

## **Betamethasone Liquid Formulation**

ardous substances and mixtures; Part I".

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
2.3	23.03.2020	2050079-00006	Date of first issue: 07.10.2017

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

<b>1.1 Product identifier</b> Trade name	:	Betamethasone Liquid Formulation
1.2 Relevant identified uses of	the s	ubstance or mixture and uses advised against
Use of the Sub- stance/Mixture	:	Pharmaceutical
1.3 Details of the supplier of the	e saf	ety data sheet
Company	:	Organon & Co. 30 Hudson Street, 33nd floor 07302 Jersey City, New Jersey, U.S.A
Telephone	:	551-430-6000
E-mail address of person	:	EHSSTEWARD@organon.com

#### **1.4 Emergency telephone number**

responsible for the SDS

215-631-6999

## **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

### Classification T.R. SEA No 28848

Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure, Category 1 Long-term (chronic) aquatic hazard, Category 1

5

H360D: May damage the unborn child. H372: Causes damage to organs through prolonged or repeated exposure. H410: Very toxic to aquatic life with long lasting effects.

### 2.2 Label elements

Signal word

Hazard pictograms

### Labelling T.R. SEA No 28848



Hazard statements	:	H360D May damage the unborn child. H372 Causes damage to organs through prolonged or re-
		peated exposure. H410 Very toxic to aquatic life with long lasting effects.



# **Betamethasone Liquid Formulation**

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2050079-00006	Date of last issue: 13.09.2019 Date of first issue: 07.10.2017
Preca	utionary statements	P264 Wash ski P273 Avoid rele	ecial instructions before use. In thoroughly after handling. ease to the environment. rective gloves/ protective clothing/ eye protec- on.
		Response:	
		P308 + P313 IF attention. P391 Collect sp	exposed or concerned: Get medical advice/
		Ab must be listed on the	-

Hazardous components which must be listed on the label: betamethasone

### 2.3 Other hazards

None known.

## **SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

### Components

Chemical name	CAS-No. EC-No. Index-No. Registration num- ber	Classification	Concentration (% w/w)
betamethasone	378-44-9 206-825-4	Acute Tox.2; H330 Repr.1B; H360D STOT RE1; H372 Aquatic Chronic1; H410 M-Factor (Chronic aquatic toxicity): 1.000	>= 0,3 - < 1
Benzalkonium chloride	8001-54-5	Acute Tox.3; H301 Acute Tox.2; H330 Acute Tox.3; H311 Skin Corr.1; H314 Eye Dam.1; H318 Aquatic Acute1; H400 Aquatic Chronic2; H411 M-Factor (Acute aquatic toxicity): 100	>= 0,0025 - < 0,025

For explanation of abbreviations see section 16.



# **Betamethasone Liquid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
2.3	23.03.2020	2050079-00006	Date of first issue: 07.10.2017

### **SECTION 4: First aid measures**

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical
		advice.
Protection of first-aiders	:	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).
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 and 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	:	Flush eyes with water as a precaution.
		Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting.
		Get medical attention. Rinse mouth thoroughly with water.
.2 Most important symptoms	and e	effects, both acute and delayed
Risks	:	May damage the unborn child.
		Causes damage to organs through prolonged or repeated exposure.
.3 Indication of any immediat	e meo	dical attention and special treatment needed
Treatment	:	Treat symptomatically and supportively.

5.1 Extinguishing media		
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.



# Betamethasone Liquid Formulation

Vers 2.3	sion	Revision Date: 23.03.2020		S Number: 50079-00006	Date of last issue: 13.09.2019 Date of first issue: 07.10.2017
5.2 \$	Special	hazards arising from	the	e substance or mi	xture
	Specific fighting	•	:	Exposure to com	pustion products may be a hazard to health.
	Hazard ucts	ous combustion prod-	:	No hazardous co	mbustion products are known
5.3	Advice	for firefighters			
	Specia for firef	l protective equipment ighters	:		e, wear self-contained breathing apparatus. tective equipment.
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do

## **SECTION 6: Accidental release measures**

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	: Use personal protective equipment. Follow safe handling advice and personal protective equip- ment recommendations.

## 6.2 Environmental precautions

Environmental precautions	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
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### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up :	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contain- ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor- bent. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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## SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



# **Betamethasone Liquid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
2.3	23.03.2020	2050079-00006	Date of first issue: 07.10.2017

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Keep container tightly closed. Take care to prevent spills, waste and minimize release to the
Hygiene measures	:	environment. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami- nated 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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases
7.3 Specific end use(s) Specific use(s)	:	No data available

### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

Occupational Exposure Limits



## **Betamethasone Liquid Formulation**

Ver 2.3	Version Revision Date: 2.3 23.03.2020				Date of last issue: 13.09.2019 Date of first issue: 07.10.2017	
	Components	(	CAS-No.	Value type (Form	Control parameters	Basis
				of exposure)		
	betamethasone 378-44-9		TWA	1 µg/m3 (OEB 4)	Internal	
	Further inform		ation: Skin			
				Wipe limit	10 μg/100 cm <sup>2</sup>	Internal

### 8.2 Exposure controls

### Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

#### Personal protective equipment

Eye protection Hand protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Material		Chemical-resistant gloves
Matorial	•	chomical resistant giovee
Remarks	:	Consider double gloving.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
		Use appropriate degowning techniques to remove potentially
Respiratory protection	:	contaminated clothing. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to TS EN 143
Filter type	:	Particulates type (P)

### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Appearance	: liquid
Colour	: colourless
Odour	: No data available
Odour Threshold	: No data available
рН	: 6,8 - 7,2



# **Betamethasone Liquid Formulation**

Vers 2.3	sion	Revision Date: 23.03.2020		S Number: 50079-00006	Date of last issue: 13.09.2019 Date of first issue: 07.10.2017
	Melting	point/freezing point	:	No data available	9
		oiling point and boiling	:	No data available	)
	range Flash p	oint	:	No data available	9
	Evapora	ation rate	:	No data available	3
	Flamma	ability (solid, gas)	:	Not applicable	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	No data available	
	Relative	e vapour density	:	No data available	9
	Relative	e density	:	No data available	
	Density	,	:	No data available	)
		er solubility n coefficient: n-	:	No data available Not applicable	
		nition temperature	:	No data available	)
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty osity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	r mixture is not classified as oxidizing.
9.2 (		f <b>ormation</b> ability (liquids)	:	No data available	9
	Particle	size	:	Not applicable	

## **SECTION 10: Stability and reactivity**

### 10.1 Reactivity

Not classified as a reactivity hazard.



# Betamethasone Liquid Formulation

2.3	Revision Date: 23.03.2020	SDS Number: 2050079-00006		Date of last issue: 13.09.2019 Date of first issue: 07.10.2017	
10.2 Cher	nical stability				
Stabl	e under normal condit	ions.			
10.3 Poss	sibility of hazardous	reactio	ons		
Haza	rdous reactions	:	Can react with s	trong oxidizing agents.	
10.4 Cond	ditions to avoid				
Cond	litions to avoid	:	None known.		
10.5 Inco	mpatible materials				
Mate	rials to avoid	:	Oxidizing agents	3	
10.6 Haza	rdous decompositio	n proc	lucts		
No ha	azardous decompositio	on pro	ducts are known.		
SECTION	N 11: Toxicological	infor	mation		
11.1 Infor	mation on toxicologi	cal ef	fects		
	nation on likely routes		Inhalation		
expo	•		Skin contact		
			Ingestion		
			-		
<b>.</b> .			Eye contact		
	e toxicity		Eye contact		
	<b>e toxicity</b> lassified based on ava	ailable	Eye contact		
Not c <u>Prod</u>	lassified based on ava	ailable	Eye contact information.		
Not c <u>Prod</u>	lassified based on ava	iilable :	Eye contact information. Acute toxicity est		
Not c <u>Prod</u>	lassified based on ava	ailable :	Eye contact information. Acute toxicity est Exposure time: 4	h	
Not c <u>Prod</u>	lassified based on ava	iilable :	Eye contact information. Acute toxicity est	h : dust/mist	
Not c <u>Prod</u> Acute	lassified based on ava	ilable :	Eye contact information. Acute toxicity est Exposure time: 4 Test atmosphere	h : dust/mist	
Not c <u>Prod</u> Acute	lassified based on ava uct: a inhalation toxicity	ilable :	Eye contact information. Acute toxicity est Exposure time: 4 Test atmosphere	h : dust/mist	
Not c <u>Prod</u> Acute <u>Com</u> betar	lassified based on ava uct: a inhalation toxicity ponents:	:	Eye contact information. Acute toxicity est Exposure time: 4 Test atmosphere	h : dust/mist ion method	
Not c <u>Prod</u> Acute <u>Com</u> betar	lassified based on ava <u>uct:</u> a inhalation toxicity <u>ponents:</u> methasone:	:	Eye contact information. Acute toxicity est Exposure time: 4 Test atmosphere Method: Calculat	h : dust/mist ion method 100 mg/kg	
Not c <u>Prod</u> Acute <u>Com</u> betar Acute	lassified based on ava <u>uct:</u> a inhalation toxicity <u>ponents:</u> methasone:	:	Eye contact information. Acute toxicity est Exposure time: 4 Test atmosphere Method: Calculat LD50 (Rat): > 5.0 LD50 (Mouse): > LC50 (Rat): 0,4 r	h : dust/mist ion method 100 mg/kg 4.500 mg/kg ng/l	
Not c <u>Prod</u> Acute <u>Com</u> betar Acute	lassified based on ava uct: inhalation toxicity ponents: methasone: e oral toxicity	:	Eye contact information. Acute toxicity est Exposure time: 4 Test atmosphere Method: Calculat LD50 (Rat): > 5.0 LD50 (Mouse): >	h : dust/mist ion method 100 mg/kg 4.500 mg/kg ng/l	
Not c <u>Prod</u> Acute <b>Com</b> <b>betar</b> Acute	lassified based on ava uct: inhalation toxicity ponents: methasone: e oral toxicity	:	Eye contact information. Acute toxicity est Exposure time: 4 Test atmosphere Method: Calculat LD50 (Rat): > 5.0 LD50 (Mouse): > LC50 (Rat): 0,4 r	h : dust/mist ion method 100 mg/kg 4.500 mg/kg ng/l	
Not c <u>Prod</u> Acute <u>Com</u> betar Acute Acute Benz	lassified based on ava uct: inhalation toxicity ponents: methasone: e oral toxicity e inhalation toxicity	:	Eye contact information. Acute toxicity est Exposure time: 4 Test atmosphere Method: Calculat LD50 (Rat): > 5.0 LD50 (Mouse): > LC50 (Rat): 0,4 r	h : dust/mist ion method 100 mg/kg 4.500 mg/kg ng/l h	
Not c <u>Prod</u> Acute <u>Com</u> betar Acute Acute Benz Acute	lassified based on ava <u>uct:</u> inhalation toxicity ponents: methasone: oral toxicity inhalation toxicity a inhalation toxicity calkonium chloride:	:	Eye contact information. Acute toxicity est Exposure time: 4 Test atmosphere Method: Calculat LD50 (Rat): > 5.0 LD50 (Mouse): > LC50 (Rat): 0,4 r Exposure time: 4	h : dust/mist ion method 00 mg/kg 4.500 mg/kg ng/l h mg/kg : > 0,05 - 0,5 mg/l	



# **Betamethasone Liquid Formulation**

rsion	Revision Date: 23.03.2020		DS Number: 050079-00006	Date of last issue: 13.09.2019 Date of first issue: 07.10.2017
			Assessment: Cor	est Guideline 403 rosive to the respiratory tract. on data from similar materials
Acute	dermal toxicity	:	LD50 (Rat, femal	e): 704 mg/kg
Skin d	corrosion/irritation			
Not cl	assified based on ava	ailable	information.	
<u>Comp</u>	oonents:			
betan	nethasone:			
Speci Resul		:	Rabbit Mild skin irritatior	)
Benza	alkonium chloride:			
Speci Resul		:	Human Corrosive after 4	hours or less of exposure
Resul				
Serio Not cl	us eye damage/eye i assified based on ava ponents:			
Serio Not cl <u>Comp</u>	assified based on ava <b>conents:</b>			
Serio Not cl <u>Comp</u> betan	assified based on ava ponents: nethasone:		information.	
Serio Not cl <u>Comp</u>	assified based on ava ponents: nethasone: es			
Serio Not cl Comp betan Specie Resul	assified based on ava ponents: nethasone: es		information. Rabbit No eye irritation	
Serio Not cl Comp betan Specie Resul	assified based on ava <u>ponents:</u> nethasone: es t alkonium chloride: es		information. Rabbit	ts on the eye
Serio Not cl Comp betan Specie Result Benza Specie Result	assified based on ava <u>ponents:</u> nethasone: es t alkonium chloride: es	ilable : : :	information. Rabbit No eye irritation Rabbit Irreversible effect	ts on the eye
Serio Not cl Comp betan Specie Result Result Result Result Result	assified based on ava <u>ponents:</u> nethasone: es t alkonium chloride: es t	ilable : : tisatic	information. Rabbit No eye irritation Rabbit Irreversible effect	ts on the eye
Serio Not cl Comp betan Specie Result Benza Specie Result Respi Skin s Not cl Respi	assified based on ava <u>ponents:</u> nethasone: es t alkonium chloride: es t iratory or skin sensit sensitisation	ailable : : tisatic ailable	information. Rabbit No eye irritation Rabbit Irreversible effect on information.	ts on the eye
Serio Not cl Comp betan Specie Resul Benza Specie Resul Resul Skin s Not cl Not cl	assified based on ava <u>conents:</u> nethasone: es t alkonium chloride: es t iratory or skin sensit sensitisation assified based on ava iratory sensitisation	ailable : : tisatic ailable	information. Rabbit No eye irritation Rabbit Irreversible effect on information.	ts on the eye
Serio Not cl Comp betan Specie Resul Benza Specie Resul Resul Skin s Not cl Respi Not cl Not cl Comp	assified based on ava <u>conents:</u> nethasone: es t alkonium chloride: es t iratory or skin sensit sensitisation assified based on ava iratory sensitisation assified based on ava	ailable : : tisatic ailable	information. Rabbit No eye irritation Rabbit Irreversible effect on information.	ts on the eye
Serio Not cl Comp betan Specia Result Benza Specia Result Result Result Skin s Not cl Respi Not cl Comp betan	assified based on ava <b>conents:</b> <b>nethasone:</b> es t <b>alkonium chloride:</b> es t <b>iratory or skin sensit</b> <b>sensitisation</b> assified based on ava <b>iratory sensitisation</b> assified based on ava <b>conents:</b> <b>nethasone:</b> sure routes	ailable : : ailable ailable	information. Rabbit No eye irritation Rabbit Irreversible effect on information.	ts on the eye

## Benzalkonium chloride:

Test Type

: Human repeat insult patch test (HRIPT)



# Betamethasone Liquid Formulation

Version 2.3	Revision Date: 23.03.2020		0S Number: 50079-00006	Date of last issue: 13.09.2019 Date of first issue: 07.10.2017
Expo Spec Resi		:	Skin contact Humans negative	
	n cell mutagenicity classified based on availa	able	information.	
Com	ponents:			
beta	methasone:			
Gen	otoxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
			Test Type: In vitro Result: negative	o mammalian cell gene mutation test
			Test Type: Chron Result: positive	nosome aberration test in vitro
Gen	otoxicity in vivo	:	Test Type: Mamn cytogenetic assay Species: Mouse Application Route Result: equivocal	
	n cell mutagenicity- As- ment	:	Weight of evidend cell mutagen.	e does not support classification as a germ
Benz	zalkonium chloride:			
Gen	otoxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
			Method: OECD T Result: negative	o mammalian cell gene mutation test est Guideline 476 on data from similar materials
			Method: OECD T Result: negative	nosome aberration test in vitro est Guideline 473 on data from similar materials
Gene	otoxicity in vivo	:	cytogenetic assay Species: Mouse Application Route Method: OECD T Result: negative	

## SAFETY DATA SHEET

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## **Betamethasone Liquid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
2.3	23.03.2020	2050079-00006	Date of first issue: 07.10.2017

### Carcinogenicity

Not classified based on available information.

### **Components:**

#### Benzalkonium chloride:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Method	:	OECD Test Guideline 453
Result	:	negative
Remarks	:	Based on data from similar materials
Species	:	Mouse
Application Route	:	Skin contact
Exposure time	:	80 weeks
Result	:	negative
Species	:	Rabbit
Application Route	:	Skin contact
Exposure time	:	90 weeks
Result	:	negative
Reproductive toxicity		

May damage the unborn child.

### Components:

betamethasone:

#### Effects on foetal develop-Species: Rabbit Application Route: Intramuscular ment Developmental Toxicity: LOAEL: 0,05 mg/kg body weight Result: Fetotoxicity, Malformations were observed. Species: Rat **Application Route: Subcutaneous** Developmental Toxicity: LOAEL: 0,42 mg/kg body weight Result: Malformations were observed. Species: Mouse **Application Route: Intramuscular** Developmental Toxicity: LOAEL: 1 mg/kg body weight Result: Malformations were observed. Reproductive toxicity - As-: Clear evidence of adverse effects on development, based on sessment animal experiments. Benzalkonium chloride: Test Type: Two-generation reproduction toxicity study Effects on fertility 1 Species: Rat **Application Route: Ingestion**



# **Betamethasone Liquid Formulation**

Version 2.3	Revision Date: 23.03.2020	-	OS Number: 50079-00006	Date of last issue: 13.09.2019 Date of first issue: 07.10.2017				
			Result: negativ	D Test Guideline 416 /e ed on data from similar materials				
	Effects on foetal develop- ment		<ul> <li>Test Type: Embryo-foetal development</li> <li>Species: Rabbit</li> <li>Application Route: Ingestion</li> <li>Method: OECD Test Guideline 414</li> <li>Result: negative</li> <li>Remarks: Based on data from similar materials</li> </ul>					
STO	T - single exposure							
Not	classified based on avai	lable	information.					
STO	T - repeated exposure	•						
Cau	ses damage to organs t	hroug	h prolonged or	repeated exposure.				
Com	<u>iponents:</u>							
beta	methasone:							
Targ	jet Organs	:	Pituitary gland Adrenal gland	, Immune system, muscle, thymus gland, Blood,				
Asse	essment	:	Causes dama exposure.	ge to organs through prolonged or repeated				
Ben	zalkonium chloride:							
Asse	essment	:		health effects observed in animals at concentra- g/kg bw or less.				
Rep	eated dose toxicity							
Com	ponents:							
beta	methasone:							
Spee		:	Rabbit					
LOA		:	0.05 %					
	lication Route		Skin contact 10 - 30 d					
	jet Organs	:		, Immune system, muscle				
Spee	cies	:	Rat					
LOA		:	0.05 %					
	lication Route	÷	Skin contact					
	osure time jet Organs	:	8 Weeks thymus gland					
Spee		:	Mouse					
LOA		:	0.1 %					
Appl	lication Route	:	Skin contact					

: 8 Weeks

thymus gland

:

Exposure time Target Organs



# Betamethasone Liquid Formulation

Version 2.3	Revision Date: 23.03.2020		DS Number: 050079-00006	Date of last issue: 13.09.2019 Date of first issue: 07.10.2017
Spec		:	Dog	
LOAE		:	0,05 mg/kg	
	cation Route	:	Oral	
	sure time	:	28 d	
Targe	et Organs	:	Blood, thymus gl	land, Adrenal gland
Benz	alkonium chloride:			
Spec	ies	:	Rat	
NOA		:	: >= 100 mg/kg	
Appli	cation Route	:	Ingestion	
Expo	sure time	:	: 12 Weeks	
Aspi	ration toxicity			
Not c	lassified based on ava	ilable	information.	
Expe	erience with human ex	xposı	ure	
Com	ponents:			
beta	methasone:			
Inhala	ation	:	Target Organs: A	Adrenal gland
Skin	contact	:	Symptoms: Redr	ness, pruritis, Irritation

## **SECTION 12: Ecological information**

## 12.1 Toxicity

**Components:** 

betamethasone:		
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Americamysis): > 50 mg/l Exposure time: 96 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic tox- icity)	:	NOEC: 0,052 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210



# **Betamethasone Liquid Formulation**

Ver 2.3	sion	Revision Date: 23.03.2020		DS Number: 50079-00006	Date of last issue: 13.09.2019 Date of first issue: 07.10.2017
					19 d latipes (Japanese medaka) ēst Guideline 229
Toxicity to daphnia and other aquatic invertebrates (Chron-ic toxicity)				1 d a magna (Water flea) est Guideline 211	
	M-Fact toxicity	or (Chronic aquatic )	:	1.000	
	Benza	lkonium chloride:			
	Toxicity	y to fish	:	LC50 (Pimephale Exposure time: 9	es promelas (fathead minnow)): 0,28 mg/l 6 h
		y to daphnia and other invertebrates	:	EC50 (Daphnia n Exposure time: 4	nagna (Water flea)): 0,0056 mg/l 8 h
	Toxicity plants	y to algae/aquatic	:	ErC50 (Chlorella Exposure time: 7	pyrenoidosa (aglae)): 0,09 mg/l 2 h
	M-Fact icity)	or (Acute aquatic tox-	:	100	
	Toxicity icity)	y to fish (Chronic tox-	:	NOEC: 0,032 mg Exposure time: 3 Species: Pimeph	
12.2	2 Persis	tence and degradabil	ity		
	<u>Comp</u>	onents:			
	Benza	lkonium chloride:			
	Biodeg	radability	:		iodegradable. est Guideline 301D on data from similar materials
12.3	3 Bioaco	cumulative potential			
	Comp	onents:			
	betam	ethasone:			
	Partitio octano	n coefficient: n- I/water	:	log Pow: 2,11	
	Benza	lkonium chloride:			
	Bioacc	umulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): < 500 on data from similar materials



# **Betamethasone Liquid Formulation**

Version 2.3	Revision Date: 23.03.2020	SDS Number:Date of last issue: 13.09.20192050079-00006Date of first issue: 07.10.2017	
Partition coefficient: n- octanol/water		: log Pow: 1,692 Remarks: Calculation	
	bility in soil		
	data available		
12.5 Results of PBT and vPvB as Not relevant		sessment	
12.6 Oth	er adverse effects		
No data available			
SECTION 13: Disposal considerations			
13.1 Wa	ste treatment methods		
Pro	duct	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, W are not product specific, but application specific. Waste codes should be assigned by the user, pr discussion with the waste disposal authorities.	
Cor	taminated packaging	<ul> <li>Empty containers should be taken to an approve dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused</li> </ul>	

## **SECTION 14: Transport information**

14.1 UN number

ADN	: UN 3082
ADR	: UN 3082
RID	: UN 3082
IMDG	: UN 3082
ΙΑΤΑ	: UN 3082
14.2 UN proper shipping name	
ADN	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
IMDG	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)



# **Betamethasone Liquid Formulation**

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2050079-00006	Date of last issue: 13.09.2019 Date of first issue: 07.10.2017
IA	ΓΑ	: Environmentall (betamethason	y hazardous substance, liquid, n.o.s. e)
14.3 Tra	ansport hazard class(es)		
AD	N	: 9	
AD	R	: 9	
RI	ס	: 9	
IM	DG	: 9	
IA	ГА	: 9	
14.4 Pa	cking group		
Cla Ha	N cking group assification Code zard Identification Number bels	: III : M6 : 90 : 9	
Cla Ha Lal	<b>PR</b> cking group assification Code zard Identification Number bels nnel restriction code	: III : M6 : 90 : 9 : (-)	
Cla Ha	D cking group assification Code zard Identification Number bels	: III : M6 : 90 : 9	
Pa Lal	<b>DG</b> cking group bels iS Code	: III : 9 : F-A, S-F	
Pa aire Pa Pa	<b>FA (Cargo)</b> cking instruction (cargo craft) cking instruction (LQ) cking group bels	: 964 : Y964 : III : Miscellaneous	
Pa gei Pa Pa	<b>FA (Passenger)</b> cking instruction (passen- r aircraft) cking instruction (LQ) cking group bels	: 964 : Y964 : III : Miscellaneous	

### 14.5 Environmental hazards

### ADN



## **Betamethasone Liquid Formulation**

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2050079-00006	Date of last issue: 13.09.2019 Date of first issue: 07.10.2017
Envir	onmentally hazardous	: yes	
<b>ADR</b> Envir	onmentally hazardous	: yes	
<b>RID</b> Envir	onmentally hazardous	: yes	
IMDO Marir	<b>B</b> ne pollutant	: yes	
	(Passenger) onmentally hazardous	: yes	
	(Cargo) onmentally hazardous	: yes	

### 14.6 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.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

: Not applicable for product as supplied.

### **SECTION 15: Regulatory information**

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) Regulation on Persistent Organic Pollutants (Number				striction for the fol- nould be considered:
30595)	ganic Foliatants (Number	·		
Regulation on prevention of	f major industrial accidents. Re	eg r	umber 30702	
		-	Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS		100 t	200 t

### Other regulations:

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I". Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry. Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

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

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

## SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Betamethasone Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
2.3	23.03.2020	2050079-00006	Date of first issue: 07.10.2017

### **SECTION 16: Other information**

Other information	:	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 H-Statements		
H301	:	Toxic if swallowed.
H311	:	Toxic in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H318	:	Causes serious eve damage.

H318	:	Causes serious eye damage.
H330	:	Fatal if inhaled.
H360D	:	May damage the unborn child.
H372	:	Causes damage to organs through prolonged or repeated
		exposure.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H411	:	Toxic to aquatic life with long lasting effects.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

#### Full text of other abbreviations

Acute Tox. :	Acute toxicity
Aquatic Acute :	Short-term (acute) aquatic hazard
Aquatic Chronic :	Long-term (chronic) aquatic hazard
Eye Dam. :	Serious eye damage
Repr. :	Reproductive toxicity
Skin Corr. :	Skin corrosion
STOT RE :	Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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



## Betamethasone Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
2.3	23.03.2020	2050079-00006	Date of first issue: 07.10.2017

Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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

### Further information

Aquatic Chronic 1

Sources of key data used t compile the Safety Data Sheet	o :	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/	
Classification of the mixt	ure:		Classification procedure:
Repr. 1B	H3	60D	Calculation method
STOT RE 1	H3	72	Calculation method

Calculation method

H410

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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