

Version 4.2	Revision Date: 09.04.2021		S Number: 12148-00010	Date of last issue: 10.10.2020 Date of first issue: 19.07.2017
SECTION	I 1. PRODUCT AND CO	MPA		TION
Prod	luct name	:	Betamethason	e Cream Formulation
Man	ufacturer or supplier's o	deta	ils	
Com	pany	:	Organon & Co	
Addr	ess	:	30 Hudson Str Jersey City, Ne	eet, 33nd floor ew Jersey, U.S.A 07302
Tele	phone	:	551-430-6000	
Eme	rgency telephone	:	215-631-6999	
E-ma	ail address	:	EHSSTEWAR	D@organon.com
GHS Repr	A 2. HAZARDS IDENTIFI	:	Category 1B	
	cific target organ toxicity - ated exposure	• :	Category 1 (Pr gland, Blood, A	tuitary gland, Immune system, muscle, thymus Adrenal gland)
Shor haza	t-term (acute) aquatic ard	:	Category 3	
Long haza	g-term (chronic) aquatic ard	:	Category 1	
GHS	a label elements			
Haza	ard pictograms	:		¥_2
Sign	al Word	:	Danger	
Haza	Hazard Statements :			mage the unborn child. damage to organs (Pituitary gland, Immune

H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure. H402 Harmful to aquatic life. H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.



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		and understoo P260 Do not b P264 Wash sk P270 Do not e P273 Avoid re	reathe vapors. in thoroughly after handling. at, drink or smoke when using this product. lease to the environment. ptective gloves/ protective clothing/ eye protec-
		-	F exposed or concerned: Get medical advice/
		Storage: P405 Store loc	sked up.
		Disposal: P501 Dispose disposal plant.	of contents/ container to an approved waste

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Petrolatum	8009-03-8	>= 10 -< 20
Paraffin oil	8012-95-1	>= 5 -< 10
Hexadecan-1-ol. Ethoxylated	9004-95-9	>= 1 -< 2,5
4-Chloro-3-methylphenol	59-50-7	>= 0,1 -< 0,25
Betamethasone	378-44-9	>= 0,025 -< 0,1

SECTION 4. FIRST AID MEASURES

General advice	In the case of accident or if you feel unwell, seek med advice immediately. When symptoms persist or in all cases of doubt seek 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 soap at of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. 	nd plenty
In case of eye contact	Flush eyes with water as a precaution. Get medical attention if irritation develops and persist	s.
If swallowed	If swallowed, DO NOT induce vomiting.	



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an de Pr	Most important symptoms : and effects, both acute and delayed Protection of first-aiders : Notes to physician :			Get medical attention. Rinse mouth thoroughly with water. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. 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.			
SECTIO	ON 5.	FIRE-FIGHTING MEA	SU	RES			
Su	uitable	extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical			
	nsuita edia	ble extinguishing	:	None known.			
Sp		hazards during fire	:		explosive mixtures with air. Soustion products may be a hazard to health.		
Ha uc		ous combustion prod-	:	: Carbon oxides			
Sp od		extinguishing meth-	 Use extinguishing measures that are appropriate cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if so. 		he surrounding environment. o cool unopened containers.		
		protective equipment ighters	:	Evacuate area. In the event of fire, wear self-contained breathing apparat Use personal protective equipment.			
SECTIO	ON 6.	ACCIDENTAL RELEA	ASE	MEASURES			
tiv	e equ	al precautions, protec- ipment and emer- rocedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).		
Er	nviron	mental precautions	:	Prevent spreading oil barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g., by containment or se of contaminated wash water. should be advised if significant spillages		

Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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



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		employed in th determine whi Sections 13 ar	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.			
SECTION	7. HANDLING AND ST	ORAGE				
Tech	nical measures		ng measures under EXPOSURE PERSONAL PROTECTION section.			
Local	/Total ventilation		ntilation is unavailable, use with local exhaust			
Advic	e on safe handling	: Do not get on Do not breathe Do not swallow Avoid contact Wash skin tho Handle in acco practice, base assessment Keep containe Do not eat, dri	v.			
Cond	itions for safe storage	: Keep in prope Store locked u Keep tightly cl				
Mate	rials to avoid		ith the following product types: ng agents			

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

CAS-No. Components Value type Control parame-Basis (Form of ters / Permissible exposure) concentration Petrolatum 8009-03-8 CMP (Mist) AR OEL 5 mg/m³ Further information: Sampled by a method which does not include vapour, lung CMP - CPT 10 mg/m³ AR OEL (Mist) Further information: lung 5 mg/m³ ACGIH TWA (Inhalable particulate matter) 8012-95-1 Paraffin oil 5 mg/m³ AR OEL CMP (Mist) CMP - CPT 10 mg/m³ AR OEL

Ingredients with workplace control parameters



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ĺ		1		(Mist)	T	1
				TWA (Inhalable particulate matter)	5 mg/m³	ACGIH
Betan	nethasone		378-44-9	TWA	1 µg/m3 (OEB 4)	Internal
			Further informa		1	1
				Wipe limit	10 µg/100 cm ²	Internal
Engir	neering measures	:	design and op protect produc Essentially no Use closed pr If handled in a cabinet, fume potential exist	erated in accor cts, workers, an open handling ocessing syster laboratory, use hood, or other	ns or containment te a properly designed containment device i tion. If this potential (chnologies. I biosafety f the
Perso	onal protective equip	ment				
Fil	iratory protection ter type protection	:	exposure assered recommended	essment demor I guidelines, us	tilation is not availab istrates exposures of e respiratory protection rganic vapor type	utside the
Ma	aterial	:	Chemical-resi	stant gloves		
	emarks rotection	:	If the work env mists or aeros Wear a facesh	lasses with side vironment or ac ols, wear the a hield or other fu	e shields or goggles. tivity involves dusty o ppropriate goggles. Il face protection if th the face with dusts, r	ere is a
Skin a	and body protection	:	Work uniform Additional boo task being per disposable su	formed (e.g., sl its) to avoid exp ite degowning t	bat. buld be used based u eevelets, apron, gau bosed skin surfaces. echniques to remove	ntlets,
Hygie	ne measures	:	If exposure to eye flushing s working place When using d Wash contam The effective of engineering co appropriate de industrial hygi	chemical is like ystems and saf o not eat, drink inated clothing operation of a fa ontrols, proper p gowning and d	before re-use. acility should include personal protective e econtamination proc medical surveillance	the review of quipment, edures,

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

SAFETY DATA SHEET



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Colo	r	:	No data available	
Odor	r	:	No data available)
Odor	r Threshold	:	No data available)
pН		:	5	
Melti	ng point/freezing point	:	No data available	
Initia rang	l boiling point and boiling e	:	No data available	
Flash	n point	:	> 93,3 °C	
Evap	poration rate	:	No data available)
Flam	mability (solid, gas)	:	Not applicable	
Flam	mability (liquids)	:	Not applicable	
	er explosion limit / Upper mability limit	:	No data available	
	er explosion limit / Lower mability limit	:	No data available	
Vapo	or pressure	:	No data available)
Rela	tive vapor density	:	No data available)
Rela	tive density	:	No data available)
Dens	sity	:	No data available	9
	bility(ies) /ater solubility	:	No data available	9
	tion coefficient: n-	:	Not applicable	
	nol/water ignition temperature	:	No data available)
Deco	omposition temperature	:	No data available	9
Visco V	osity iscosity, kinematic	:	No data available	
Explo	osive properties	:	Not explosive	
Oxid	izing properties	:	The substance or	mixture is not classified as oxidizing.
Parti	cle size	:	Not applicable	



has no acute dermal

Betamethasone Cream Formulation

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SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Vapors may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products	:	None known. Oxidizing agents No hazardous decomposition products are known.

SEC

CTION 11. TOXICOLOGIC	AL INFO	DRMATION
Information on likely routes exposure	s of :	Inhalation Skin contact Ingestion Eye contact
Acute toxicity		
Not classified based on av	ailable	information.
Product: Acute oral toxicity	:	Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method
Components:		
Petrolatum:		
Acute oral toxicity	:	LD50 (Rat): > 5.000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rat): > 2.000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no a toxicity Remarks: Based on data from similar materials
Paraffin oil:		
Acute oral toxicity	:	LD50 (Rat): > 5.000 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 2.000 mg/kg

Assessment: The substance or mixture has no acute dermal toxicity

Acute oral toxicity	:	LD50 (Rat): 2.500 mg/kg
4-Chloro-3-methylphenol:		

Acute oral toxicity	: LD50 (Mouse): 600 mg/kg
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SAFETY DATA SHEET



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	Acute	inhalation toxicity	:	LC50 (Rat): > 2,8 Exposure time: 4 Test atmosphere:	h	
	Acute	dermal toxicity	:	LD50 (Rat): > 5.000 mg/kg		
	Betam	nethasone:				
	Acute	oral toxicity	:	LD50 (Rat): > 5.0	00 mg/kg	
				LD50 (Mouse): >	4.500 mg/kg	
	Acute	inhalation toxicity	:	LC50 (Rat): 0,4 mg/l Exposure time: 4 h		
		corrosion/irritation assified based on availa	able	information.		
	<u>Comp</u>	onents:				
	Petrol	atum:				
	Specie		:	Rabbit	lin - 404	
	Metho Result		•	OECD Test Guide No skin irritation	aine 404	
	Remai		:		m similar materials	
	Paraff	in oil:				
	Specie Result		:	Rabbit No skin irritation		
	4-Chlo	oro-3-methylphenol:				
	Specie		:	Rabbit		
	Metho Result		:	OECD Test Guide Corrosive after 1	eline 404 to 4 hours of exposure	
	Betam	nethasone:				
	Specie Result		:	Rabbit Mild skin irritation		
		us eye damage/eye irri				
		assified based on availa onents:	able	information.		
	Petrol					
	Specie			Rabbit		
	Result		÷	No eye irritation		
	Metho	d	:	OECD Test Guide		
	Remai	rks	:	Based on data fro	m similar materials	



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Paraf	fin oil:				
Speci	es	: Rabbit			
Resul		: No eye irritatior	1		
	decan-1-ol. Ethoxyl				
Resul			s, reversing within 21 days		
Rema	arks	: Based on data	from similar materials		
4-Chl	oro-3-methylpheno	l:			
Speci	es	: Rabbit			
Resul		: Irreversible effe	cts on the eye		
Metho	bd	: OECD Test Gu	ideline 405		
Betar	nethasone:				
Speci	es	: Rabbit			
Resul		: No eye irritatior	1		
Deem	irotony or okin conc				
-	iratory or skin sens	Sitization			
Skin	sensitization				
Skin : Not cl	sensitization assified based on av	vailable information.			
Skin Not cl Resp	sensitization	vailable information. n			
Skin s Not cl Resp Not cl	sensitization assified based on av iratory sensitization	vailable information. n			
Skin s Not cl Resp Not cl <u>Comp</u>	sensitization lassified based on av iratory sensitization lassified based on av	vailable information. n			
Skin s Not cl Resp Not cl <u>Comp</u>	sensitization lassified based on av iratory sensitization lassified based on av ponents: latum:	vailable information. n			
Skin Not cl Resp Not cl Comp Petro Test T Route	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure	vailable information. n vailable information. : Buehler Test : Skin contact			
Skin Skin Skin Skin Skin Skin Skin Skin	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig			
Skin : Not cl Resp Not cl Com Petro Test T Route Speci Resul	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es lt	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative			
Skin Skin Skin Skin Skin Skin Skin Skin	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es lt	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative	from similar materials		
Skin Skin Skin Skin Skin Skin Skin Skin	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es lt	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative : Based on data	from similar materials		
Skin S Not cl Resp Not cl Comp Petro Test Route Speci Resul Rema A-Chl Test	sensitization lassified based on av iratory sensitization lassified based on av <u>ponents:</u> latum: Type es of exposure es lt arks oro-3-methylpheno Type	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative : Based on data			
Skin Skin Skin Skin Skin Skin Skin Skin	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es it arks oro-3-methylpheno Type es of exposure	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative : Based on data ol: : Maximization T : Skin contact			
Skin S Not cl Resp Not cl Comp Petro Test Route Speci Resul Rema A-Chl Test	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es it arks oro-3-methylpheno Type es of exposure	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative : Based on data ol: : Maximization T			
Skin S Not cl Resp Not cl Comp Petro Test T Route Speci Resul Rema A-ChI Test T Route Speci	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es it arks oro-3-methylpheno Type es of exposure	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative : Based on data ol: : Maximization T : Skin contact : Guinea pig : Probability or e			
Skin S Not cl Resp Not cl Comp Petro Test T Route Speci Resul Rema A-ChI Test T Route Speci	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es lt arks oro-3-methylpheno Type es of exposure es	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative : Based on data ol: : Maximization T : Skin contact : Guinea pig	est		
Skin S Not cl Resp Not cl Comp Petro Test T Route Speci Resul Rema Asses	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es lt arks oro-3-methylpheno Type es of exposure es	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative : Based on data ol: : Maximization T : Skin contact : Guinea pig : Probability or e	est		
Skin S Not cl Resp Not cl Comp Petro Test T Route Speci Resul Rema 4-Chl Test T Route Speci Speci Asses Betar	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es lt arks oro-3-methylpheno Type es of exposure es ssment	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative : Based on data ol: : Maximization T : Skin contact : Guinea pig : Probability or e	est		
Skin S Not cl Resp Not cl Comp Petro Test T Route Speci Resul Rema 4-Chl Test T Route Speci Speci Asses Betar	sensitization lassified based on av iratory sensitization lassified based on av <u>conents:</u> latum: Type es of exposure es t arks oro-3-methylpheno Type es of exposure es ssment methasone: es of exposure es	vailable information. n vailable information. : Buehler Test : Skin contact : Guinea pig : negative : Based on data ol: : Maximization T : Skin contact : Guinea pig : Probability or e rate in humans	est vidence of low to moderate skin sensitizatio		

Not classified based on available information.



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Com	ponents:				
Petr	olatum:				
Gen	otoxicity in vitro	:	Result: negative	nosome aberration test in vitro on data from similar materials	
Gen	otoxicity in vivo	 Test Type: Mammalian erythrocyte micronucleus test cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials 		r) : Intraperitoneal injection est Guideline 474	
4-Cł	loro-3-methylphenol:				
Gen	otoxicity in vitro	: Test Type: Bacterial reverse mutation assay (Result: negative		ial reverse mutation assay (AMES)	
Beta	methasone:				
Gen			Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)	
			Test Type: In vitro Result: negative	o mammalian cell gene mutation test	
			Test Type: Chrom Result: positive	nosome aberration test in vitro	
Gen	otoxicity in vivo	:	: Test Type: Mammalian erythrocyte micronucleus test (in cytogenetic assay) Species: Mouse Application Route: Oral Result: equivocal		
	n cell mutagenicity - essment	:	Weight of evidend cell mutagen.	e does not support classification as a germ	

Carcinogenicity

Not classified based on available information.

Components:

Petrolatum:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Result	:	negative

Reproductive toxicity

May damage the unborn child.



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<u>Com</u> p	oonents:			
Petro	latum:			
Effect	s on fertility	:	test Species: Rat Application Route Result: negative	oduction/Developmental toxicity screening e: Ingestion on data from similar materials
Effect	ffects on fetal development		Species: Rat Application Route Result: negative	yo-fetal development e: Skin contact on data from similar materials
4-Chl	oro-3-methylphenol:			
Effect	s on fertility	:	Test Type: One-o Species: Rat Application Route Result: negative	generation reproduction toxicity study e: Ingestion
Effect	s on fetal development	:	Test Type: Repro test Species: Rat Application Route Result: negative	oduction/Developmental toxicity screening
Betar	nethasone:			
	s on fetal development	:		e: Intramuscular oxicity: LOAEL: 0,05 mg/kg body weight ity., Malformations were observed.
				e: Subcutaneous oxicity: LOAEL: 0,42 mg/kg body weight tions were observed.
				e: Intramuscular oxicity: LOAEL: 1 mg/kg body weight tions were observed.
Repro sessn	oductive toxicity - As- nent	:	Clear evidence o animal experime	f adverse effects on development, based or nts.

STOT-single exposure

Not classified based on available information.



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<u>Comp</u>	oonents:						
4-Chl	oro-3-methylphenol	:					
	sment		respiratory irritation.				
A3300	Sinent	. May cause					
STOT	-repeated exposure						
	es damage to organs gland) through prolor		mune system, muscle, thymus gland, Blood, Adposure.				
<u>Com</u>	oonents:						
Betar	nethasone:						
Targe	t Organs	: Pituitary gla Adrenal gla	nd, Immune system, muscle, thymus gland, Bloo				
Asses	ssment		hage to organs through prolonged or repeated				
Repe	ated dose toxicity						
Comp	oonents:						
Petro	latum:						
Speci		: Rat					
NOAE		: 5.000 mg/kg]				
	cation Route	: Ingestion					
Expos	sure time	: 2 y					
Paraf	fin oil:						
Speci	es	: Rat, female					
LÖAE		: 161 mg/kg					
	cation Route	: Ingestion					
Expos	sure time	: 90 Days					
4-Chl	oro-3-methylphenol	:					
Speci	es	: Rat					
NOAE		: 200 mg/kg					
LOAE		: 400 mg/kg					
	cation Route sure time	: Ingestion : 28 Days					
Expos		. 20 Days					
Betar	nethasone:						
Speci	es	: Rabbit					
LÒAE	E	: 0.05 %					
	cation Route		: Skin contact				
	sure time		: 10 - 30 d				
rarge	t Organs	. Pituitary gla	nd, Immune system, muscle				
Speci		: Rat					
LÒAE	E	: 0.05 %					
	cation Route	: Skin contact					
	sure time	: 8 Weeks	d				
raige	t Organs	: thymus glar					



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Expo		: Mouse : 0.1 % : Skin contact : 8 Weeks : thymus gland	
Expo		: Dog : 0,05 mg/kg : Oral : 28 d : Blood, thymus	s gland, Adrenal gland

Aspiration toxicity

Not classified based on available information.

Components:

Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

Experience with human exposure

Components:

Betamethasone:

Inhalation	:	Target Organs: Adrenal gland
Skin contact	:	Symptoms: Redness, pruritis, Irritation

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity	
Components:	
Petrolatum:	
Toxicity to fish	 LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	 EC50 (Daphnia magna (Water flea)): > 10.000 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	 NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials



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aqua	Toxicity to daphnia and other aquatic invertebrates (Chron-ic toxicity)		NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials	
	affin oil: city to fish	:	Exposure time: 9 Test substance: \	nus maximus (turbot)): > 100 mg/l 6 h Water Accommodated Fraction on data from similar materials
	city to daphnia and other atic invertebrates	:		
Toxi plan	city to algae/aquatic ts	:	Exposure time: 72 Test substance: \	ma costatum (marine diatom)): > 100 mg/l 2 h Water Accommodated Fraction on data from similar materials
			Exposure time: 72 Test substance: \	nema costatum (marine diatom)): > 1 mg/l 2 h Water Accommodated Fraction on data from similar materials
Hex	adecan-1-ol. Ethoxylate	d:		
	city to fish	:	LC50: > 1 - 10 mg Exposure time: 9 Remarks: Based	
	city to daphnia and other atic invertebrates		Exposure time: 4	
Toxi plan	city to algae/aquatic ts	:	EC50: > 10 - 100 Exposure time: 7 Remarks: Based	
4-Cl	nloro-3-methylphenol:			
	city to fish	:	LC50 (Oncorhynd Exposure time: 9	chus mykiss (rainbow trout)): 917 μg/l 6 h
	city to daphnia and other atic invertebrates	:	Exposure time: 4	nagna (Water flea)): 1,5 mg/l 8 h ïest Guideline 202
Toxi plan	city to algae/aquatic ts	:	Exposure time: 7	pyrenoidosa): 15 mg/l 2 h est Guideline 201
			EC10 (Chlorella p	oyrenoidosa): 2,3 mg/l



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			Exposure time: 72 Method: OECD To	
	ctor (Acute aquatic tox-	:	1	
icity) Toxici icity)	ty to fish (Chronic tox-	:	NOEC (Oncorhyn Exposure time: 28 Method: OECD Te	
	ty to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
Toxici	ty to microorganisms	:	EC50: 22,86 mg/l Exposure time: 60) h
Betan	nethasone:			
	ty to daphnia and other ic invertebrates	:	EC50 (Americamy Exposure time: 96	
Toxici plants	ty to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD To	
			mg/l Exposure time: 72 Method: OECD Te	
Toxici icity)	ty to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te	
			NOEC (Oryzias la Exposure time: 21 Method: OECD Te	
	ty to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
M-Fac toxicit	ctor (Chronic aquatic y)	:	1.000	
Persi	stence and degradabili	ty		
<u>Comp</u>	oonents:			
	latum:			
Biode	gradability	:	Result: Not readily Biodegradation: 3 Exposure time: 28	31 %



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				Test Guideline 301F d on data from similar materials
Hexa	decan-1-ol. Ethoxylat	ed:		
Biode	egradability	:	Result: Readily Biodegradation: Exposure time:	> 99 %
4-Ch	loro-3-methylphenol:			
Biode	egradability	:	Result: Readily Biodegradation: Exposure time: Method: OECD	78 %
Bioa	ccumulative potential			
Com	ponents:			
Parat	ffin oil:			
	ion coefficient: n- ol/water	:	log Pow: > 4 Remarks: Calcu	lation
4-Ch	loro-3-methylphenol:			
Bioac	cumulation	:	Species: Cyprin Bioconcentration	us carpio (Carp) n factor (BCF): 5,5 - 13
	ion coefficient: n- ol/water	:	log Pow: 0,477	
	methasone:			
	ion coefficient: n- ol/water	:	log Pow: 2,11	
Mobi	lity in soil			
No da	ata available			
	r adverse effects			
No da	ata available			

SECTION 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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG



Vers 4.2	sion	Revision Date: 09.04.2021		OS Number: 42148-00010	Date of last issue: 10.10.2020 Date of first issue: 19.07.2017
	UN number Proper shipping name		:	UN 3082 ENVIRONMENTA N.O.S. (betamethasone)	ALLY HAZARDOUS SUBSTANCE, LIQUID,
	Class Packing Labels	g group	:	(19 9 111 9	
	IATA-E UN/ID Proper		:	UN 3082 Environmentally h (Betamethasone	nazardous substance, liquid, n.o.s.
	Class Packing Labels	g group	:	9 III Miscellaneous	
	aircraft Packin	g instruction (passen-	:	964 964	
		mentally hazardous	:	yes	
	IMDG- UN nur Proper		:	UN 3082 ENVIRONMENTA N.O.S. (Betamethasone)	ALLY HAZARDOUS SUBSTANCE, LIQUID,
	Labels EmS C	g group ode pollutant		9 III 9 F-A, S-F 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 applicableRegistry.

Control of precursors and essential chemicals for the : Not applicable preparation of drugs.

International Regulations

The ingredients of this product are reported in the following inventories:



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AICS		: not determined		
DSL		: not determined		
IECS	С	: not determined		

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations

ACGIH AR OEL		USA. ACGIH Threshold Limit Values (TLV) Argentina. Occupational Exposure Limits
ACGIH / TWA AR OEL / CMP AR OEL / CMP - CPT	:	8-hour, time-weighted average 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 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



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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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