Hazard pictograms



Mometasone Dry Powder Inhaler Formulation

Version 3.4	Revision Date: 10.10.2020		S Number: 3775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016				
SECTIO	SECTION 1. PRODUCT AND COMPANY IDENTIFICATION							
Pro	Product name :		Mometasone Dry	Mometasone Dry Powder Inhaler Formulation				
Manufacturer or supplier's details								
Co	mpany	:	Organon & Co.					
Ad	Address			30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302				
Te	lephone	:	551-430-6000					
En	Emergency telephone		215-631-6999					
E-ı	E-mail address		EHSSTEWARD@organon.com					
Re	commended use of the cl	hem	ical and restriction	ons on use				
Re	Recommended use		Pharmaceutical					
SECTIO	DN 2. HAZARDS IDENTIFI	САТ	ION					
Gŀ	IS Classification							
-	productive toxicity	:	Category 1B					
rep	ecific target organ toxicity - beated exposure halation)	:	Category 2 (Imm	nune system, Liver, Kidney, Skin)				
	ng-term (chronic) aquatic zard	:	Category 1					
Gŀ	IS label elements							

¥2

:

 \checkmark \mathbf{v} Signal Word Danger : Hazard Statements H360Df May damage the unborn child. Suspected of damaging : fertility. H373 May cause damage to organs (Immune system, Liver, Kidney, Skin) through prolonged or repeated exposure if inhaled. H410 Very toxic to aquatic life with long lasting effects. **Precautionary Statements** 2 **Prevention:** P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read

and understood.



ersion .4	Revision Date: 10.10.2020	-	OS Number: 3775-00012		sue: 23.03.2020 sue: 28.01.2016
				lease to the enviro otective gloves/ pro	nment. otective clothing/ eye protec-
	Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention. P391 Collect spillage.				
	Storage: P405 Store locked up.				
			Disposal: P501 Dispose disposal plant		iner to an approved waste
ECTION	form explosive dust-a 3. COMPOSITION/II tance / Mixture				
	ponents	·	MIXIULE		
	nical name			CAS-No.	Concentration (% w/w)
Mom	etasone			83919-23-7	>= 10 -< 20
ECTION	4. FIRST AID MEAS	URES			
	4. FIRST AID MEAS	URES :	advice immedi	ately.	eel unwell, seek medical cases of doubt seek medical
	eral advice	: ; ;	advice immedi When symptor advice.	ately. ns persist or in all o ove to fresh air.	

-	of water.
	Remove contaminated clothing and shoes.
	Get medical attention.
	Wash clothing before reuse.
	Thoroughly clean shoes before reuse.
:	If in eyes, rinse well with water.
	Get medical attention if irritation develops and persists.
:	If swallowed, DO NOT induce vomiting.
	Get medical attention.
	Rinse mouth thoroughly with water.
:	May damage the unborn child. Suspected of damaging fertili-
	ty.
	May cause damage to organs through prolonged or repeated exposure if inhaled.
	:



Version 3.4	Revision Date: 10.10.2020	-	OS Number: 3775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016			
			the skin.	st can cause mechanical irritation or drying of			
Protection of first-aiders		:	Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment				
Notes	s to physician	:	when the potential for exposure exists (see section 8). Treat symptomatically and supportively.				
SECTION	5. FIRE-FIGHTING ME	ASL	JRES				
Suital	Suitable extinguishing media		Water spray Alcohol-resistar Carbon dioxide Dry chemical				
Unsu media	itable extinguishing	:	None known.				
Spec	Specific hazards during fire fighting		concentrations, potential dust e	g dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a xplosion hazard. mbustion products may be a hazard to health.			
Haza ucts	Hazardous combustion prod- ucts Specific extinguishing meth- ods		Carbon oxides Chlorine compo	bunds			
•			cumstances and Use water sprag	ng measures that are appropriate to local cir- d the surrounding environment. y to cool unopened containers. naged containers from fire area if it is safe to do			
	ial protective equipment e-fighters	:	Evacuate area. In the event of f	ire, wear self-contained breathing apparatus. rotective equipment.			
SECTION	6. ACCIDENTAL RELE	AS	E MEASURES				
tive e	onal precautions, protec- quipment and emer- y procedures	:	Follow safe har	rotective equipment. Idling advice (see section 7) and personal Internet recommendations (see section 8).			
Envir	onmental precautions	:	Prevent further Retain and disp	o the environment. leakage or spillage if safe to do so. lose of contaminated wash water. s should be advised if significant spillages ained.			
Metho	ods and materials for	:	Sweep up or va	cuum up spillage and collect in suitable			

Methods and materials for containment and cleaning up	 Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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



Version 3.4	Revision Date: 10.10.2020	SDS Number: 493775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016				
		Sections 13 and	h regulations are applicable. d 15 of this SDS provide information regarding national requirements.				
SECTION	7. HANDLING AND ST	ORAGE					
Technical measures		causing an exp Provide adequa	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.				
Loca	I/Total ventilation		tilation is unavailable, use with local exhaust				
	ce on safe handling	: Do not get on s Do not breathe Do not swallow Avoid contact w Handle in accor practice, based assessment Keep container Keep container Keep away from Take precaution Take care to pr environment.	dust. 				
Cond	ditions for safe storage	Store locked up Keep tightly clo					
Mate	erials to avoid		th the following product types: g agents				

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Mometasone	83919-23-7	TWA	1 µg/m3 (OEB 4)	Internal
	Further informa	ation: Skin		
		Wipe limit	10 µg/100 cm²	Internal

Engineering measures : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility



Version 3.4	Revision Date: 10.10.2020	SDS Number: 493775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016				
		protect proc Essentially	operated in accordance with GMP principles to ducts, workers, and the environment. no open handling permitted. processing systems or containment technologies.				
Perso	onal protective equip	ment					
Respiratory protection		: If adequate exposure a	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.				
	Filter type Hand protection		s type				
M	aterial	: Chemical-re	Chemical-resistant gloves				
	emarks protection	: Wear safet If the work mists or ae Wear a face	ouble gloving. y glasses with side shields or goggles. environment or activity involves dusty conditions, rosols, wear the appropriate goggles. eshield or other full face protection if there is a r direct contact to the face with dusts, mists, or				
Skin	and body protection	Additional t task being disposable	m or laboratory coat. body garments should be used based upon the performed (e.g., sleevelets, apron, gauntlets, suits) to avoid exposed skin surfaces. briate degowning techniques to remove potentially ed clothing.				
Hygie	ene measures	: If exposure eye flushing working pla When using Wash conta The effectiv engineering appropriate industrial h	to chemical is likely during typical use, provide g systems and safety showers close to the				

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available



Ver 3.4	sion	Revision Date: 10.10.2020		S Number: 3775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016
	Flash p	point	:	Not applicable	
	Evaporation rate		:	No data available	
	Flamm	ability (solid, gas)	:	May form explosi handling or other	ve dust-air mixture during processing, means.
	Flamm	ability (liquids)	:	No data available)
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	oressure	:	No data available)
	Relativ	e vapor density	:	No data available)
	Relativ	e density	:	No data available)
	Density	,	:	No data available)
	Solubili Wat	ty(ies) er solubility	:	No data available	
	Partitio octanol	n coefficient: n-	:	No data available	9
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	No data available)
	Explosi	ve properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance of	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	3
	Particle	e size	:	No data available)

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.



rsion	Revision Date: 10.10.2020	-	S Number: 3775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016
	patible materials dous decomposition cts	:		ents s decomposition products are known.
CTION	11. TOXICOLOGICAL	INFO	ORMATION	
Inform expos	nation on likely routes o sure	of :	Inhalation Skin contact Ingestion Eye contact	
	e toxicity assified based on avail	able	information.	
Comp	oonents:			
-	etasone:			
Acute	oral toxicity	:	LD50 (Rat): >	2.000 mg/kg
			LD50 (Mouse)	: > 2.000 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > Exposure time Test atmosphe Remarks: No	e: 4 h
			LC50 (Mouse) Exposure time Test atmosphe	e: 4 h
	toxicity (other routes o istration)	f:		00 mg/kg oute: Subcutaneous reathing difficulties
•••••	corrosion/irritation assified based on avail	able	information.	
Comp	oonents:			
Mome	etasone:			
Speci Resul		:	Rabbit No skin irritati	on
	us eye damage/eye in assified based on avail			
<u>Comp</u>	oonents:			
Mome	etasone:			
Speci Resul		:	Rabbit No eye irritatio	on



Version 3.4	Revision Date: 10.10.2020	SDS Number: 493775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016						
Resp	biratory or skin sensit	ization							
-	Skin sensitization Not classified based on available information. Respiratory sensitization Not classified based on available information.								
-									
<u>Com</u>	Components:								
Mom	etasone:								
Rout Spec	ssment It	: negative	se skin sensitization. a test on guinea pigs showed this substance to						
	n cell mutagenicity classified based on ava	ilable information.							
<u>Com</u>	ponents:								
Mom	etasone:								
Geno	otoxicity in vitro	: Test Type: Ba Result: negati	cterial reverse mutation assay (AMES) ve						
			romosomal aberration Chinese hamster lung cells ve						
			rromosomal aberration Chinese hamster ovary cells re						
		Test Type: Mo Result: negati	ouse 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							
0									

Germ cell mutagenicity - : Weight of evidence does not support classification as a germ



Vers 3.4	sion	Revision Date: 10.10.2020		S Number: 3775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016
	Asses	sment		cell mutagen.	
	Carcir	nogenicity			
	Not cla	assified based on availa	ble	information.	
	<u>Comp</u>	onents:			
	Mome	etasone:			
		ation Route sure time	:	Rat Inhalation 2 Years 0.067 mg/kg body negative	/ weight
		ation Route ure time		Mouse Inhalation 19 Months 0.160 mg/kg body negative	/ weight
	May d	oductive toxicity amage the unborn child	l. Su	spected of damag	ing fertility.
	Components:				
	Mome	etasone:			
	Effects	s on fertility	:	Symptoms: Redu weight.	
	Effects	s on fetal development	:	Species: Mouse Application Route Embryo-fetal toxi	city.: LOAEL: 0,06 mg/kg body weight xic effects., Teratogenicity and
				Species: Rat Application Route	city.: LOAEL: 0,3 mg/kg body weight
				Species: Rabbit Application Route Embryo-fetal toxi Result: Embryo-fet	vo-fetal development e: Dermal city.: LOAEL: 0,15 mg/kg body weight etal toxicity., Malformations were observed. vo-fetal development



23.03.2020 28.01.2016
ng/kg body weight
t g/kg body weight nations were observed.
development, based or of adverse effects on animal experiments.
ation criteria are not me
ough prolonged or re-
h prolonged or repeated
Skin, thymus gland
Skin, thymus gland
5



ersion 4	Revision Date: 10.10.2020	SDS Number: 493775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016
NOAE	=1	: 0,00013 mg/l	
	cation Route	: inhalation (du	ist/mist/fume)
Expos	sure time	: 90 d	
Targe	et Organs		d, Lungs, Lymph nodes, spleen, Bone marrow, , thymus gland
Speci NOAE		: Dog	
-	=∟ cation Route	: 0,0005 mg/l : inhalation (du	st/mist/fume)
	sure time	: 90 d	
Targe	et Organs		d, Lungs, Lymph nodes, spleen, Bone marrow, us gland, Liver
-	ation toxicity		
Not cl	lassified based on ava	ilable information.	
<u>Comp</u>	oonents:		
Mom	etasone:		
Not a	pplicable		
Expe	rience with human ex	kposure	
Com	ponents:		
Mome	etasone:		
Inhala	ation	piratory tract	llergic rhinitis, Headache, pharyngitis, upper res- infection, sinusitis, oral candidiasis, Back pain, etal pain, immune system effects, indigestion
Skin d	contact		ermatitis, Itching
Furth	er information		
Com	oonents:		
Mom	etasone:		
Rema	arks	: Dermal absor	ption possible
	12. ECOLOGICAL IN	FORMATION	
Ecoto	oxicity		
<u>Com</u>	ponents:		
Mome	etasone:		
Toxic	ity to fish	Exposure time	a beryllina (Silverside)): 0,11 mg/l e: 96 h toxicity at the limit of solubility.
		Exposure time	odon variegatus (sheepshead minnow)): > 5 mg e: 7 d toxicity at the limit of solubility.
-			

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 5 mg/l



ersion 4	Revision Date: 10.10.2020		S Number: 3775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016
aquatic invertebrates			Exposure time: 48 Method: OECD To Remarks: No toxi	
Toxici plants	ty to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD Te	
Toxici icity)	ty to fish (Chronic tox-	:	NOEC (Pimephale mg/l Exposure time: 32 Method: OECD Te	
	ty to daphnia and other ic invertebrates (Chron- city)	:	Exposure time: 27 Method: OECD T	
	ctor (Chronic aquatic	:	100	
toxicit Toxici	y) ty to microorganisms	:	EC50: > 1.000 mg Exposure time: 3 Test Type: Respir Method: OECD To Remarks: No toxi	h ration inhibition
			NOEC: 1.000 mg/ Exposure time: 3 Test Type: Respir Method: OECD To Remarks: No toxio	h ration inhibition
Persis	stence and degradabil	ity		
Comp	oonents:			
	etasone: gradability	:	Result: Not readily Biodegradation: 4 Exposure time: 28 Method: OECD T	50 % 3 d
Stabili	ity in water	:	Hydrolysis: 50 %(Method: OECD T	



Version 3.4	Revision Date: 10.10.2020		DS Number: 3775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016
Bioac	cumulative potential			
Comp	oonents:			
Mome	etasone:			
Bioac	cumulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): 107,1 est Guideline 305
	on coefficient: n- ol/water	:	log Pow: 4,68	
Mobil	ity in soil			
Comp	oonents:			
Mome	etasone:			
	oution among environ- al compartments	:	log Koc: 4,02	
Other	adverse effects			
No da	ta available			

SECTION 13. DISPOSAL CONSIDERATIONS

Disposa	I methods
---------	-----------

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
Class	:	9
Packing group	:	
Labels	:	9
IATA-DGR		
UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Mometasone)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passen- ger aircraft)	:	956
Environmentally hazardous	:	yes



Version 3.4	Revision Date: 10.10.2020		OS Number: 3775-00012	Date of last issue: 23.03.2020 Date of first issue: 28.01.2016
UN	OG-Code number per shipping name	:	UN 3077 ENVIRONMEN N.O.S. (Mometasone)	TALLY HAZARDOUS SUBSTANCE, SOLID,
Clas	SS	:	9	
Pac	king group	:	III	
Lab	els	:	9	
Em	S Code	:	F-A, S-F	
Mar	ine pollutant	:	yes	

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

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable
Control of precursors and essential chemicals for the preparation of drugs.	:	Not applicable

International Regulations

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

Full text of other abbreviations



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	493775-00012	Date of first issue: 28.01.2016

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

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.

AR / Z8