

Version 3.0	Revision Date: 30.09.2020	SDS Number: 4371269-00004					
SECTION	1. PRODUCT AND C	COMPANY IDENTIFI	CATION				
Prod	uct name	: Betamethas	one (0.05%) Lotion Formulation				
Manu	ufacturer or supplier	's details					
Com	pany	: Organon & O	: Organon & Co.				
Addro	ess		30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302				
Telep	phone	: 551-430-60	00				
Emei	rgency telephone	: 215-631-699	99				
E-ma	ail address	: EHSSTEWA	EHSSTEWARD@organon.com				
Reco	ommended use of the	e chemical and rest	rictions on use				
Reco	ommended use	: Pharmaceut	ical				

GHS Classification		
Flammable liquids	:	Category 2
Eye irritation	:	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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		prolonged or re	e, thymus gland, Blood, Adrenal gland) through epeated exposure. ic to aquatic life with long lasting effects.
Precautionary Statements		P202 Do not h and understoo P210 Keep aw and other igniti P260 Do not b P264 Wash sk P270 Do not e P271 Use only P273 Avoid rel	ay from heat, hot surfaces, sparks, open flames on sources. No smoking. reathe mist or vapors. 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.	 P338 IF IN EYES: Rinse cautiously with water utes. Remove contact lenses, if present and ntinue rinsing. F exposed or concerned: Get medical advice/ f eye irritation persists: Get medical advice/ at-
		Storage: P405 Store loc Disposal: P501 Dispose disposal plant.	ked up. of contents/ container to an approved waste

Other hazards which do not result in classification

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

: Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	>= 30 -< 50
Betamethasone	378-44-9	>= 0,025 -< 0,1

SECTION 4. FIRST AID MEASURES



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General advice		:	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medica advice.			
lf inh	aled	:	If inhaled, remove			
In ca	se of skin contact	:	 Get medical attention. In case of contact, immediately flush skin with plenty of wa Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. 			
In ca	se of eye contact	 In case of contact, immediately flush eyes with plenty of for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention. 				
lf swa	allowed	:	 If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Causes serious eye irritation. May cause drowsiness or dizziness. May damage the unborn child. Causes damage to organs through prolonged or repeated 			
	important symptoms effects, both acute and red	:				
Prote	ction of first-aiders	:	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 MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides
ods	:	cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.



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SECTION	6. ACCIDENTAL RELE	AS	E MEASURES	
tive e	onal precautions, protec- quipment and emer- / procedures	:	Follow safe har	
Enviro	onmental precautions	:	Prevent further Prevent spread oil barriers). Retain and disp	o the environment. leakage or spillage if safe to do so. ing over a wide area (e.g., by containment or oose of contaminated wash water. s should be advised if significant spillages ained.
	ods and materials for inment and cleaning up	:	Soak up with in Suppress (know jet. For large spills, containment to can be pumped container. Clean up remai absorbent. Local or nationa disposal of this employed in the determine whic Sections 13 and	pols should be used. ert absorbent material. ck down) gases/vapors/mists with a water spray provide diking or other appropriate keep material from spreading. If diked material l, store recovered material in appropriate ning materials from spill with suitable al regulations may apply to releases and material, as well as those materials and items e cleanup of releases. You will need to h regulations are applicable. d 15 of this SDS provide information regarding national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures		See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. If sufficient ventilation is unavailable, use with local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equip-
Advice on safe handling	:	ment. Do not get on skin or clothing. Do not breathe mist or vapors. 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 assessment Non-sparking tools should be used. Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges.



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Conditions for safe storage		 Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment. Keep in properly labeled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. 					
Materials to avoid		: Do not store wit Strong oxidizing Organic peroxid Flammable solid Pyrophoric liquid Pyrophoric solid Self-heating sub	les ds ds ds ostances and mixtures d mixtures which in contact with water emit				

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis			
Propan-2-ol	67-63-0	CMP	400 ppm	AR OEL			
	Further information: Irritation						
		CMP - CPT	500 ppm	AR OEL			
	Further information: Irritation						
		TWA	200 ppm	ACGIH			
		STEL	400 ppm	ACGIH			
Betamethasone	378-44-9	TWA	1 µg/m3 (OEB 4)	Internal			
	Further inform	ation: Skin					
		Wipe limit	10 µg/100 cm ²	Internal			

Ingredients with workplace control parameters

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		2 mg/g Creatinine	AR BEI
		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.



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		Use closed If handled i cabinet, fur potential ex	no open handling permitted. processing systems or containment technologies. n a laboratory, use a properly designed biosafety ne hood, or other containment device if the ists for aerosolization. If this potential does not e over lined trays or benchtops.	
		Use explos equipment.	on-proof electrical, ventilating and lighting	
Perse	onal protective equip	ment		
Respiratory protection		exposure a	local exhaust ventilation is not available or ssessment demonstrates exposures outside the led guidelines, use respiratory protection.	
Hand	protection aterial	C I	esistant gloves	
Re	emarks	flammable,	ouble gloving. Take note that the product is which may impact the selection of hand	
Eye p	protection	 protection. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty cond mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there i potential for direct contact to the face with dusts, mists 		
Skin	and body protection	Additional t task being disposable	m or laboratory coat. ody garments should be used based upon the performed (e.g., sleevelets, apron, gauntlets, suits) to avoid exposed skin surfaces. riate 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 systems and safety showers close to the	

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	lotion
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available

SAFETY DATA SHEET



Betamethasone (0.05%) Lotion Formulation

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	рН		:	No data available	
	Melting	point/freezing point	:	No data available	
	Initial bo range	oiling point and boiling	:	No data available	
	Flash p	oint	:	21,4 °C	
l	Evapora	ation rate	:	No data available	
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available	
	Relative	e vapor density	:	No data available	
	Relative	e density	:	No data available	
	Density		:	No data available	
	Solubili Wate	ty(ies) er solubility	:	No data available	
	Partition octanol	n coefficient: n-	:	Not applicable	
		ition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosit Visc	ty osity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance or	mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	
	Particle	size	:	Not applicable	

SECTION 10. STABILITY AND REACTIVITY

Reactivity

: Not classified as a reactivity hazard.



Chemical stability :: Stable under normal conditions. Possibility of hazardous reac- tions : Highly flammable liquid and vapor. Can react with strong oxidizing agents. Incompatible materials :: Oxidizing agents Hazardous decomposition :: No hazardous decomposition products are known. products SECTION 11. TOXICOLOGICAL INFORMATION Information on likely routes of :: Inhalation exposure :: Inhalation Skin contact Ingestion Eye contact Acute toxicity Not classified based on available information. <u>Components:</u> Propan-2-0I: Acute oral toxicity :: LD50 (Rat): > 5.000 mg/kg Acute inhalation toxicity :: LD50 (Rat): > 5.000 mg/kg Acute dermal toxicity :: LD50 (Rat): > 5.000 mg/kg Acute dermal toxicity :: LD50 (Rat): > 5.000 mg/kg Acute dermal toxicity :: LD50 (Rat): > 5.000 mg/kg Acute inhalation toxicity :: LD50 (Rat): > 5.000 mg/kg Acute dermal toxicity :: LD50 (Rat): > 5.000 mg/kg Acute inhalation toxicity :: LD50 (Rat): > 5.000 mg/kg Acute oral toxicity :: LD50 (Rat): > 5.000 mg/kg Acute inhalation toxicity :: LD50 (Rat): > 5.000 mg/kg Acute inhalation toxicity :: LC50 (Rat): > 5.000 mg/kg Acute inhalation toxicity :: LD50 (Rat): > 5.000 mg/kg Acute inhalation toxicity :: LC50 (Rat): 0.4 mg/l Exposure time: 4 h Skin corrosion/irritation Not classified based on available information. <u>Components:</u> Propan-2-01: Species :: Rabbit Result :: No skin irritation Betamethasone: Deturnethasone: Propan-2-01: Species :: Rabbit Result :: No skin irritation	Versic 3.0	on	Revision Date: 30.09.2020		9S Number: 71269-00004	Date of last issue: 25.09.2020 Date of first issue: 30.05.2019
Incompatible materials : Oxidizing agents Hazardous decomposition : No hazardous decomposition products are known. products : No hazardous decomposition products are known. SECTION 11. TOXICOLOGICAL INFORMATION Information on likely routes of : Inhalation exposure Sin contact ingestion : Skin contact ingestion Exposure : Skin contact Information on likely routes of : Inhalation : Skin contact Propan-2-ol: : Costo (Rat): > 5.000 mg/kg Acute oral toxicity : LD50 (Rat): > 25 mg/l Exposure time: 6 h : Test atmosphere: vapor Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg Betamethasone: : LD50 (Mouse): > 4.500 mg/kg Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg Acute inhalation toxicity : LD50 (Rat): > 5.000 mg/kg Acute oral toxicity : LD50 (Rat): > 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: : Secies : Rabbit Species : No skin irritation Betamethasone: : No	F	Possibi		:	Highly flammable Vapors may form	e liquid and vapor. a explosive mixture with air.
Information on likely routes of exposureInhalation Skin contact Ingestion Eye contactAcute toxicityMot classified based on available information.Components:Propan-2-ol: Acute oral toxicityAcute oral toxicityLC50 (Rat): > 5.000 mg/kgAcute inhalation toxicityLC50 (Rat): > 25 mg/l Exposure time: 6 h Test atmosphere: vaporAcute dermal toxicityLD50 (Rat): > 5.000 mg/kgAcute oral toxicityLD50 (Rat): > 5.000 mg/kgAcute oral toxicityLD50 (Rat): > 5.000 mg/kgAcute oral toxicityLD50 (Rat): > 5.000 mg/kgAcute inhalation toxicityLD50 (Mouse): > 4.500 mg/kgAcute inhalation toxicityLD50 (Mouse): > 4.500 mg/kgAcute inhalation toxicityLD50 (Mouse): > 4.500 mg/kgAcute inhalation toxicityLD50 (Rat): 0,4 mg/l Exposure time: 4 hSkin corrosion/irritationNot classified based on available information.Components:Propan-2-ol:SpeciesSpeciesSpeciesStaticResultResultStaticAcuteBetamethasone:	 Ir ⊢	ncomp Hazard	atible materials ous decomposition	:	Oxidizing agents	
exposureSkin contact ingestion Eye contactAcute toxicityEye contactNot classified based on available information.Components:Propan-2-ol: Acute oral toxicityILD50 (Rat): > 5.000 mg/kgAcute inhalation toxicityILD50 (Rat): > 25 mg/l Exposure time: 6 h Test atmosphere: vaporAcute dermal toxicityILD50 (Rabbit): > 5.000 mg/kgBetamethasone: Acute oral toxicityILD50 (Rabbit): > 5.000 mg/kgBetamethasone: Acute oral toxicityILD50 (Rabbit): > 5.000 mg/kgAcute oral toxicityILD50 (Rabbit): > 5.000 mg/kgBetamethasone: Components:ILD50 (Mouse): > 4.500 mg/kgSkin corrosion/irritation Not classified based on available information.Ecsoure time: 4 hSpeciesIRabbit ResultBetamethasone:IBetamethasone:Betamethasone: </td <td>SECT</td> <td></td> <td>1. TOXICOLOGICAL I</td> <td>NFC</td> <td>ORMATION</td> <td></td>	SECT		1. TOXICOLOGICAL I	NFC	ORMATION	
Not classified based on available information. Components: Propan-2-ol: Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg Acute inhalation toxicity : LC50 (Rat): > 25 mg/l Exposure time: 6 h Test atmosphere: vapor Acute dermal toxicity : Betamethasone: Acute oral toxicity : Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg Betamethasone: Acute oral toxicity : LD50 (Mouse): > 4.500 mg/kg Acute inhalation toxicity : 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 : Mot classified basence: Species : Not skin irritation Betamethasone:			-	:	Skin contact Ingestion	
Propan-2-ol:Acute oral toxicity:LD50 (Rat): > 5.000 mg/kgAcute inhalation toxicity:LC50 (Rat): > 25 mg/l Exposure time: 6 h Test atmosphere: vaporAcute dermal toxicity:LD50 (Rabbit): > 5.000 mg/kgBetamethasone:.Acute oral toxicity:LD50 (Rat): > 5.000 mg/kgAcute oral toxicity:LD50 (Rat): > 5.000 mg/kgAcute oral toxicity:LD50 (Rat): > 4.500 mg/kgAcute inhalation toxicity:LC50 (Rat): 0,4 mg/l Exposure time: 4 hSkin corrosion/irritation.Not classified based on available information.Components:Propan-2-ol:Species:Result:No skin irritationBetamethasone:			•	ble	information.	
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Exposure time: 6 h Test atmosphere: vapor 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:		-		:	LD50 (Rat): > 5.0	00 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 : Rabbit Result : No skin irritation Betamethasone:	Д	Acute ir	nhalation toxicity	:	Exposure time: 6	h
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 : Betamethasone:	Ą	Acute d	ermal toxicity	:	LD50 (Rabbit): > \$	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:	E	Betame	ethasone:			
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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
Not classified based on available information. Components: Propan-2-ol: Species : Rabbit Result : No skin irritation Betamethasone:	Д	Acute ir	nhalation toxicity	:		•
Propan-2-ol: Species : Rabbit Result : No skin irritation Betamethasone:	-			ble	information.	
Species : Rabbit Result : No skin irritation Betamethasone: : Rabbit	<u>c</u>	Compo	onents:			
Result : No skin irritation Betamethasone:	P	Propan	-2-ol:			
			3	:		
	B	Betame	ethasone:			
Result : Rabbit : Mild skin irritation		Species Result	5	:	Rabbit Mild skin irritation	



rsion	Revision Date: 30.09.2020		S Number: 1269-00004	Date of last issue: 25.09.2020 Date of first issue: 30.05.2019
Seriou	ıs eye damage/eye	irritatio	'n	
Cause	s serious eye irritati	on.		
<u>Comp</u>	onents:			
Propa	n-2-ol:			
Specie	es	:	Rabbit	
Result		:	Irritation to eyes	s, reversing within 21 days
Betam	ethasone:			
Specie			Rabbit	
Result		:	No eye irritation	
Respi	ratory or skin sens	itizatior	ı	
	ensitization			
	assified based on av		nformation.	
-	ratory sensitization			
Not cla	assified based on av	ailable i	nformation.	
<u>Comp</u>	onents:			
Propa	n-2-ol:			
Test T			Buehler Test	
Specie	s of exposure		Skin contact Guinea pig	
Metho			OECD Test Gui	deline 406
Result		:	negative	
Betam	ethasone:			
Routes	s of exposure	:	Dermal	
Specie			Guinea pig Weak sensitize	
Result			vveak sensitize	
Germ	cell mutagenicity			
Not cla	assified based on av	ailable i	nformation.	
<u>Comp</u>	onents:			
Propa	n-2-ol:			
Genote	oxicity in vitro		Test Type: Bac Result: negative	terial reverse mutation assay (AMES) e
			Test Type: In vi Result: negative	tro mammalian cell gene mutation test e
Genote	oxicity in vivo		cytogenetic ass Species: Mouse	



ersion)	Revision Date: 30.09.2020		OS Number: 71269-00004	Date of last issue: 25.09.2020 Date of first issue: 30.05.2019
Betar	nethasone:			
Geno	toxicity in vitro	:	Test Type: Bact Result: negative	erial reverse mutation assay (AMES)
			Test Type: In vit Result: negative	tro mammalian cell gene mutation test
			Test Type: Chro Result: positive	pmosome aberration test in vitro
Geno	toxicity in vivo	:	Test Type: Man cytogenetic ass Species: Mouse Application Rou Result: equivoca	te: Oral
	cell mutagenicity - ssment	:	Weight of evide cell mutagen.	nce does not support classification as a gerr
	nogenicity assified based on availa	ble	information.	
<u>Comp</u>	oonents:			
Propa	an-2-ol:			
Speci		:	Rat	
	cation Route sure time	÷	inhalation (vapo 104 weeks	r)
Metho Resul	bd	:	OECD Test Gui negative	deline 451
-	oductive toxicity lamage the unborn child			
Comp	oonents:			
Propa	an-2-ol:			
Effect	s on fertility	:	Test Type: Two Species: Rat Application Rou Result: negative	
Effect	s on fetal development	:	Test Type: Emb Species: Rat Application Rou Result: negative	
			- 3	
	nethasone:			
Effect	s on fetal development	:	Developmental	te: Intramuscular Toxicity: LOAEL: 0,05 mg/kg body weight city., Malformations were observed.



rsion)	Revision Date: 30.09.2020	-	S Number: 71269-00004	Date of last issue: 25.09.2020 Date of first issue: 30.05.2019
			Developmental	ite: Subcutaneous Toxicity: LOAEL: 0,42 mg/kg body weight ations were observed.
			Developmental	e ite: Intramuscular Toxicity: LOAEL: 1 mg/kg body weight iations were observed.
Repro sessn	oductive toxicity - As- nent	:	Clear evidence animal experim	of adverse effects on development, based o ents.
	-single exposure cause drowsiness or diz	zzines	SS.	
<u>Comp</u>	oonents:			
Propa	an-2-ol:			
	ssment	:	May cause drow	vsiness or dizziness.
	oonents:			
Targe	nethasone: ht Organs	:	Adrenal gland	
Targe		:	Adrenal gland	Immune system, muscle, thymus gland, Bloc e to organs through prolonged or repeated
Targe Asses	t Organs	:	Adrenal gland Causes damage	
Targe Asses Repe	t Organs	:	Adrenal gland Causes damage	
Targe Asses Repe	ated dose toxicity	:	Adrenal gland Causes damage	Immune system, muscle, thymus gland, Bloc e to organs through prolonged or repeated
Targe Asses Repe Comp Propa Speci	ated dose toxicity ponents: an-2-ol: es	:	Adrenal gland Causes damag exposure. Rat	
Targe Asses Repe Comp Propa Speci NOAE Applic	ated dose toxicity ponents: an-2-ol: es		Adrenal gland Causes damag exposure.	e to organs through prolonged or repeated
Targe Asses Repe Comp Propa Speci NOAE Applic Expos	ated dose toxicity ponents: an-2-ol: EL cation Route		Adrenal gland Causes damage exposure. Rat 12,5 mg/l inhalation (vapo	e to organs through prolonged or repeated
Targe Asses Repe Comp Propa Speci NOAE Applic Expos Betar Speci	ated dose toxicity ated dose toxicity ponents: an-2-ol: es EL cation Route sure time methasone: es		Adrenal gland Causes damage exposure. Rat 12,5 mg/l inhalation (vapo 104 Weeks Rabbit	e to organs through prolonged or repeated
Targe Asses Repe Comp Propa Speci NOAE Applic Expose Betar Speci LOAE	ated dose toxicity ated dose toxicity ponents: an-2-ol: es EL cation Route sure time methasone: es EL		Adrenal gland Causes damage exposure. Rat 12,5 mg/l inhalation (vapo 104 Weeks	e to organs through prolonged or repeated
Targe Asses Repea Comp Propa Speci NOAE Applic Expos Betar Speci LOAE Applic Expos	ated dose toxicity ated dose toxicity ponents: an-2-ol: es EL cation Route sure time methasone: es		Adrenal gland Causes damage exposure. Rat 12,5 mg/l inhalation (vapo 104 Weeks Rabbit 0.05 % Skin contact 10 - 30 d	e to organs through prolonged or repeated
Targe Asses Repea Comp Propa Speci NOAE Applic Expos Betar Speci LOAE Applic Expos	ated dose toxicity ated dose toxicity ponents: an-2-ol: es EL cation Route sure time methasone: es EL cation Route sure time to Organs es		Adrenal gland Causes damage exposure. Rat 12,5 mg/l inhalation (vapo 104 Weeks Rabbit 0.05 % Skin contact 10 - 30 d	e to organs through prolonged or repeated



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	Exposu Target	re time Organs	:	8 Weeks thymus gland	
	Exposu		:	Mouse 0.1 % Skin contact 8 Weeks thymus gland	
	Exposu		:	Dog 0,05 mg/kg Oral 28 d Blood, thymus gla	nd, Adrenal gland
	-	t ion toxicity ssified based on availa	ble	information.	
I	Experie	ence with human exp	osu	ire	
9	Compo	onents:			
I	Betame	ethasone:			
	Inhalati Skin co		:	Target Organs: Ao Symptoms: Redno	drenal gland ess, pruritis, Irritation
SEC	TION 1	2. ECOLOGICAL INFO	DRN	IATION	
I	Ecotox	icity			
9	Compo	onents:			
	Propan Toxicity		:	LC50 (Pimephales Exposure time: 96	s promelas (fathead minnow)): 9.640 mg/l S h
		to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 24	agna (Water flea)): > 10.000 mg/l l h
-	Toxicity	to microorganisms	:	EC50 (Pseudomo Exposure time: 16	nas putida): > 1.050 mg/l S h
1	Betame	ethasone:			
-	Toxicity	to daphnia and other invertebrates	:	EC50 (Americamy Exposure time: 96	
	Toxicity plants	r to algae/aquatic	:	EC50 (Pseudokiro mg/l	chneriella subcapitata (green algae)): > 34

Exposure time: 72 h

mg/l

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 34



ersion)	Revision Date: 30.09.2020		OS Number: 71269-00004	Date of last issue: 25.09.2020 Date of first issue: 30.05.2019
				72 h Test Guideline 201 xicity at the limit of solubility.
Toxici icity)	ty to fish (Chronic tox-	:	Exposure time:	ales promelas (fathead minnow)): 0,052 mg/ 32 d Test Guideline 210
			Exposure time:	latipes (Japanese medaka)): 0,07 μg/l 219 d Test Guideline 229
	ty to daphnia and other ic invertebrates (Chron- city)	:	Exposure time:	a magna (Water flea)): 8 mg/l 21 d Test Guideline 211
M-Fac toxicit	ctor (Chronic aquatic y)	:	1.000	
Persi	stence and degradabili	ity		
<u>Comp</u>	oonents:			
Propa	an-2-ol:			
Biode	gradability	:	Result: rapidly c	legradable
BOD/	COD	:	BOD: 1.19 (BOI	D5)COD: 2.23BOD/COD: 53 %
Bioac	cumulative potential			
<u>Comp</u>	oonents:			
Partiti	an-2-ol: on coefficient: n- ol/water	:	log Pow: 0,05	
Betar	nethasone:			
	on coefficient: n- ol/water	:	log Pow: 2,11	
	ity in soil ta available			
	adverse effects ta available			

Disposal methods

Waste from residues Contaminated packaging	:	Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or
		expose such containers to heat, flame, sparks, or other



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			death.	n. They may explode and cause injury and/or pecified: Dispose of as unused product.
SECTION	14. TRANSPORT INFO	RM	ATION	
Inter	national Regulations			
Prope Class	umber er shipping name s ing group		UN 1219 ISOPROPANOL 3 II 3	SOLUTION
UN/IE Prope Class Packi Labe Packi aircra	er shipping name ing group ls ing instruction (cargo ift) ing instruction (passen-		UN 1219 Isopropanol solut 3 II Flammable Liquid 364 353	
UN n Prope Class Packi Label EmS	ing 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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture Argentina. Carcinogenic Substances and Agents : Not applicable Registry. Control of precursors and essential chemicals for the preparation of drugs. : Propan-2-ol



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Interr	national Regulations		
The i AICS	•	duct are reported in : not determined	the following inventories:
DSL		: not determined	
IECS	C	: 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/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of other abbreviations

ACGIH ACGIH BEI AR BEI AR OEL	:	USA. ACGIH Threshold Limit Values (TLV) ACGIH - Biological Exposure Indices (BEI) Argentina. Biological Exposure Indices Argentina. Occupational Exposure Limits
ACGIH / TWA ACGIH / STEL AR OEL / CMP AR OEL / CMP - CPT	:	8-hour, time-weighted average Short-term exposure limit TLV (Threshold Limit Value) STEL (Short Term Limit Value)

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



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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 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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