

### Betamethasone (0.05%) Lotion Formulation

Versi 5.1	on	Revision Date: 2024/04/06		S Number: /1272-00011	Date of last issue: 2023/09/30 Date of first issue: 2019/05/30
1. PR	ODUC	T AND COMPANY IDI	ENT	IFICATION	
F	Product	name	:	Betamethasone (	0.05%) Lotion Formulation
I	Manufa	cturer or supplier's d	letai	ls	
(	Compa	ny	:	Organon & Co.	
/	Addres	6	:	JL Raya Pandaaı Pandaan, Jawa T	
-	Telepho	one	:	+1-551-430-6000	)
E	Emerge	ency telephone number	· :	+1-215-631-6999	)
E	E-mail a	address	:	EHSSTEWARD@	⊉organon.com

#### Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

### 2. HAZARDS IDENTIFICATION

GHS Classification Flammable liquids	:	Category 2
Serious eye damage/eye irri- tation	:	Category 2A
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - single exposure	:	Category 3
Specific target organ toxicity - repeated exposure	:	Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Long-term (chronic) aquatic hazard	:	Category 1
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger



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Haza	rd statements	H319 Causes H336 May cau H360D May da H372 Causes tem, muscle, th longed or repe	ammable liquid and vapour. serious eye irritation. se drowsiness or dizziness. amage the unborn child. damage to organs (Pituitary gland, Immune sys- nymus gland, Blood, Adrenal gland) through pro- ated exposure. ic to aquatic life with long lasting effects.
Preca	autionary statements	P202 Do not h and understoo P210 Keep aw No smoking. P233 Keep con P241 Use expl ment. P242 Use only P243 Take pre P260 Do not b P264 Wash sk P270 Do not e P271 Use only P273 Avoid rel	ay from heat/ sparks/ open flames/ hot surfaces. htainer tightly closed. osion-proof electrical/ ventilating/ lighting equip- non-sparking tools. cautionary measures against static discharge. reathe mist or vapours. in thoroughly after handling. at, drink or smoke when using this product. outdoors or in a well-ventilated area. ease to the environment. otective gloves/ protective clothing/ eye protec-
		ly all contamina P304 + P340 + and keep comf doctor if you fe P305 + P351 + for several min easy to do. Co P308 + P313 I attention. P337 + P313 I tention. P391 Collect s	<ul> <li>P338 IF IN EYES: Rinse cautiously with water utes. Remove contact lenses, if present and ntinue rinsing.</li> <li>F exposed or concerned: Get medical advice/</li> <li>f eye irritation persists: Get medical advice/ at-</li> </ul>
		Storage: P403 + P235 S P405 Store loc Disposal:	Store in a well-ventilated place. Keep cool. ked up.
		•	of contents/ container to an approved waste



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

Vapours may form explosive mixture with air.

#### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	>= 30 -< 60
betamethasone	378-44-9	>= 0.025 -< 0.25

#### 4. FIRST AID MEASURES

Specific hazards during fire-

fighting

	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.
	in innalou	•	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. Wash clothing before reuse.
			Thoroughly clean shoes before reuse.
	In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water
			for at least 15 minutes. If easy to do, remove contact lens, if worn.
			Get medical attention.
	If swallowed		If swallowed, DO NOT induce vomiting.
		•	Get medical attention.
			Rinse mouth thoroughly with water.
	Most important symptoms	:	Causes serious eye irritation.
	and effects, both acute and		May cause drowsiness or dizziness.
	delayed		May damage the unborn child.
			Causes damage to organs through prolonged or repeated
	Protection of first-aiders		exposure. First Aid responders should pay attention to self-protection,
	Trotection of mat-alders	•	and use the recommended personal protective equipment
			when the potential for exposure exists (see section 8).
	Notes to physician	:	Treat symptomatically and supportively.
5 6	FIREFIGHTING MEASURES		
5.1			
	Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2)
	Unsuitable extinguishing		Dry chemical High volume water jet
	media	•	righ volume water jet

:

fire.

Do not use a solid water stream as it may scatter and spread



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			Vapours may for	ble over considerable distance. m explosive mixtures with air. bustion products may be a hazard to health.	
Haza ucts	rdous combustion prod-	:	Carbon oxides		
Speci ods	ific extinguishing meth-	:	cumstances and Use water spray Remove undama so.	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. Iged containers from fire area if it is safe to do	
	ial protective equipment efighters	:		e, wear self-contained breathing apparatus. tective equipment.	
6. ACCIDE	ENTAL RELEASE MEAS	SUF	RES		
tive e	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 pr tective equipment recommendations (see section 8).		
Envir	onmental precautions	:	Prevent spreadin barriers). Retain and dispo	eakage or spillage if safe to do so. g over a wide area (e.g. by containment or o se of contaminated wash water. should be advised if significant spillages	
	ods and materials for inment and cleaning up	:	Soak up with ine Suppress (knock spray jet. For large spills, p ment to keep ma be pumped, store Clean up remain bent. Local or national posal of this mate employed in the o mine which regul Sections 13 and	It absorbent material. down) gases/vapours/mists with a water provide dyking or other appropriate contain- terial from spreading. If dyked material can be recovered material in appropriate container ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- ations are applicable. 15 of this SDS provide information regarding ational requirements.	

### 7. HANDLING AND STORAGE

Technical measures

: See Engineering measures under EXPOSURE



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Loca	al/Total ventilation	: If sufficient ventilation. Use explosio	PERSONAL PROTECTION section. entilation is unavailable, use with local exhaust n-proof electrical, ventilating and lighting equip-				
Advi	ice on safe handling	Do not breat Do not swalk Do not get in Wash skin th Handle in acc practice, bas sessment Non-sparking Keep contain Keep away fr other ignition Take precau Do not eat, d	Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-				
Con	ditions for safe storage	Store locked Keep tightly o Keep in a co Store in acco					
Mate	erials to avoid	: Do not store Self-reactive Organic pero Oxidizing age Flammable g Pyrophoric lie Pyrophoric se	with the following product types: substances and mixtures xides ents lases quids olids substances 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	NAB	400 ppm 983 mg/m3	ID OEL
		PSD	500 ppm 1,230 mg/m3	ID OEL
		TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH



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betamethasone	378-44-9	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	de pro Es Us If I ca tia	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 equ	ipment					
Respiratory protection Filter type Hand protection	su on	adequate local re assessment nmended guide ganic vapour ty	demonstrate lines, use re	es exposure	es outside the	
Material	: Ch	emical-resista	nt gloves			
Remarks		onsider double able, which ma				
Eye protection	: We If t mi We po	ear safety glass he work enviro sts or aerosols ear a faceshield tential for direc rosols.	ses with side nment or act , wear the ap d or other ful	e shields or tivity involve opropriate g I face prote	goggles. es dusty condi goggles. ection if there is	tions, s a
Skin and body protection	Ac tas po Us co	ork uniform or l ditional body g sk being perfor sable suits) to se appropriate o ntaminated clo	arments sho med (e.g., slo avoid expose degowning te thing.	ould be used eevelets, ap ed skin surf echniques t	pron, gauntlets aces. o remove pote	s, dis- entially
Hygiene measures		exposure to che e flushing syste				



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ing 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	lotion
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	21.4 °C
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	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-	:	Not applicable



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	ol/water ignition temperature	:	No data available	9
Deco	mposition temperature	:	No data available	9
Visco Vis	sity scosity, kinematic	:	No data available	9
Explo	sive properties	:	Not explosive	
	zing properties cular weight	:	The substance o	r mixture is not classified as oxidizing.
Partic	cle characteristics cle size	:	Not applicable	,
0. STABI	ILITY AND REACTIVITY	1		
	tivity nical stability bility of hazardous reac-	:	Stable under nor Highly flammable Vapours may for	a reactivity hazard. mal conditions. e liquid and vapour. m explosive mixture with air. rong oxidizing agents.
Incom	itions to avoid npatible materials rdous decomposition icts	:	Heat, flames and Oxidizing agents No hazardous de	
11. TOXIC		ΓΙΟΝ		
Inforn expos	nation on likely routes of sure		Inhalation Skin contact Ingestion Eye contact	
	e toxicity lassified based on availa	ıble ir	nformation.	
Com	ponents:			
Prop	an-2-ol·			

Propan-2-ol: Acute oral toxicity		LD50 (Rat): > 5,000 mg/kg
Acute oral toxicity	•	ED50 (Rat). > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 25 mg/l Exposure time: 6 h Test atmosphere: vapour
Acute dermal toxicity	:	LD50 (Rabbit): > 5,000 mg/kg



betamethasone:         Acute oral toxicity       :       LD50 (Rat): > 5,000 mg/kg         LD50 (Mouse): > 4,500 mg/kg         Acute inhalation toxicity       :       LC50 (Rat): 0.4 mg/l         Exposure time: 4 h         Skin corrosion/irritation         Not classified based on available information.         Components:         Propan-2-ol:         Species       :         Result       :       No skin irritation         betamethasone:         Species       :       Rabbit         Result       :       No skin irritation         Components:       :       No skin irritation         Propan-2-ol:       :       :         Species       :       Rabbit         Result       :       Mild skin irritation         Causes serious eye irritation.       :       Components:         Propan-2-ol:       :       :         Species       :       Rabbit         Result       :       :         Species       :       Rabbit         Result       :       :         Species       :       Rabbit         Result       :       :         Species<	019/05/30
Acute oral toxicity       :       LD50 (Rat): > 5,000 mg/kg         LD50 (Mouse): > 4,500 mg/kg       LD50 (Mouse): > 4,500 mg/kg         Acute inhalation toxicity       :       LC50 (Rat): 0.4 mg/l Exposure time: 4 h         Skin corrosion/irritation       Not classified based on available information.         Components:       Propan-2-ol:         Species       :       Rabbit         Result       :       No skin irritation         betamethasone:	
Acute oral toxicity       :       LD50 (Rat): > 5,000 mg/kg         LD50 (Mouse): > 4,500 mg/kg       LD50 (Mouse): > 4,500 mg/kg         Acute inhalation toxicity       :       LC50 (Rat): 0.4 mg/l Exposure time: 4 h         Skin corrosion/irritation       Not classified based on available information.         Components:       Propan-2-ol:         Species       :       Rabbit         Result       :       No skin irritation         betamethasone:	
LD50 (Mouse): > 4,500 mg/kg         Acute inhalation toxicity       :       LC50 (Rat): 0.4 mg/l Exposure time: 4 h         Skin corrosion/irritation         Not classified based on available information.         Components:         Propan-2-ol:         Species       :         Result       :       No skin irritation         betamethasone:         Species       :       Rabbit         Result       :       No skin irritation         betamethasone:       :       Serious eye damage/eye irritation         Causes serious eye irritation.       Components:         Propan-2-ol:       :       Mild skin irritation         Serious eye damage/eye irritation       Causes serious eye irritation.         Causes serious eye irritation.       :       Endetta serious eye irritation.         Species       :       Rabbit         Result       :       Irritation to eyes, reversing within 21 data         betamethasone:       :       No eye irritation.         Species       :       Rabbit         Result       :       No eye irritation.         Stin sensitisation       :       No eye irritation.         Kespiratory or skin sensitisation.       :         Sk	
Acute inhalation toxicity       :       LC50 (Rat): 0.4 mg/l Exposure time: 4 h         Skin corrosion/irritation       Not classified based on available information.         Components:       Propan-2-ol:         Species       :       Rabbit         Result       :       No skin irritation         betamethasone:       :       Nold skin irritation         Species       :       Rabbit         Result       :       No skin irritation         Serious eye damage/eye irritation       Causes serious eye irritation.         Causes serious eye irritation.       Components:         Propan-2-ol:       :         Species       :         Result       :         Mild skin irritation       Causes serious eye irritation.         Components:       :         Propan-2-ol:       :         Species       :         Species       :         Result       :         Irritation to eyes, reversing within 21 data         betamethasone:       :         Species       :         Species       :         Result       :         No eye irritation         Result       :         Result	
Exposure time: 4 h   Skin corrosion/irritation   Not classified based on available information.   Components:   Propan-2-ol:   Species   Result   Species   Result   Serious eye damage/eye irritation   Causes serious eye irritation.   Components:   Propan-2-ol:   Species   Result   Serious eye damage/eye irritation   Causes serious eye irritation.   Components:   Propan-2-ol:   Species   Result   Result <td></td>	
Not classified based on available information.         Components:         Propan-2-ol:         Species       : Rabbit         Result       : No skin irritation         betamethasone:         Species       : Rabbit         Result       : No skin irritation         betamethasone:         Species       : Rabbit         Result       : Mild skin irritation         Serious eye damage/eye irritation         Causes serious eye irritation.         Components:         Propan-2-ol:         Species       : Rabbit         Result       : Irritation to eyes, reversing within 21 data         betamethasone:         Species       : Rabbit         Result       : Irritation to eyes, reversing within 21 data         betamethasone:         Species       : Rabbit         Result       : No eye irritation         Result       : No eye irritation         Respiratory or skin sensitisation         Skin sensitisation         Not classified based on available information.	
Propan-2-ol:   Species :   Result :   No skin irritation   betamethasone:   Species :   Result :   Result :   Mild skin irritation   Serious eye damage/eye irritation Causes serious eye irritation.   Causes serious eye irritation.   Causes serious eye irritation.   Causes serious eye irritation.   Components:   Propan-2-ol:   Species :   Result :   Irritation to eyes, reversing within 21 data   betamethasone:   Species :   Result :   No eye irritation   Result :   No eye irritation   Skin sensitisation   Not classified based on available information.	
Species : Rabbit   Result : No skin irritation   betamethasone: :   Species :   Result :   Mild skin irritation   Serious eye damage/eye irritation Causes serious eye irritation. Causes serious eye irritation. Components: Propan-2-ol: Species : Rabbit Result : Irritation to eyes, reversing within 21 data to eyes, reversing with	
Result       : No skin irritation         betamethasone:       .         Species       : Rabbit         Result       : Mild skin irritation         Serious eye damage/eye irritation       .         Causes serious eye irritation.       .         Causes serious eye irritation.       .         Components:       .         Propan-2-ol:       .         Species       : Rabbit         Result       : Irritation to eyes, reversing within 21 data         betamethasone:       .         Species       : Rabbit         Result       : Irritation to eyes, reversing within 21 data         betamethasone:       .         Species       : No eye irritation         Kesult       : No eye irritation         Action of the sensitisation       .         Skin sensitisation       .         Not classified based on available information.	
Species : Rabbit Result : Mild skin irritation Serious eye damage/eye irritation Causes serious eye irritation. Components: Propan-2-ol: Species : Rabbit Result : Irritation to eyes, reversing within 21 da betamethasone: Species : Rabbit Result : No eye irritation Respiratory or skin sensitisation Skin sensitisation Not classified based on available information.	
Result : Mild skin irritation   Serious eye damage/eye irritation   Causes serious eye irritation.   Components:   Propan-2-ol:   Species   Result   Species   irritation to eyes, reversing within 21 data   betamethasone:   Species   Species   Result   Species   Result   Species   Species   Species   Species   Shin sensitisation   Not classified based on available information.	
Serious eye damage/eye irritation   Causes serious eye irritation.   Components:   Propan-2-ol:   Species   Result   Edit   Species   Species <t< td=""><td></td></t<>	
Species       :       Rabbit         Result       :       Irritation to eyes, reversing within 21 data         betamethasone:       :       Rabbit         Species       :       Rabbit         Result       :       No eye irritation         Respiratory or skin sensitisation       Skin sensitisation         Not classified based on available information.	
Result       :       Irritation to eyes, reversing within 21 data         betamethasone:       :         Species       :       Rabbit         Result       :       No eye irritation         Respiratory or skin sensitisation       Skin sensitisation         Not classified based on available information.	
betamethasone:         Species       : Rabbit         Result       : No eye irritation         Respiratory or skin sensitisation         Skin sensitisation         Not classified based on available information.	
Species       : Rabbit         Result       : No eye irritation         Respiratory or skin sensitisation         Skin sensitisation         Not classified based on available information.	ys
Result       : No eye irritation         Respiratory or skin sensitisation         Skin sensitisation         Not classified based on available information.	
Respiratory or skin sensitisation Skin sensitisation Not classified based on available information.	
Skin sensitisation Not classified based on available information.	
Not classified based on available information.	
Respiratory sensitisation	
Not classified based on available information.	
Components:	
Propan-2-ol:	
Test Type : Buehler Test	
Exposure routes : Skin contact Species : Guinea pig	
Method : OECD Test Guideline 406	



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Resu	lt	:	negative	
betai	methasone:			
Expo Spec Resu		::	Dermal Guinea pig Weak sensitizer	
	n cell mutagenicity lassified based on ava	ilable i	information.	
<u>Com</u>	ponents:			
•	an-2-ol: otoxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
			-	o mammalian cell gene mutation test
Genc	otoxicity in vivo	:	cytogenetic assa Species: Mouse	nalian erythrocyte micronucleus test (in vivo /) e: Intraperitoneal injection
betai	methasone:			
	otoxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
			Test Type: In vitre Result: negative	o mammalian cell gene mutation test
			Test Type: Chron Result: positive	nosome aberration test in vitro
Genc	otoxicity in vivo	:	Test Type: Mamr cytogenetic assay Species: Mouse Application Route Result: equivocal	e: Oral
	n cell mutagenicity - ssment	:	Weight of evidencell mutagen.	ce does not support classification as a germ

### Carcinogenicity

Not classified based on available information.



rsion	Revision Date: 2024/04/06		9S Number: 71272-00011	Date of last issue: 2023/09/30 Date of first issue: 2019/05/30
Com	ponents:			
Prop	an-2-ol:			
Speci	ies	:	Rat	
	cation Route	:	inhalation (vapo	ur)
Expo: Metho	sure time	:	104 weeks OECD Test Guid	deline 151
Resu		:	negative	
-	oductive toxicity			
May o	damage the unborn chi	ld.		
<u>Com</u>	ponents:			
-	<b>an-2-ol:</b> ts on fertility		Test Type: Two-	-generation reproduction toxicity study
Enco	to off fortility	•	Species: Rat	generation represented entry ettaly
			Application Rou	
			Result: negative	
Effect	ts on foetal develop-	:		ryo-foetal development
ment			Species: Rat	to Indeption
			Application Rour Result: negative	
betar	nethasone:			
Effect	ts on foetal develop-	:	Species: Rabbit	
ment				te: Intramuscular
				Toxicity: LOAEL: 0.05 mg/kg body weight city, Malformations were observed.
			Species: Rat	
				te: Subcutaneous Toxicity: LOAEL: 0.42 mg/kg body weight
				ations were observed.
			Species: Mouse	
				te: Intramuscular Toxicity: LOAEL: 1 mg/kg body weight
				ations were observed.
Repro sessr	oductive toxicity - As-	:	Clear evidence of animal experime	of adverse effects on development, basec
0701				
	<b>Γ - single exposure</b> cause drowsiness or di	zzine	SS.	
Com	ponents:			
Prop	an-2-ol:			
A				

: May cause drowsiness or dizziness.



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STOT	- repeated exposure	2	
Cause renal	es damage to organs gland) through prolon	(Pituitary gland, Immu	une system, muscle, thymus gland, Blood, Ad- sure.
Comp	oonents:		
	nethasone:		
Targe	et Organs	: Pituitary gland Adrenal gland	I, Immune system, muscle, thymus gland, Blood
Asses	ssment		ge to organs through prolonged or repeated
Repe	ated dose toxicity		
<u>Comp</u>	oonents:		
Propa	an-2-ol:		
Speci NOAE		: Rat	
-	cation Route	: 12.5 mg/l : inhalation (vap	oour)
Expos	sure time	: 104 Weeks	
betan	nethasone:		
Speci		: Rabbit	
LOAE	L cation Route	: 0.05 % : Skin contact	
	sure time	: 10 - 30 d	
Targe	t Organs	: Pituitary gland	l, Immune system, muscle
Speci		: Rat	
LOAE		: 0.05 % : Skin contact	
	cation Route sure time	: 8 Weeks	
	t Organs	: thymus gland	
Speci	es	: Mouse	
LÖAE		: 0.1 %	
	cation Route sure time	: Skin contact : 8 Weeks	
	et Organs	: thymus gland	
Speci	es	: Dog	
LÖAE	E	: 0.05 mg/kg	
	cation Route sure time	: Oral : 28 d	
	t Organs		gland, Adrenal gland

#### Aspiration toxicity

Not classified based on available information.



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	Experi	ence with human exp	osi	ire					
	Components:								
	betamethasone:								
	Inhalat Skin co		:	Target Organs: A Symptoms: Redn	drenal gland ess, pruritis, Irritation				
12. I	ECOLO	GICAL INFORMATION	N						
	Ecoto	cicity							
	Compo	onents:							
	Propa			LOGO (Dimenhala					
	IOXICIT	y to fish	•	Exposure time: 96	s promelas (fathead minnow)): 9,640 mg/l S h				
		y to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 24	agna (Water flea)): > 10,000 mg/l I h				
	Toxicity	y to microorganisms	:	EC50 (Pseudomo Exposure time: 16	nas putida): > 1,050 mg/l S h				
	betam	ethasone:							
		y to daphnia and other invertebrates	:	EC50 (Americam) Exposure time: 96					
	Toxicit <u>y</u> plants	y to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD T					
				mg/l Exposure time: 72 Method: OECD To					
	Toxicity	y to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te					
				NOEC (Oryzias la Exposure time: 2' Method: OECD Te					
		y to daphnia and other invertebrates (Chron- ity)		NOEC (Daphnia r Exposure time: 2 <sup>4</sup> Method: OECD Te					





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M-Fa toxici	ctor (Chronic aquatic ty)	:	1,000	
Persi	stence and degradab	ility		
<u>Com</u>	ponents:			
Prop	an-2-ol:			
-	gradability	:	Result: rapidly o	legradable
BOD/	COD	:	BOD: 1,19 (BOI COD: 2,23 BOD/COD: 53 %	
Bioad	ccumulative potential			
Com	ponents:			
Prop	an-2-ol:			
	ion coefficient: n- ol/water	:	log Pow: 0.05	
	nethasone:			
	ion coefficient: n- ol/water	:	log Pow: 2.11	
Mobi	lity in soil			
No da	ata available			
	r adverse effects			
No da	ata available			
3. DISPC	SAL CONSIDERATIO	NS		
Dispo	osal methods			
Wast	e from residues	:	Do not dispose	of waste into sewer.

waste from residues	-	Do not dispose of waste into sewer.
		Dispose of in accordance with local regulations.
Contaminated packaging	:	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.

### 14. TRANSPORT INFORMATION

### International Regulations

UNRTDG

UN number Proper shipping name Class	:	UN 1219 ISOPROPANOL SOLUTION 3
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Lab	king group els ironmentally hazardous	:	ll 3 ves	
IAT UN/ Proj Clas Pac Lab Pac airc Pac	<b>A-DGR</b> ID No. ber shipping name ss king group els king instruction (cargo	: : : : : : : : : : : : : : : : : : : :	UN 1219 Isopropanol solut 3 II Flammable Liquid 364 353	
UN Proj Clas Pac Lab Ems	king group	: : : : : : : : : : : : : : : : : : : :	UN 1219 ISOPROPANOL (betamethasone) 3 II 3 F-E, S-D 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.

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

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

#### Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Propan-2-ol
Prohibited substances	:	Not applicable



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Restr	icted substances		: Not applicable
Regu Mate	-	of Trade No. 7 of 202	22 on Distribution and Control of Hazardous
	of hazardous materials ol, Annex I	subject to distributior	n and : Not applicable
	of hazardous materials ol, Annex II	subject to distributior	n and : Not applicable
The c AICS	•	oduct are reported in : not determined	n the following inventories:
DSL		: not determined	
IECS	С	: not determined	
16. OTHE	R INFORMATION		
Revis	sion Date	: 2024/04/06	
Furth	er information		
	ces of key data used to ile the Safety Data t		al data, data from raw material SDSs, OECD earch results and European Chemicals Agen- europa.eu/
Date	format	: yyyy/mm/dd	
Full t	ext of other abbreviati	ons	
ACGI ACGI ID OE	H BEI	: ACGIH - Biolog	hreshold Limit Values (TLV) ical Exposure Indices (BEI) upational Exposure Limits
ACGI ID OE	H / TWA H / STEL EL / NAB EL / PSD	<ul> <li>8-hour, time-we</li> <li>Short-term expo</li> <li>Long term expo</li> <li>Short term expo</li> </ul>	osure limit osure limit
Land Carci Stand x% re	of Brazil; ASTM - Ame nogen, Mutagen or Re dardisation; DSL - Dome esponse; ELx - Loading	rican Society for the eproductive Toxicant estic Substances List g rate associated wir	als; ANTT - National Agency for Transport by Testing of Materials; bw - Body weight; CMR ; DIN - Standard of the German Institute fo (Canada); ECx - Concentration associated with th x% response; EmS - Emergency Schedule (Japan): ErCx - Concentration associated with

ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% response, ErCs - 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



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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; TECI - Thailand Existing Chemicals Inventory; 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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