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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier Trade name	:	Mometasone Metered Dose Inhaler Formulation			
1.2 Relevant identified uses of the substance or mixture and uses advised against Use of the Sub- : Pharmaceutical stance/Mixture					
1.3 Details of the supplier of Company	the safe	ety data sheet Organon & Co. Shotton Lane			
Telephone	:	NE23 3JU Cramlington NU - Great Britain 44 1 670 59 30 00			
E-mail address of person responsible for the SDS	:	EHSSTEWARD@organon.com			

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Aerosols, Category 3 Long-term (chronic) aquatic hazard, Category 2 H229: Pressurised container: May burst if heated. H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) Hazard pictograms • Signal word Warning 1 Hazard statements Pressurised container: May burst if heated. 2 H229 H411 Toxic to aquatic life with long lasting effects. Precautionary statements : **Prevention:** P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P251 Do not pierce or burn, even after use. 1/21



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P273 Avoid release to the environment.

Response:

P391 Collect spillage.

Storage:

P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F.

Additional Labelling

Contains fluorinated greenhouse gases. (HFC-227ea) 2.5 % by mass of the contents are flammable.

2.3 Other hazards

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

May displace oxygen and cause rapid suffocation.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Ethanol#	64-17-5	Flam. Liq. 2; H225	>= 1.8 - <= 2.5
	200-578-6	Eye Irrit. 2; H319	
	603-002-00-5		
Mometasone	83919-23-7	Repr. 1B; H360Df	>= 0.08 - <=
		STOT RE 2; H373	0.18
		(Immune system,	
		Liver, Kidney, Skin)	
		Aquatic Chronic 1;	
		H410	
		M Faster (Chronie	
		M-Factor (Chronic	
		aquatic toxicity): 100	

Voluntarily-disclosed non-hazardous substance

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For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

In the case of accident or if you feel unwell, seek medical advice immediately.



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			When symptoms advice.	persist or in all cases of doubt seek medical	
Protection of first-aiders		:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).		
If inhaled		:	If breathing is dif	e to fresh air. give artificial respiration. ficult, give oxygen. ntion immediately.	
In case of skin contact		:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.		
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. Rinse mouth thoroughly with water.		
4.2 Most	important symptoms a	nd e	effects, both acut	e and delayed	
Risks	3	:	Gas reduces oxy	gen available for breathing.	
	-	me		d special treatment needed	
Treat	ment	:	Treat symptomat	ically and supportively.	
SECTIO	N 5: Firefighting mea	sur	es		
5.1 Exting	guishing media				
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical		
Unsu medi	itable extinguishing a	:	: None known.		
5.2 Speci	al hazards arising from	n the	e substance or m	ixture	
-	ific hazards during fire-	:	Exposure to com	bustion products may be a hazard to health. e rises there is danger of the vessels bursting	
Haza	rdous combustion prod-	:	Carbon oxides		



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ucts			Fluorine compour	nds
Specia for fire	for firefighters Il protective equipment fighters ic extinguishing meth-	:	Use personal pro Use extinguishing cumstances and Use water spray	e, wear self-contained breathing apparatus. tective equipment. 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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures				
Personal precautions :	Evacuate personnel to safe areas. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).			
6.2 Environmental precautions				

Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
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6.3 Methods and material for containment and cleaning up

Methods for cleaning up	 Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment 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 absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
	certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.



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SECTION 7: Handling and storage

7.1 Precautions for safe handling	
Technical measures :	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation :	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling :	Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures :	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami- nated clothing before re-use.
7.2 Conditions for safe storage, in	
Requirements for storage : areas and containers	Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Do not pierce or burn, even after use. Keep cool. Protect from sunlight.
Advice on common storage	 Do not store with the following product types: Self-reactive substances and mixtures Organic peroxides Oxidizing agents Flammable solids Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which in contact with water, emit flammable gases Explosives Gases
7.3 Specific end use(s)	
Specific use(s) :	No data available
	No data available



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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis		
Ethanol	64-17-5	TWA	1,000 ppm 1,920 mg/m3	GB EH40		
		Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.				
Mometasone	83919-23-7	83919-23-7 TWA 1 µg/m3 (OEB 4) Internal				
	Further inform	Further information: Skin				
		Wipe limit 10 µg/100 cm ² Internal				

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

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Ethanol	Workers	Inhalation	Long-term systemic effects	950 mg/m3
	Workers	Skin contact	Long-term systemic effects	343 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m3
	Consumers	Skin contact	Long-term systemic effects	206 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	87 mg/kg bw/day
1,1,1,2,3,3,3- Heptafluoropropane	Workers	Inhalation	Long-term systemic effects	61279 mg/m3
	Consumers	Inhalation	Long-term systemic effects	6533 mg/m3

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

Substance name	Environmental Compartment	Value
Ethanol	Fresh water	0.96 mg/l
	Freshwater - intermittent	2.75 mg/l
	Marine water	0.79 mg/l
	Sewage treatment plant	580 mg/l
	Fresh water sediment	3.6 mg/kg dry
		weight (d.w.)
	Marine sediment	2.9 mg/kg dry
		weight (d.w.)
	Soil	0.63 mg/kg dry
		weight (d.w.)
	Oral (Secondary Poisoning)	380 mg/kg food
1,1,1,2,3,3,3-Heptafluoropropane	Fresh water	0.1 mg/l
	Intermittent use/release	1 mg/l
	Sewage treatment plant	1.73 mg/l
	Fresh water sediment	1.3 mg/kg



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8.2 Exposure controls

Personal protective equipment					
Skin and body protection	: Skin should be washed after contact.				
Respiratory protection	 If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to BS EN 137 				
Filter type	: Self-contained breathing apparatus				

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	:	Aerosol containing a dissolved gas white to off-white odourless No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	-16 °C
range 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
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1 g/cm ³
Solubility(ies) Water solubility Partition coefficient: n- octanol/water Auto-ignition temperature	:	insoluble No data available No data available



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Dee	composition temperature	:	No data availabl	e
	cosity Viscosity, kinematic	:	No data availabl	e
Explosive properties		:	Not explosive	
Oxidizing properties		:	The substance c	or mixture is not classified as oxidizing.
Мо	er information lecular weight ticle size	:	No data availabl No data availabl	-
rai		•	NO Gald availabl	5

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	: If the temperature rises there is danger of the vessels bursting
	due to the high vapor pressure.
	Can react with strong oxidizing agents.

10.4 Conditions to avoid

: None known.

10.5 Incompatible materials

Conditions to avoid

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Not classified based on available information.

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according to Regulation (EC) No. 1907/2006

sion S	Revision Date: 09.04.2021	-	987-00017	Date of last issue: 16.10.2020 Date of first issue: 28.10.2014	
Com	ponents:				
Ethar	nol:				
Acute	e oral toxicity	:	LD50 (Rat): > 5,0 Method: OECD To		
Acute inhalation toxicity		:	LC50 (Rat): 124.7 mg/l Exposure time: 4 h Test atmosphere: vapour		
Mome	etasone:				
Acute	e oral toxicity	:	LD50 (Rat): > 2,0	00 mg/kg	
			LD50 (Mouse): >	2,000 mg/kg	
Acute	inhalation toxicity	:	Exposure time: 4 Test atmosphere:	h	
			LC50 (Mouse): > Exposure time: 4 Test atmosphere:	h	
	e toxicity (other routes of nistration)	:	LD50 (Rat): 300 n Application Route Symptoms: Breat	: Subcutaneous	
Not cl	corrosion/irritation lassified based on availal ponents:	blei	information.		
Ethar					
Speci	nol: ies	:	Rabbit		
	nol: ies od	:	Rabbit OECD Test Guide No skin irritation	eline 404	
Speci Metho Resul	n ol: ies od It		OECD Test Guide	eline 404	
Speci Metho Resul	nol: ies od It etasone:		OECD Test Guide	eline 404	
Speci Metho Resul	nol: ies od It etasone: ies	: : : : : : : : : : : : : : : : : : : :	OECD Test Guide No skin irritation	eline 404	
Speci Metho Resul Mome Speci Resul Serio	nol: ies od It etasone: ies It vus eye damage/eye irrit		OECD Test Guide No skin irritation Rabbit No skin irritation	eline 404	
Speci Metho Resul Speci Resul Serio Not cl	nol: ies od lt etasone: ies lt vus eye damage/eye irri e lassified based on availal		OECD Test Guide No skin irritation Rabbit No skin irritation	eline 404	
Speci Metho Resul Speci Resul Serio Not cl	nol: ies od It etasone: ies It vus eye damage/eye irrit		OECD Test Guide No skin irritation Rabbit No skin irritation	eline 404	
Speci Metho Resul Speci Resul Serio Not cl	nol: ies od lt etasone: ies lt pus eye damage/eye irri lassified based on availal ponents: nol:		OECD Test Guide No skin irritation Rabbit No skin irritation	eline 404	

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rsion 6	Revision Date: 09.04.2021	SDS Numb 25987-000	
Resul	lt	: Irritatio	n to eyes, reversing within 21 days
Mome	etasone:		
Speci	es	: Rabbit	
Resul		: No eye	irritation
Resp	iratory or skin sens	tisation	
Skin	sensitisation		
Not cl	assified based on av	ailable informat	on.
Resp	iratory sensitisation		
-	assified based on av		on.
<u>Comp</u>	oonents:		
Ethar	nol:		
Test 1	Гуре	: Local Iv	mph node assay (LLNA)
	sure routes	: Skin co	
Speci		: Mouse	
Resul		: negativ	e
Mome	etasone:		
Test 7	Гуре	: Maximi	sation Test
	sure routes	: Dermal	
Speci	es	: Guinea	pig
Asses	ssment	: Does n	ot cause skin sensitisation.
Resul	lt	: negativ	
Rema	arks		ults of a test on guinea pigs showed this substance eak skin sensitiser.
Germ	cell mutagenicity		
Not cl	assified based on av	ailable informat	on.
<u>Comp</u>	oonents:		
Ethar			
Geno	toxicity in vitro		pe: In vitro mammalian cell gene mutation test negative
		Test Ty	pe: Bacterial reverse mutation assay (AMES)
		Result:	negative
Geno	toxicity in vivo	: Test Ty Species Applica	C C C C C C C C C C C C C C C C C C C
	toxicity in vivo	: Test Ty Species Applica	pe: Rodent dominant lethal test (germ cell) (in vivo) s: Mouse tion Route: Ingestion
Mome		: Test Ty Specie: Applica Result:	pe: Rodent dominant lethal test (germ cell) (in vivo) s: Mouse tion Route: Ingestion

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			romosomal aberration Chinese hamster lung cells
			romosomal aberration Chinese hamster ovary cells e
		Test Type: Mo Result: negati	buse Lymphoma ve
Geno	otoxicity in vivo	: Test Type: Mi Species: Mou Application Ro Result: negati	oute: Oral
		Test Type: Ch Species: Rat Cell type: Bon Result: negati	
		Test Type: un Species: Rat Cell type: Live Result: negati	
	n cell mutagenicity- As- ment	: Weight of evic cell mutagen.	lence does not support classification as a germ
	inogenicity classified based on availa	able information.	
<u>Com</u>	ponents:		
Mom	netasone:		
	ication Route osure time	: Rat : Inhalation : 2 Years : 0.067 mg/kg b : negative	oody weight
	ication Route osure time	: Mouse : Inhalation : 19 Months : 0.160 mg/kg b : negative	oody weight

Reproductive toxicity

Not classified based on available information.



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<u>c</u>	Compo	onents:				
	Ethanol: Effects on fertility		 Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative 			
Ν	/lomet	asone:				
E	Effects	on fertility	:	Symptoms: Reduc weight		
	Effects on foetal develop- ment		:	Species: Mouse Application Route Embryo-foetal tox	o-foetal development : Subcutaneous icity: LOAEL: 0.06 mg/kg body weight kic effects., Teratogenicity and developmen-	
				Species: Rat Application Route	icity: LOAEL: 0.3 mg/kg body weight	
				Species: Rabbit Application Route Embryo-foetal tox	o-foetal development : Dermal icity: LOAEL: 0.15 mg/kg body weight betal toxicity, Malformations were observed.	
				Species: Rat Application Route	icity: LOAEL: 0.15 mg/kg body weight	
				Species: Rabbit Application Route Embryo-foetal tox	o-foetal development : Oral icity: LOAEL: 0.7 mg/kg body weight betal toxicity, Malformations were observed.	
	Reprod	uctive toxicity - As- ent	:	animal experimen	adverse effects on development, based on ts., Some evidence of adverse effects on nd fertility, based on animal experiments.	



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	Γ - single exposure lassified based on avail	able information.				
Components:						
Mom Rema	etasone: arks	: Based on ava	ilable data, the classification criteria are not met.			
	Γ - repeated exposure lassified based on avail	able information.				
Com	ponents:					
Expo Targe	etasone: sure routes et Organs ssment	 inhalation (dust/mist/fume) Immune system, Liver, Kidney, Skin May cause damage to organs through prolonged or repea exposure. 				
Repe	ated dose toxicity					
<u>Com</u>	ponents:					
	ies EL	: Rat : 1,280 mg/kg : 3,156 mg/kg : Ingestion : 90 Days				
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		: Rat : 0.00013 mg/l : inhalation (dus : 90 d : Adrenal gland Kidney, Liver,	, Lungs, Lymph nodes, spleen, Bone marrow,			



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Species:NOAEL:Application Route:Exposure time:Target Organs:			st/mist/fume) I, Lungs, Lymph nodes, spleen, Bone marrow, us gland, Liver
•	ation toxicity assified based on ava	ilable information.	
Com	oonents:		
	e tasone: oplicable		
Expe	rience with human ex	cposure	
Com	oonents:		
Mome	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	er information		
Com	oonents:		
Mome	etasone:		
Rema	ırks	: Dermal absor	ption possible

SECTION 12: Ecological information

12.1 Toxicity

Components:	

Ethanol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 72 h
		EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l Exposure time: 72 h



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-	Toxicity	to microorganisms	:	EC50 (Pseudomo Exposure time: 16	nas putida): 6,500 mg/l S h		
ä		to daphnia and other invertebrates (Chron- ty)	:	: NOEC: 9.6 mg/l Exposure time: 9 d Species: Daphnia magna (Water flea)			
	Mometa	asone:					
-	Toxicity	to fish	:	Exposure time: 96	ryllina (Silverside)): 0.11 mg/l 5 h city at the limit of solubility		
				Exposure time: 7	n variegatus (sheepshead minnow)): > 5 mg/l d city at the limit of solubility		
		to daphnia and other invertebrates	:	Exposure time: 48 Method: OECD Te			
				EC50 (Americamy Exposure time: 96 Method: US-EPA Remarks: No toxic	5 h		
	Toxicity plants	to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD Te			
-	Toxicity	to microorganisms	:	EC50 : > 1,000 m Exposure time: 3 Test Type: Respir Method: OECD Te Remarks: No toxic	h ation inhibition		
				NOEC : 1,000 mg Exposure time: 3 Test Type: Respir Method: OECD Te Remarks: No toxic	h ation inhibition		
	Toxicity icity)	to fish (Chronic tox-	:	NOEC: 0.00014 m Exposure time: 32 Species: Pimepha Method: OECD Te	2 d Iles promelas (fathead minnow)		
ä		to daphnia and other invertebrates (Chron- ty)	:	NOEC: 0.34 mg/l Exposure time: 21 Species: Daphnia	d magna (Water flea)		



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				D Test Guideline 211 toxicity at the limit of solubility
M-Fa toxici	ctor (Chronic aquatic ty)	:	100	
12.2 Pers	istence and degradabi	lity		
Com	ponents:			
Etha	nol:			
Biode	egradability	:	Result: Readil Biodegradatio Exposure time	
Mom	etasone:			
Biode	egradability	:	Biodegradatio Exposure time	
Stabi	lity in water	:	Hydrolysis: 50 Method: OEC	9 %(12 d) D Test Guideline 111
12.3 Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Etha	nol:			
	ion coefficient: n- ol/water	:	log Pow: -0.35	5
Mom	etasone:			
Bioad	ccumulation	:	Bioconcentrat	omis macrochirus (Bluegill sunfish) ion factor (BCF): 107.1 D Test Guideline 305
	ion coefficient: n- nol/water	:	log Pow: 4.68	
12.4 Mobi	ility in soil			
Com	ponents:			
Mom	etasone:			
	bution among environ- al compartments	:	log Koc: 4.02	
12.5 Resı	ılts of PBT and vPvB a	isse	ssment	
Prod	uct:			
	ssment	:	to be either pe	e/mixture contains no components considered ersistent, bioaccumulative and toxic (PBT), or t and very bioaccumulative (vPvB) at levels of



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		0.1% or highe	r.					
12.6 Othe	r adverse effects							
Prod								
Endo tial	crine disrupting poten-	ered to have e REACH Articl	e/mixture does not contain components consid- endocrine disrupting properties according to e 57(f) or Commission Delegated regulation 00 or Commission Regulation (EU) 2018/605 at o or higher.					
Glob	al warming potential							
Regu	Regulation (EU) No 517/2014 on fluorinated greenhouse gases							
<mark>Prod</mark> ۱00-۱	<u>uct:</u> /ear global warming po	tential: 3,159						
SECTIO	N 13: Disposal cons	iderations						
13 1 Was	te treatment methods							
Prod		: Dispose of in According to t are not produc Waste codes	accordance with local regulations. he European Waste Catalogue, Waste Codes ct specific, but application specific. should be assigned by the user, preferably in th the waste disposal authorities.					
Conta	aminated packaging	: Empty contair dling site for r If not otherwis	ners should be taken to an approved waste han- ecycling or disposal. se specified: Dispose of as unused product. e aerosol cans are sprayed completely empty					

(including propellant)

SECTION 14: Transport information

14.1 UN number

ADN	:	UN 1950
ADR	:	UN 1950
RID	:	UN 1950
IMDG	:	UN 1950
ΙΑΤΑ	:	UN 1950
14.2 UN proper shipping name		
ADN	:	AEROSOLS
ADR	:	AEROSOLS
RID	:	AEROSOLS
IMDG	:	AEROSOLS (Mometasone)

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ΙΑΤΑ		:	Aerosols, non-fl	ammable
14.3 Tran	sport hazard class(es)		,	
ADN		:	2	
ADR		:	2	
RID		:	2	
IMDO	6	:	2.2	
ΙΑΤΑ		:	2.2	
14.4 Pack	ing group			
	ing group sification Code Is	:	Not assigned by 5A 2.2	regulation
Class Labe	ing group sification Code Is el restriction code	:	Not assigned by 5A 2.2 (E)	regulation
Class	ing group sification Code rd Identification Number Is	:	Not assigned by 5A 20 2.2	regulation
Labe	ing group	:	Not assigned by 2.2 F-D, S-U	regulation
Pack	(Cargo) ing instruction (cargo	:	203	
	ing instruction (LQ) ing group	:	Y203 Not assigned by Non-flammable,	
Pack	(Passenger) ing instruction (passen- ircraft)	:	203	
	ing instruction (LQ) ing group Is	:	Y203 Not assigned by Non-flammable,	
14.5 Envi	ronmental hazards			
ADN Envir	onmentally hazardous	:	yes	
ADR Envir	onmentally hazardous	:	yes	



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RID

Environmentally hazardous : yes IMDG Marine pollutant : yes

14.6 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.

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

Remarks	: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

	REACH - Restrictions on the r the market and use of certain preparations and articles (Ann	dar	:	Not applicable					
	REACH - Candidate List of Su Concern for Authorisation (Art	ıbst	ances of Very High	:	Not applicable				
	REACH - List of substances s (Annex XIV)		,	:	Not applicable				
	Regulation (EC) No 1005/2009 plete the ozone layer	9 o	n substances that de-	:	Not applicable				
	Regulation (EU) 2019/1021 or tants (recast)	n pe	ersistent organic pollu-	:	Not applicable				
	Regulation (EC) No 649/2012 ment and the Council concern of dangerous chemicals	:	Not applicable						
	Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control on major-accident hazards involving dangerous substances.								
	·,····	3	3		Quantity 1	Quantity 2			
	E2		ENVIRONMENTAL HAZARDS		200 t	500 t			
The components of this product are reported in the following inventories:									
	AICS		· ·						
	AIUS	:							
	DSL	:	not determined						
	IECSC	:	not determined						

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information

: Items where changes have been made to the previous version



Mometasone Metered Dose Inhaler Formulation

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			are highlighted in lines.	the body of this document by two vertical			
Full te	xt of H-Statements						
H225		:	Highly flammable liquid and vapour.				
H319		:	Causes serious eye irritation.				
H360Df		:	May damage the unborn child. Suspected of damaging fertili-				
			ty.				
H373		:	May cause damage to organs through prolonged or repeated exposure if inhaled.				
H410		:	Very toxic to aquatic life with long lasting effects.				
Full text of other abbreviations							
Aquatio	Aquatic Chronic		Long-term (chronic) aquatic hazard				
Eye Irrit.		:	Eye irritation				
Flam. Liq.		:	Flammable liquids	3			
Repr.		:	Reproductive toxi	city			
STOT RE		:	Specific target organ toxicity - repeated exposure				
GB EH40		:	UK. EH40 WEL - Workplace Exposure Limits				
GB EH40 / TWA		:	Long-term exposure limit (8-hour TWA reference period)				

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways: ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS -Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP -Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL -International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS -Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative



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Furth	er information					
Sourc	ces of key data used to ile the Safety Data	eChem Portal s	: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/			
Class	sification of the mixtu	re:	Classification procedure:			
Aeros	sol 3	H229	Based on product data or assessment			
Aqua	tic Chronic 2	H411	Calculation method			

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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