

Versior 3.5	n Revision Date: 09.04.2021		S Number: 91628-00012	Date of last issue: 05.10.2020 Date of first issue: 15.02.2017
1. PRO	DUCT AND COMPANY ID	ENT	IFICATION	
Pr	oduct name	:	Mometasone Lot	tion Formulation
Ma	anufacturer or supplier's o	deta	ils	
Co	ompany	:	Organon & Co.	
Ac	ldress	:	30 Hudson Stree Jersey City, New	et, 33nd floor / Jersey, U.S.A 07302
Te	lephone	:	551-430-6000	
Er	nergency telephone numbe	r :	215-631-6999	
E-	mail address	:	EHSSTEWARD	@organon.com
Re	ecommended use of the cl	hem	ical and restriction	ons on use
Re	ecommended use	:	Pharmaceutical	

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Very highly flammable liquids

#### **GHS Classification**

Flammable liquids	:	Category 2
Serious eye damage/eye irri- tation	:	Category 2A
Specific target organ toxicity - single exposure	:	Category 3
Long-term (chronic) aquatic hazard	:	Category 2
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H225 Highly flammable liquid and vapo





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Preca	autionary statements	and other ignit P261 Avoid br P264 Wash sk P271 Use only P273 Avoid rel	ray from heat, hot surfaces, sparks, open flames ion sources. No smoking. eathing mist or vapours. in thoroughly after handling. outdoors or in a well-ventilated area. lease to the environment. otective gloves/ protective clothing/ eye protec- ection.
		ly all contamin P304 + P340 + and keep comi unwell. P305 + P351 + for several min easy to do. Co	f eye irritation persists: Get medical help.
		<b>Storage:</b> P405 Store loc	ked up.
		<b>Disposal:</b> P501 Dispose disposal plant.	of contents/ container to an approved waste

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

Vapours may form explosive mixture with air.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture :	Mixture
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Components

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	>= 30 - < 50
Mometasone	83919-23-7	>= 0.1 - < 0.25

#### 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention.



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In case of eye contact If swallowed		Thoroughl In case of for at least If easy to o Get medic	ning before reuse. y clean shoes before reuse. contact, immediately flush eyes with plenty of water 15 minutes. do, remove contact lens, if worn. al attention. ed, DO NOT induce vomiting.				
an	ost important symptoms d effects, both acute and laved	Rinse mou : Causes se	al attention. th thoroughly with water. rious eye irritation. e drowsiness or dizziness.				
delayed Protection of first-aiders Notes to physician		and use th when the p	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). Treat symptomatically and supportively.				
5. FIRE	FIGHTING MEASURES						
Un	itable extinguishing media suitable extinguishing	Carbon die Dry chemi	sistant foam oxide (CO2)				
Sp	ecific hazards during fire- hting	fire. Flash bacł Vapours m	e a solid water stream as it may scatter and spread possible over considerable distance. hay form explosive mixtures with air. to combustion products may be a hazard to health.				
Ha uct	zardous combustion prod- ts	: Carbon ox	ides				
Sp od:	ecific extinguishing meth- s	cumstance Use water	uishing measures that are appropriate to local cir- es and the surrounding environment. spray to cool unopened containers. Indamaged containers from fire area if it is safe to do				
	ecial protective equipment firefighters	: In the ever	nt of fire, wear self-contained breathing apparatus. nal protective equipment.				

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- 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).



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				ose of contaminated wash water. s should be advised if significant spillages ained.			
Methods and materials for containment and cleaning up		:	<ul> <li>Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapours/mists with a water spray jet. 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.</li> </ul>				
7. HAND	DLING AND STORAGE						
Tec	hnical measures	:		g measures under EXPOSURE RSONAL PROTECTION section.			
Local/Total ventilation		:	If sufficient ventilation is unavailable, use with local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equip ment.				
Advice on safe handling		:	<ul> <li>Do not get on skin or clothing.</li> <li>Avoid breathing mist or vapours.</li> <li>Do not swallow.</li> <li>Do not get in eyes.</li> <li>Wash skin thoroughly after handling.</li> <li>Handle in accordance with good industrial hygiene and sa practice, based on the results of the workplace exposure a sessment</li> <li>Non-sparking tools should be used.</li> <li>Keep container tightly closed.</li> <li>Keep away from heat, hot surfaces, sparks, open flames a other ignition sources. No smoking.</li> <li>Take precautionary measures against static discharges.</li> <li>Take care to prevent spills, waste and minimize release to the surface of the static discharges.</li> </ul>				
Conditions for safe storage		:	environment. Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.				
Mat	erials to avoid	:	Do not store wit	S			



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		Pyrophoric liqui Pyrophoric solic Self-heating su Poisonous gase Explosives	ds bstances and mixtures

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
		. ,		
Propan-2-ol	67-63-0	TWA	200 ppm	ACGIH
		STEL	400 ppm	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

#### **Biological occupational exposure limits**

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentra- tion	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work- week	40 mg/l	ACGIH BEI

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.	
		Use explosion-proof electrical, ventilating and lighting equip- ment.	
Personal protective equipme	ent		
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.	
Filter type Hand protection	:	Combined particulates and organic vapour type	
Material	:	Chemical-resistant gloves	
Remarks	:	Consider double gloving. Take note that the product is flam- mable, which may impact the selection of hand protection.	
Eye protection	:	Wear safety glasses with side shields or goggles.	



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		mists or aerosc Wear a faceshi potential for dir aerosols.	ronment or activity involves dusty conditions, ls, wear the appropriate goggles. eld or other full face protection if there is a ect contact to the face with dusts, mists, or
Skin a	Skin and body protection :		r laboratory coat. garments should be used based upon the task d (e.g., sleevelets, apron, gauntlets, disposable exposed skin surfaces. e degowning techniques to remove potentially lothing.
Hygie	ene measures	: If exposure to c flushing system place. When using do Wash contamin The effective of engineering con appropriate deg	hemical is likely during typical use, provide eye is and safety showers close to the working not eat, drink or smoke. hated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	lotion
Colour	:	colourless, clear, to, translucent
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	4.5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	18.4 °C
		Method: closed cup
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Ignitable (see flash point)
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available



### **Mometasone Lotion Formulation**

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Vapour	pressure	:	No data available	9
Relative	e vapour density	:	No data available	)
Relative	e density	:	No data available	)
Density		:	No data available	)
Solubilit Wate	ty(ies) er solubility	:	No data available	)
Partitior octanol	n coefficient: n-	:	No data available	9
	nition temperature	:	No data available	)
Decom	position temperature	:	No data available	)
Viscosit Visc	ty osity, kinematic	:	No data available	9
Explosi	ve properties	:	Not explosive	
Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
Molecu	lar weight	:	Not applicable	
Particle	size	:	: Not applicable	
. STABILI	TY AND REACTIVITY	1		
	ity al stability lity of hazardous reac-	:	Stable under nor Highly flammable Vapours may for	a reactivity hazard. mal conditions. liquid and vapour. m explosive mixture with air. rong oxidizing agents.
Incomp	ons to avoid atible materials ous decomposition s	:	Heat, flames and Oxidizing agents No hazardous de	sparks. composition products are known.
1. TOXICO	LOGICAL INFORMAT	ΓΙΟΝ	l	
Informa exposui	tion on likely routes of re	:	Inhalation Skin contact Ingestion Eye contact	

Not classified based on available information.

#### Components:

#### Propan-2-ol:



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Acute	oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 25 r Exposure time: 6 Test atmosphere:	h
Acute	dermal toxicity	:	LD50 (Rabbit): > 5	5,000 mg/kg
Mome	etasone:			
Acute	oral toxicity	:	LD50 (Rat): > 2,00	00 mg/kg
			LD50 (Mouse): > 2	2,000 mg/kg
Acute	inhalation toxicity	:	Exposure time: 4 Test atmosphere:	h
			LC50 (Mouse): > 3 Exposure time: 4 Test atmosphere:	h
	toxicity (other routes of istration)	:	LD50 (Rat): 300 n Application Route Symptoms: Breath	: Subcutaneous
Not cla	corrosion/irritation assified based on availa conents:	ble	information.	
	ın-2-ol:			
Specie Result	es	:	Rabbit No skin irritation	
Mome	etasone:			
Specie Result		:	Rabbit No skin irritation	
	us eye damage/eye irri es serious eye irritation.	tati	on	
<u>Comp</u>	onents:			
Propa	in-2-ol:			
Specie Result		:	Rabbit Irritation to eyes, r	eversing within 21 days
Mome	etasone:			
Specie Result		:	Rabbit No eye irritation	



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Resp	piratory or skin sens	itisation	
Skin	sensitisation		
Not o	classified based on av	ailable information.	
-	<b>biratory sensitisatior</b> classified based on av		
Com	ponents:		
Prop	an-2-ol:		
Test	Туре	: Buehler Test	
Expo	sure routes	: Skin contact	
Spec	cies	: Guinea pig	
Meth	od	: OECD Test Gu	ideline 406
Resu	ılt	: negative	
Mom	netasone:		
Test	Туре	: Maximisation T	est
	sure routes	: Dermal	
Spec		: Guinea pig	
	essment		e skin sensitisation.
Resu		, pogotivo	
	//L	. negative	
Rem		: negative : The results of a	a test on guinea pigs showed this substance to
Rem		: The results of a	
Rem Gerr	arks	: The results of a be a weak skin	
Rem <b>Gerr</b> Not o	arks n cell mutagenicity	: The results of a be a weak skin	
Rem Gerr Not o <u>Com</u> Prop	arks n cell mutagenicity classified based on av ponents: pan-2-ol:	: The results of a be a weak skin	sensitiser.
Rem Gerr Not o <u>Com</u> Prop	arks n cell mutagenicity classified based on av ponents:	: The results of a be a weak skin	sensitiser.
Rem Gerr Not o <u>Com</u> Prop	arks n cell mutagenicity classified based on av ponents: pan-2-ol:	<ul> <li>The results of a be a weak skin</li> <li>railable information.</li> <li>Test Type: Bac Result: negative</li> </ul>	terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test
Rem Not o <u>Com</u> Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol:	<ul> <li>The results of a be a weak skin</li> <li>railable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vi Result: negative</li> <li>Test Type: Mar</li> </ul>	sensitiser. tterial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo
Rem Not o <u>Com</u> Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>railable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vir Result: negative</li> <li>Test Type: Mar cytogenetic ass</li> </ul>	sensitiser. tterial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say)
Rem Not o <u>Com</u> Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>railable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vi Result: negative</li> <li>Test Type: Mar cytogenetic ass Species: Mouse</li> </ul>	sensitiser. eterial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say) e
Rem Not o <u>Com</u> Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>railable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vi Result: negative</li> <li>Test Type: Mar cytogenetic ass Species: Mouse</li> </ul>	sensitiser. terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say) e ute: Intraperitoneal injection
Rem Not o <u>Com</u> Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>railable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vi Result: negative</li> <li>Test Type: Mar cytogenetic ass Species: Mouse Application Rot</li> </ul>	sensitiser. eterial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say) e ute: Intraperitoneal injection
Rem Not o Com Prop Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>railable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vi Result: negative</li> <li>Test Type: Mar cytogenetic ass Species: Mouse Application Rou Result: negative</li> </ul>	sensitiser. terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e nmalian erythrocyte micronucleus test (in vivo say) e ute: Intraperitoneal injection e
Rem Not o Com Prop Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>railable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vi Result: negative</li> <li>Test Type: Mar cytogenetic ass Species: Mouse Application Rou Result: negative</li> </ul>	sensitiser. terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say) e ute: Intraperitoneal injection e terial reverse mutation assay (AMES)
Rem Not o Com Prop Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>ailable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vi Result: negative</li> <li>Test Type: Mar cytogenetic ass Species: Mouse Application Rou Result: negative</li> <li>Test Type: Bac Result: negative</li> </ul>	sensitiser. terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say) e ute: Intraperitoneal injection e terial reverse mutation assay (AMES) e
Rem Not o Com Prop Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>ailable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vi Result: negative</li> <li>Test Type: Mar cytogenetic ass Species: Mouse Application Roo Result: negative</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: Bac Result: negative</li> </ul>	sensitiser. terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say) e ute: Intraperitoneal injection e terial reverse mutation assay (AMES) e omosomal aberration
Rem Not o Com Prop Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>ailable information.</li> <li>Test Type: Bac Result: negative Test Type: In vi Result: negative</li> <li>Test Type: Mar cytogenetic ass Species: Mouse Application Rou Result: negative</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: Bac Result: negative</li> </ul>	sensitiser. terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say) e ute: Intraperitoneal injection e terial reverse mutation assay (AMES) e omosomal aberration hinese hamster lung cells
Rem Not o Com Prop Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>railable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vi Result: negative</li> <li>Test Type: Mar cytogenetic ass Species: Mouse Application Rou Result: negative</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: Chronology</li> </ul>	sensitiser. terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say) e ute: Intraperitoneal injection e terial reverse mutation assay (AMES) e omosomal aberration hinese hamster lung cells e
Rem Not o Com Prop Geno	arks n cell mutagenicity classified based on av ponents: pan-2-ol: ptoxicity in vitro ptoxicity in vitro	<ul> <li>The results of a be a weak skin</li> <li>railable information.</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: In vi Result: negative</li> <li>Test Type: Mar cytogenetic ass Species: Mouse Application Rou Result: negative</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: Bac Result: negative</li> <li>Test Type: Chronic Test Type: Chronic Result: negative</li> </ul>	sensitiser. terial reverse mutation assay (AMES) e itro mammalian cell gene mutation test e mmalian erythrocyte micronucleus test (in vivo say) e ute: Intraperitoneal injection e terial reverse mutation assay (AMES) e omosomal aberration hinese hamster lung cells



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		Result: positiv	/e
		Test Type: M Result: negat	ouse Lymphoma ive
Geno	toxicity in vivo	: Test Type: M Species: Mou Application R Result: negat	oute: Oral
		Test Type: Cl Species: Rat Cell type: Bor Result: negat	
		Test Type: ur Species: Rat Cell type: Live Result: negat	
	cell mutagenicity -	: Weight of evi cell mutagen.	dence does not support classification as a germ
Not c	nogenicity lassified based on ava ponents:	ilable information.	
Propa	an-2-ol:		
	cation Route sure time od	: Rat : inhalation (va : 104 weeks : OECD Test G : negative	
Mom	etasone:		
Speci Applic	es 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
Repr	oductive toxicity		
-	lassified based on ava	ilable information.	
Com	oonents:		

Propan-2-ol:



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Effect	Effects on fertility Effects on foetal develop- ment		Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative			
			: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative			
Mome	etasone:					
Effect	s on fertility	:	Symptoms: Redu weight			
Effect ment	s on foetal develop-	:	Species: Mouse Application Route Embryo-foetal to	yo-foetal development e: Subcutaneous xicity: LOAEL: 0.06 mg/kg body weight xic effects., Teratogenicity and developmen-		
			Species: Rat Application Route	kicity: LOAEL: 0.3 mg/kg body weight		
			Species: Rabbit Application Route Embryo-foetal to	yo-foetal development e: Dermal kicity: LOAEL: 0.15 mg/kg body weight oetal toxicity, Malformations were observed.		
			Species: Rat Application Route	<pre>kicity: LOAEL: 0.15 mg/kg body weight</pre>		
			Species: Rabbit Application Route Embryo-foetal to	yo-foetal development e: Oral kicity: LOAEL: 0.7 mg/kg body weight oetal toxicity, Malformations were observed.		
Repro sessn	ductive toxicity - As- nent	:	animal experime	f adverse effects on development, based on nts., Some evidence of adverse effects on nd fertility, based on animal experiments.		



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STOT	- single exposure		
	cause drowsiness or	dizziness.	
Com	oonents:		
Propa	an-2-ol:		
Asses	ssment	: May cause drowsin	ess or dizziness.
Mom	etasone:		
Rema	arks	: Based on available	data, the classification criteria are not me
STO	- repeated exposu	re	
Not c	lassified based on av	ailable information.	
<u>Com</u>	oonents:		
Mom	etasone:		
	sure routes	: inhalation (dust/mis	
-	et Organs	: Immune system, Li	
Asses	ssment	: May cause damage exposure.	e to organs through prolonged or repeated
Repe	ated dose toxicity		
<u>Com</u>	oonents:		
Propa	an-2-ol:		
Speci		_	
•		: Rat	
NOAE	ΞL	: 12.5 mg/l	
NOAE Applic	EL cation Route	: 12.5 mg/l : inhalation (vapour)	
NOAE Applic	ΞL	: 12.5 mg/l	
NOAE Applic Expos	EL cation Route sure time etasone:	: 12.5 mg/l : inhalation (vapour) : 104 Weeks	
NOAE Applic Expos <b>Mom</b> Speci	EL cation Route sure time etasone: es	: 12.5 mg/l : inhalation (vapour) : 104 Weeks : Rat	
NOAE Applic Expos Mom Speci NOAE	EL cation Route sure time etasone: es EL	<ul> <li>12.5 mg/l</li> <li>inhalation (vapour)</li> <li>104 Weeks</li> <li>Rat</li> <li>0.005 mg/kg</li> </ul>	
NOAE Applic Expose Mome Speci NOAE LOAE	EL cation Route sure time etasone: es EL EL	<ul> <li>12.5 mg/l</li> <li>inhalation (vapour)</li> <li>104 Weeks</li> <li>Rat</li> <li>0.005 mg/kg</li> <li>0.3 mg/kg</li> </ul>	
NOAE Applic Expose Speci NOAE LOAE Applic	EL cation Route sure time etasone: es EL EL cation Route	<ul> <li>12.5 mg/l</li> <li>inhalation (vapour)</li> <li>104 Weeks</li> <li>Rat</li> <li>0.005 mg/kg</li> <li>0.3 mg/kg</li> <li>Oral</li> </ul>	
MOAE Applic Expose Speci NOAE LOAE Applic Expose	EL cation Route sure time etasone: es EL EL	<ul> <li>12.5 mg/l</li> <li>inhalation (vapour)</li> <li>104 Weeks</li> <li>Rat</li> <li>0.005 mg/kg</li> <li>0.3 mg/kg</li> <li>Oral</li> <li>30 d</li> </ul>	r, Adrenal gland, Skin, thymus gland
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NOAE Applia Expose Specia NOAE LOAE Applia Expose Targe Specia NOAE Applia Expose Targe	EL cation Route sure time etasone: es EL cation Route sure time et Organs es EL cation Route sure time et Organs	<ul> <li>12.5 mg/l</li> <li>inhalation (vapour)</li> <li>104 Weeks</li> <li>Rat</li> <li>0.005 mg/kg</li> <li>0.3 mg/kg</li> <li>Oral</li> <li>30 d</li> <li>Lymph nodes, Live</li> <li>Dog</li> <li>0.5 mg/kg</li> <li>Oral</li> <li>30 d</li> <li>Lymph nodes, Live</li> <li>Rat</li> <li>0.00013 mg/l</li> <li>inhalation (dust/mis</li> <li>90 d</li> </ul>	r, Adrenal gland, Skin, thymus gland



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Expos			st/mist/fume) , Lungs, Lymph nodes, spleen, Bone marrow, us gland, Liver
-	ation toxicity		
	assified based on avai	lable information.	
	oonents:		
	etasone:		
NOT A	pplicable		
Expe	rience with human ex	posure	
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	arks	: Dermal absor	ption possible

### 12. ECOLOGICAL INFORMATION

Ecotoxicity		
Components:		
<b>Propan-2-ol:</b> Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 24 h
Toxicity to microorganisms	:	EC50 (Pseudomonas putida): > 1,050 mg/l Exposure time: 16 h
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: 7	n variegatus (sheepshead minnow)): > 5 mg/l d city at the limit of solubility
	ity to daphnia and other tic invertebrates	:	Exposure time: 48 Method: OECD To Remarks: No toxid EC50 (Americany Exposure time: 96 Method: US-EPA	est Guideline 202 city at the limit of solubility ysis): > 5 mg/l 5 h OPPTS 850.1035
Toxic plants	ity to algae/aquatic s	:	EC50 ( Pseudokir mg/l Exposure time: 72 Method: OECD To	
Toxic	ity to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Test Type: Respin Method: OECD To Remarks: No toxic	h ration inhibition
			NOEC: 1,000 mg/ Exposure time: 3 Test Type: Respin Method: OECD To Remarks: No toxi	h ration inhibition
Toxic icity)	ity to fish (Chronic tox-	:		
	ity to daphnia and other tic invertebrates (Chron- icity)	:	Method: OECD T	magna (Water flea)
M-Fa toxici	ctor (Chronic aquatic ty)	:	100	
Persi	stence and degradabili	ity		
Com	ponents:			
-	<b>an-2-ol:</b> egradability	:	Result: rapidly de	gradable
BOD/	/COD	:	BOD: 1.19 (BOD5	5)COD: 2.23BOD/COD: 53 %



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-	<b>etasone:</b> egradability	:	Result: Not readil Biodegradation:				
			Exposure time: 28 d Method: OECD Test Guideline 314				
Stabi	Stability in water		Hydrolysis: 50 %(12 d) Method: OECD Test Guideline 111				
Bioa	ccumulative potential						
<u>Com</u>	ponents:						
Partit	<b>an-2-ol:</b> ion coefficient: n- ool/water	:	log Pow: 0.05				
Mom	etasone:						
Bioad	ccumulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): 107.1 est Guideline 305			
	ion coefficient: n- nol/water	:	log Pow: 4.68				
Mobi	lity in soil						
<u>Com</u>	ponents:						
Distri	etasone: bution among environ- al compartments	:	log Koc: 4.02				
	<b>r adverse effects</b> ata available						

#### **13. DISPOSAL CONSIDERATIONS**

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. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or ex- pose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.



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14. TRAN	SPORT INFORMATION	I		
Interi	national Regulations			
Prope Class	umber er shipping name s ing group	:	UN 1219 ISOPROPANOL 3 II 3	SOLUTION
UN/IE Prope Class Packi Label Packi aircra Packi	er shipping name ing group Is ing instruction (cargo		UN 1219 Isopropanol solu 3 II Flammable Liqu 364 353	
UN n Prope Class Packi Label EmS	ing group		UN 1219 ISOPROPANOL (Mometasone) 3 II 3 F-E, S-D yes	SOLUTION
	sport in bulk according	g to		5
		-		

Not applicable for product as supplied.

#### Special precautions for user

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

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

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

#### The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined



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16. C	OTHER INFORMATION							
	Further information							
	Sources of key data used to compile the Safety Data Sheet		Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/					
	Date format		dd.mm.yyyy					
	Full text of other abbreviations							
	ACGIH ACGIH BEI		USA. ACGIH Threshold Limit Values (TLV) ACGIH - Biological Exposure Indices (BEI)					
	ACGIH / TWA : ACGIH / STEL :		8-hour, time-weighted average Short-term exposure limit					

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



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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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