:	Result: negativ Test Type: Bac Result: negativ	e terial reverse mutation assay (AMES) e
-		:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr	e terial reverse mutation assay (AMES) e omosome aberration test in vitro
-		:	Result: negativ Test Type: Bac Result: negativ	e terial reverse mutation assay (AMES) e omosome aberration test in vitro
-		÷	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e
-		:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ Test Type: DN/	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e
-		:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ Test Type: DN/	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e A damage and repair, unscheduled DNA syn- nalian cells (in vitro)
Geno	toxicity in vitro	:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ Test Type: DN/ thesis in mamn	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e A damage and repair, unscheduled DNA syn- nalian cells (in vitro)
Geno	toxicity in vitro	:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ Test Type: DN/ thesis in mamn Result: negativ	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e A damage and repair, unscheduled DNA syn- nalian cells (in vitro) e
Geno	toxicity in vitro	:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ Test Type: DN/ thesis in mamn Result: negativ	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e A damage and repair, unscheduled DNA syn- nalian cells (in vitro) e terial reverse mutation assay (AMES)
Geno	toxicity in vitro	:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ Test Type: DN/ thesis in mamn Result: negativ Test Type: Bac Result: negativ	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e A damage and repair, unscheduled DNA syn- nalian cells (in vitro) e terial reverse mutation assay (AMES) e
Geno	toxicity in vitro	:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ Test Type: DN/ thesis in mamn Result: negativ Test Type: Bac Result: negativ	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e A damage and repair, unscheduled DNA syn- nalian cells (in vitro) e terial reverse mutation assay (AMES) e
Geno Cellu Geno	toxicity in vitro lose: toxicity in vitro	:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ Test Type: DNA thesis in mamn Result: negativ Test Type: Bac Result: negativ Test Type: In v Result: negativ	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e A damage and repair, unscheduled DNA syn- nalian cells (in vitro) e terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e
Geno Cellu Geno	toxicity in vitro	:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ Test Type: DN/ thesis in mamn Result: negativ Test Type: Bac Result: negativ Test Type: In v Result: negativ Test Type: In v Result: negativ	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e A damage and repair, unscheduled DNA syn- nalian cells (in vitro) e terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e nmalian erythrocyte micronucleus test (in vivo
Geno Cellu Geno	toxicity in vitro lose: toxicity in vitro	:	Result: negativ Test Type: Bac Result: negativ Test Type: Chr Result: negativ Test Type: DNA thesis in mamn Result: negativ Test Type: Bac Result: negativ Test Type: In v Result: negativ	e terial reverse mutation assay (AMES) e omosome aberration test in vitro e A damage and repair, unscheduled DNA syn- nalian cells (in vitro) e terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say)



sion 2	Revision Date: 16.10.2020		Number: )-00016	Date of last issue: 13.09.2019 Date of first issue: 21.10.2014
			oplication Ro esult: negati	oute: Ingestion ve
Mome	etasone:			
Genot	toxicity in vitro		est Type: Ba esult: negati	cterial reverse mutation assay (AMES) ve
		Τe		rromosomal aberration Chinese hamster lung cells ve
		Τe		rromosomal aberration Chinese hamster ovary cells re
			est Type: Mo esult: negati	buse Lymphoma ve
Genot	toxicity in vivo	Sr Ar	est Type: Mi becies: Mou oplication Ro esult: negati	oute: Oral
		Sp Ce	est Type: Ch becies: Rat ell type: Bon esult: negati	
		Sp Ce	est Type: un becies: Rat ell type: Live esult: negati	
	cell mutagenicity - sment		eight of evic Il mutagen.	lence does not support classification as a gern
Carci	nogenicity			
	assified based on ava	ailable info	ormation.	
	oonents:			
Glyce			<b>-</b> t	
Specie	es ation Route	: Ra : In	at gestion	
	sure time		Years	
Resul		: ne	egative	
Cellul	lose:			
Speci		: Ra		
	ation Route		gestion	
Expos Resul	sure time t		2 weeks egative	
	ι		gauve	



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Mome	etasone:		
	cation Route sure time	: Rat : Inhalation : 2 Years : 0.067 mg/kg b : negative	ody weight
	cation Route sure time	: Mouse : Inhalation : 19 Months : 0.160 mg/kg b : negative	ody weight
-	oductive toxicity assified based on ava	ilable information.	
Comp	oonents:		
<b>Glyce</b> Effect	e <b>rine:</b> s on fertility	: Test Type: Tw Species: Rat Application Ro Result: negativ	
Effect ment	s on foetal develop-	: Test Type: Em Species: Rat Application Ro Result: negativ	
Cellu	lose:		
Effect	s on fertility	: Test Type: On Species: Rat Application Rc Result: negativ	
Effect ment	s on foetal develop-	: Test Type: Fer Species: Rat Application Ro Result: negativ	
Mome	etasone:		
Effect	s on fertility	Fertility: NOAE Symptoms: Re weight	rtility pute: Subcutaneous EL: 0.015 mg/kg body weight educed embryonic survival, Reduced foetal ects on fertility, Effect on reproduction capacity
Effect ment	s on foetal develop-	Species: Mous Application Ro	nbryo-foetal development se bute: Subcutaneous toxicity: LOAEL: 0.06 mg/kg body weight



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			Result: Embryo tal toxicity	toxic effects., Teratogenicity and developmen-
			Species: Rat Application Rou	oxicity: LOAEL: 0.3 mg/kg body weight
			Species: Rabbi Application Rou Embryo-foetal t	
			Species: Rat Application Rou	oryo-foetal development ite: Subcutaneous oxicity: LOAEL: 0.15 mg/kg body weight on newborn
			Species: Rabbi Application Rou Embryo-foetal t	
Repro sessn	oductive toxicity - As- nent	:	animal experim	of adverse effects on development, based on ents., Some evidence of adverse effects on and fertility, based on animal experiments.
	- single exposure assified based on avail	able	information.	
<u>Comp</u>	oonents:			
<b>Mome</b> Rema	<b>etasone:</b> ırks	:	Based on availa	able data, the classification criteria are not met
	- repeated exposure assified based on avail	able	information.	
Comp	oonents:			
Expos Targe	etasone: sure routes st Organs ssment	:		/mist/fume) n, Liver, Kidney, Skin nage to organs through prolonged or repeated



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Repe	ated dose toxicity		
Com	ponents:		
-	erine:		
	EL	: Rat : 0.167 mg/l : 0.622 mg/l : inhalation (dus : 13 Weeks	st/mist/fume)
		: Rat : 8,000 - 10,000 : Ingestion : 2 yr	) mg/kg
		: Rabbit : 5,040 mg/kg : Skin contact : 45 Weeks	
	ies	: Rat : >= 9,000 mg/ł : Ingestion : 90 Days	۶g
Mom	etasone:		
Expo	EL	: Rat : 0.005 mg/kg : 0.3 mg/kg : Oral : 30 d : Lymph nodes	, Liver, Adrenal gland, Skin, thymus gland
Expo		: Dog : 0.5 mg/kg : Oral : 30 d : Lymph nodes	, Liver, Adrenal gland, Skin, thymus gland
Expo			st/mist/fume) , Lungs, Lymph nodes, spleen, Bone marrow, thymus gland
Expo			st/mist/fume) , Lungs, Lymph nodes, spleen, Bone marrow, ıs gland, Liver



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-	ration toxicity lassified based on ava	ailable	information.	
Com	ponents:			
	<b>etasone:</b> pplicable			
Expe	rience with human e	exposu	ire	
Com	ponents:			
Mom	etasone:			
Inhala	ation	:	piratory tract i	lergic rhinitis, Headache, pharyngitis, upper res- nfection, sinusitis, oral candidiasis, Back pain, tal pain, immune system effects, indigestion
Skin o	contact	:		ermatitis, Itching
Furth	ner information			
Com	ponents:			
<b>Mom</b> Rema	<b>etasone:</b> arks	:	Dermal absor	ption possible

### Section 12: Ecological information

Ecotoxicity		
Components:		
Glycerine:		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,955 mg/l Exposure time: 48 h
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 10,000 mg/l Exposure time: 16 h Method: DIN 38 412 Part 8
Cellulose:		
Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Mometasone:		
Toxicity to fish	:	LC50 (Menidia beryllina (Silverside)): 0.11 mg/l Exposure time: 96 h Remarks: No toxicity at the limit of solubility



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			Exposure time:	lon variegatus (sheepshead minnow)): > 5 mg 7 d pxicity at the limit of solubility
Toxicity to daphnia and other : aquatic invertebrates		:	Exposure time: Method: OECD	magna (Water flea)): > 5 mg/l 48 h Test Guideline 202 xicity at the limit of solubility
			Exposure time: Method: US-EF	mysis): > 5 mg/l 96 h PA OPPTS 850.1035 exicity at the limit of solubility
Toxici plants	ty to algae/aquatic	:	mg/l Exposure time: Method: OECD	tirchneriella subcapitata (green algae)): > 3.2 72 h Test Guideline 201 pricity at the limit of solubility
Toxici icity)	ty to fish (Chronic tox-	:	mg/l Exposure time:	ales promelas (fathead minnow)): 0.00014 32 d Test Guideline 210
	ty to daphnia and other ic invertebrates (Chron- city)	:	Exposure time: Method: OECD	a magna (Water flea)): 0.34 mg/l 21 d Test Guideline 211 xicity at the limit of solubility
Toxici	ty to microorganisms	:	Method: OECD	
			Method: OECD	
Persi	stence and degradabili	ity		
<u>Comp</u>	oonents:			
<b>Glyce</b> Biode	e <b>rine:</b> gradability	:	Result: Readily Biodegradation Exposure time:	: 92 %



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Biode	gradability	:	: Result: Readily biodegradable.			
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>			
Stabil	ity in water	:	Hydrolysis: 50 % Method: OECD T	(12 d) est Guideline 111		
Bioad	cumulative potential					
<u>Comp</u>	oonents:					
Glyce	erine:					
	on coefficient: n- ol/water	:	log Pow: -1.75			
Mome	etasone:					
Bioac	cumulation	:	: Species: Lepomis macrochirus (Bluegill sunfish Bioconcentration factor (BCF): 107.1 Method: OECD Test Guideline 305			
	Partition coefficient: n- octanol/water		log Pow: 4.68			
Mobil	lity in soil					
<u>Comp</u>	oonents:					
Mom	etasone:					
	oution among environ- al compartments	:	log Koc: 4.02			
Other	adverse effects					
No da	ita available					

Disposal methods	
Waste from residues Contaminated packaging	Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### Section 14: Transport information

### **International Regulations**

### UNRTDG

UN number Proper shipping name	-	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
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			(Mometasone	Benzalkonium chloride)
Class		:	9	
Packi	ng group	:	III	
Label	S	:	9	
IATA	-DGR			
UN/IE		:	UN 3082	
-	er shipping name	:		/ hazardous substance, liquid, n.o.s. Benzalkonium chloride)
Class		:	9	
	ng group	÷		
Label	s ng instruction (cargo	÷	Miscellaneous 964	
aircra		•	304	
	ng instruction (passen-	:	964	
ger ai	rcraft)			
Enviro	onmentally hazardous	:	yes	
IMDG	i-Code			
	umber	:	UN 3082	
Prope	er shipping name	:	N.O.S.	TALLY HAZARDOUS SUBSTANCE, LIQUID
Class				Benzalkonium chloride)
Class Packi	ng group	:	9 	
Label		÷	9	
EmS		:	F-A, S-F	
Marin	e pollutant	:	: yes	
Trans	sport in bulk according	ı to	Annex II of MAR	POL 73/78 and the IBC Code
	pplicable for product as			
Natio	nal Regulations			
NZS	5433			
	umber	:	UN 3082	
Prope	er shipping name	:		TALLY HAZARDOUS SUBSTANCE, LIQUID
			N.O.S.	5
Class			(Mometasone, 9	Benzalkonium chloride)
	ng group	:	9 III	
Label		:	9	
	nem Code	:	3Z	
Spec	ial precautions for use	r		
-	•		vided herein are	for informational purposes only, and solely
based	d upon the properties of	the	unpackaged mat	erial as it is described within this Safety Data mode of transportation, package sizes, and v

Section 15: Regulatory information

iations in regional or country regulations.

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



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#### HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

#### **HSW Controls**

Certified handler certificate not required. Tracking hazardous substance not required. Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:			
AICS	:	not determined	
DSL	:	not determined	
IECSC	:	not determined	

#### Section 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 Agency, http://echa.europa.eu/			
Date format	:	dd.mm.yyyy			
Full text of other abbreviations					
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)			
NZ OEL	:	New Zealand. Workplace Exposure Standards for Atmospher- ic Contaminants			
ACGIH / TWA	:	8-hour, time-weighted average			
NZ OEL / WES-TWA	:	Workplace Exposure Standard - 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 Develop-



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ment; 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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