Commission Regulation (EU) 2020/878



# **Dexamethasone (0.28%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.12.2023
3.0	06.04.2024	5498620-00012	Date of first issue: 10.03.2020

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

**DEXADRESON INJECTION (52298)** 

# **1.1 Product identifier** Trade name : Dexamethasone (0.28%) Formulation Other means of identification : Dexadreson (A001421)

## 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- stance/Mixture	:	Veterinary product
Recommended restrictions on use	:	Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company	:	MSD Kilsheelan Clonmel Tipperary, IE
Telephone	:	353-51-601000
E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

## **1.4 Emergency telephone number**

+1-908-423-6000

## **SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Long-term (chronic) aquatic hazard, Cat-	H412: Harmful to aquatic life with long lasting ef-
egory 3	fects.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)						
Hazard statements	:	H412	Harmful to aquatic life with long lasting effects.			
Precautionary statements	:	<b>Preve</b> P273	<b>ntion:</b> Avoid release to the environment.			



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#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319 Acute toxicity esti- mate Acute oral toxicity: 1.620 mg/kg	>= 1 - < 10
Dexamethasone	50-02-2 200-003-9	Repr. 1B; H360D STOT RE 2; H373 (Adrenal gland, Immune system, thymus gland) Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1	>= 0,25 - < 0,3

For explanation of abbreviations see section 16.

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

#### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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		vice immedia When sympt advice.	ately. toms persist or in all cases of doubt seek medical		
Protection of first-aiders		and use the	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).		
lf inha	aled	: If inhaled, re Get medical	move to fresh air. attention.		
In cas	se of skin contact	of water. Remove cor Get medical Wash clothir	ontact, immediately flush skin with soap and plenty ntaminated clothing and shoes. attention. ng before reuse. clean shoes before reuse.		
In cas	e of eye contact : Flush eyes with water as a preca Get medical attention if irritation		vith water as a precaution. attention if irritation develops and persists.		
lf swa	If swallowed		If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.		
	mportant symptoms known.	and effects, both	acute and delayed		
4.3 Indica	tion of any immediat	e medical attentio	n and special treatment needed		
Treat	-		omatically and supportively.		
SECTION	1 5: Firefighting me	asures			
5.1 Exting	uishing media				

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2)
		Dry chemical

Unsuitable extinguishing	:	None known.
media		

# 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Metal oxides



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5.3 Advice	for firefighters			
	al protective equipment fighters	:		e, wear self-contained breathing apparatus. tective equipment.
Specific extinguishing meth- ods		:	: Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to c so. Evacuate area.	

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

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

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so.

Environmental precautions	:	Avoid release to the environment.
		Prevent further leakage or spillage if safe to do so.
		Prevent spreading over a wide area (e.g. by containment or oil
		barriers).
		Retain and dispose of contaminated wash water.
		Local authorities should be advised if significant spillages
		cannot be contained.

#### 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.

## 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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3.0     06.04.2024     8       Local/Total ventilation       Advice on safe handling       Hygiene measures		<ul> <li>If sufficient ventilation is unavailable, use with local exh ventilation.</li> <li>Do not get on skin or clothing.</li> <li>Do not breathe vapours or spray mist.</li> <li>Do not swallow.</li> <li>Avoid contact with eyes.</li> <li>Handle in accordance with good industrial hygiene and practice, based on the results of the workplace exposur sessment</li> <li>Keep container tightly closed.</li> <li>Take care to prevent spills, waste and minimize release environment.</li> <li>If exposure to chemical is likely during typical use, prov flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash compared to the set of the set</li></ul>				
		The effective ope engineering cont appropriate dego industrial hygiene	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 Con	7.2 Conditions for safe storage, including any incompatibilities					
	uirements for storage as and containers		labelled containers. Keep tightly closed. nce with the particular national regulations.			
Adv	ice on common storage	: Do not store with Strong oxidizing	a the following product types: agents			

Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides

#### Explosives Gases

## 7.3 Specific end use(s)

Specific use(s) : No data available

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

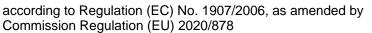
## 8.1 Control parameters

## Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
Dexamethasone	50-02-2	TWA	10 µg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	100 μg/100 cm²	Internal	

## Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
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Benzy	yl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
		Workers	Inhalation	Acute systemic ef- fects	110 mg/m3
		Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
		Workers	Skin contact	Acute systemic ef- fects	40 mg/kg bw/day
		Consumers	Inhalation	Long-term systemic effects	5,4 mg/m3
		Consumers	Inhalation	Acute systemic ef- fects	27 mg/m3
		Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
		Consumers	Skin contact	Acute systemic ef- fects	20 mg/kg bw/day
		Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
		Consumers	Ingestion	Acute systemic ef- fects	20 mg/kg bw/day

# Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	2,3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5,27 mg/kg
	Marine sediment	0,527 mg/kg
	Soil	0,456 mg/kg

# 8.2 Exposure controls

## **Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

## Personal protective equipment

Eye/face 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



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	Remarks : Skin and body protection :		le gloving. or laboratory coat. y garments should be used based upon the task ed (e.g., sleevelets, apron, gauntlets, disposable exposed skin surfaces. te degowning techniques to remove potentially clothing		
	ratory protection ter type	: If adequate loc sure assessme ommended gu Equipment sho	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 NS EN 14387 Combined particulates and organic vapour type (A-P)		

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

## 9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available
Viscosity Viscosity, kinematic	:	No data available

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		lity(ies) ter solubility	:	No data available	e	
	Partition coefficient: n- octanol/water		:	Not applicable		
	Vapou	r pressure	:	No data available	e	
	Relative density		:	No data available	e	
	Density		:	: No data available		
	Relative vapour density		:	No data available	e	
		e characteristics ticle size	:	Not applicable		
9.2		nformation				
	Explos	ives	:	Not explosive		
	Oxidizi	ing properties	:	The substance c	r mixture is not classified as oxidizing.	
	Evapo	ration rate	:	No data available	e	
	Molecu	ular weight	:	No data availabl	e	

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

## 10.1 Reactivity

Not classified as a reactivity hazard.

# 10.2 Chemical stability

Stable under normal conditions.

0.3 Possibility of hazardous reactions					
Hazardous reactions	:	Can react with strong oxidizing agents.			

# 10.4 Conditions to avoid

Conditions to avoid : None known.

## 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

## 10.6 Hazardous decomposition products

No hazardous decomposition products are known.



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## **SECTION 11: Toxicological information**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 Information on likely routes of : Inhalation exposure Skin contact Ingestion Eye contact Acute toxicity Not classified based on available information. **Product:** : Acute toxicity estimate: > 2.000 mg/kg Acute oral toxicity Method: Calculation method Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method Components: **Benzyl alcohol:** Acute oral toxicity : LD50 (Rat): 1.620 mg/kg Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 **Dexamethasone:** LD50 (Rat): > 2.000 mg/kg Acute oral toxicity : LD50 (Mouse): > 6.500 mg/kg Acute toxicity (other routes of : LD50 (Rat): 14 mg/kg administration) **Application Route: Subcutaneous** Skin corrosion/irritation Not classified based on available information. **Components: Benzyl alcohol:** Species : Rabbit Method : OECD Test Guideline 404 Result • No skin irritation **Dexamethasone:** Species Rabbit :

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ersion .0	Revision Date: 06.04.2024		98620-00012	Date of last issue: 14.12.2023 Date of first issue: 10.03.2020
Resu	lt	:	Mild skin irritatio	n
	us eye damage/eye			
	lassified based on ava	ailable	information.	
Comp	oonents:			
	yl alcohol:		5.1.1	
Speci Metho		:	Rabbit OECD Test Guid	deline 405
Resu		:		, reversing within 21 days
	methasone:			
Speci Resul		:	Rabbit Mild eye irritation	n
			-	
Resp	iratory or skin sensi	itisatic	n	
-	sensitisation lassified based on ava	ailable	information.	
Resp	iratory sensitisation	1		
Not cl	lassified based on ava	ailable	information.	
<u>Comp</u>	oonents:			
Benz	yl alcohol:			
Test	-	:	Maximisation Te	st
Expos	sure routes	:	Skin contact	
Speci Metho		:	Guinea pig OECD Test Guid	deline 106
Resul	lt	:	negative	
Germ	cell mutagenicity			
	lassified based on ava	ailable	information.	
Com	oonents:			
Benz	yl alcohol:			
	toxicity in vitro	:	Test Type: Bactor Result: negative	erial reverse mutation assay (AMES)
Geno	toxicity in vivo	:	cytogenetic assa Species: Mouse	e: Intraperitoneal injection

## Dexamethasone:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES)
		Result: negative

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			Test Type: in vitro Test system: mou Result: negative	o assay ise lymphoma cells
Ger	notoxicity in vivo	:	Test Type: Micron Species: Mouse Application Route Result: negative	
Car	cinogenicity			
Not	classified based on avai	lable	information.	
<u>Co</u>	mponents:			
	nzyl alcohol:			
App Exp	ecies blication Route posure time	:	Mouse Ingestion 103 weeks	
Res	thod sult	:	OECD Test Guidenegative	eine 451
Not <u>Cor</u>	productive toxicity classified based on avail mponents: nzyl alcohol:	lable	information.	
Effe	ects on fertility	:	Species: Rat Application Route Result: negative	y/early embryonic development e: Ingestion on data from similar materials
Effe mei	ects on foetal develop- nt	:	Test Type: Embry Species: Mouse Application Route Result: negative	vo-foetal development e: Ingestion
Dex	kamethasone:			
Effe mei	ects on foetal develop- nt	:		
				e: Intramuscular oxicity: NOAEL: 0,025 mg/kg body weight levelopmental abnormalities
			Species: Rabbit	
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		Developm	n Route: Intramuscular ental Toxicity: LOAEL: >= 0,062 mg/kg body weight pecific developmental abnormalities
		Developm	Rat n Route: Subcutaneous ental Toxicity: LOAEL: >= 0,02 mg/kg body weight celetal and visceral variations, Retardations
	productive toxicity - As- ssment	: May dama	age the unborn child.
	<b>OT - single exposure</b> t classified based on availa	able informatior	I.
	OT - repeated exposure		
	t classified based on availa mponents:	able information	l.
De	xamethasone:		
Та	posure routes rget Organs sessment		and, Immune system, thymus gland e damage to organs through prolonged or repeated
Re	peated dose toxicity		
<u>Co</u>	mponents:		
	nzyl alcohol:		
	ecies DAEL	: Rat : 1,072 mg	1
	plication Route		(dust/mist/fume)
	posure time thod	: 28 Days : OECD Te	st Guideline 412
De	xamethasone:		
	ecies	: Rat	
	OAEL plication Route	: 0,0015 m : Oral	g/kg
	posure time	: 7 d	
	rget Organs marks	: Liver : Significan	t toxicity observed in testing
Sp	ecies	: Rat	
	AEL	: 0,003 mg	kg
	plication Route	: Oral : 90 d	
	rget Organs		renal gland, thymus gland
Re	marks		t toxicity observed in testing
Sp	ecies	: Rat	

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Expo	cation Route sure time et Organs	: C : 6 : A	0,125 mg/kg Dral 6 Weeks Adrenal gland 6ignificant toxici	ty observed in testing
Expos	EL cation Route sure time et Organs	: C : C : 3	Rat 0,4 mg/kg Dral 3 Months mmune system Bignificant toxici	ty observed in testing
Expos	EL cation Route sure time et Organs	: 8 : 0 : 3	Dog 3 mg/kg Dral 3 Months mmune system Significant toxicir	ty observed in testing

## Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

## Endocrine disrupting properties

## Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## Experience with human exposure

#### **Components:**

#### Dexamethasone:

Ingestion

Target Organs: Immune system Target Organs: Adrenal gland Target Organs: Bone Symptoms: muscle weakness

## **SECTION 12: Ecological information**

#### 12.1 Toxicity

Components:

## Benzyl alcohol:

Toxicity to fish

: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

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			Exposure time: 96	5 h
	/ to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
Toxicity plants	y to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD Te	
			NOEC (Pseudokir mg/l Exposure time: 72 Method: OECD Te	
	invertebrates (Chron-	:	NOEC: 51 mg/l Exposure time: 21 Species: Daphnia Method: OECD Te	magna (Water flea)
Dexam	ethasone:			
	y to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
Toxicity plants	y to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD Te	
			NOEC (Pseudokir mg/l Exposure time: 72 Method: OECD Te	
Toxicity	y to microorganisms	:	EC50 : > 1.000 m Exposure time: 3 Test Type: Respir Method: OECD Te	h ation inhibition
			NOEC : 1.000 mg Exposure time: 3 Test Type: Respir Method: OECD Te	h ation inhibition
Toxicity icity)	y to fish (Chronic tox-	:	NOEC: 0,033 mg/ Exposure time: 32 Species: Pimepha Method: OECD Te	? d Iles promelas (fathead minnow)
M-Fact	or (Chronic aquatic	:	1	



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Exposure time: 3,54 d

Method: OECD Test Guideline 314

# toxicity)

## 12.2 Persistence and degradability

## **Benzyl alcohol:**

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d
Dexamethasone:		
Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 50 %

## 12.3 Bioaccumulative potential

## **Components:**

Partition coefficient: n- octanol/water	:	log Pow: 1,05
Dexamethasone:		

Partition coefficient: n-	:	log Pow: 1,83
octanol/water		-

## 12.4 Mobility in soil

No data available

## 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 12.6 Endocrine disrupting properties

Product:	
Assessment	: The substance/mixture does not contain components consid- ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.



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## **SECTION 13: Disposal considerations**

13.1 Waste treatment methods	
Product	<ul> <li>Dispose of in accordance with local regulations.</li> <li>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.</li> <li>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.</li> <li>Do not dispose of waste into sewer.</li> </ul>
Contaminated packaging	<ul> <li>Empty containers should be taken to an approved waste han- dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>

## **SECTION 14: Transport information**

14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.4 Packing group		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good



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	Cargo) Passonger)	:		a dangerous good
IATA (Passenger) : Not regulated as a dangerous good 14.5 Environmental hazards Not regulated as a dangerous good				
14.6 Special precautions for user Not applicable				
14.7 Maritime transport in bulk according to IMO instruments				
Remar	ks	:	Not applicable for	product as supplied.

## **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Conditions of restriction for the fol- lowing entries should be considered: Number on list 75, 3 Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not. If you intend to use this product as tattoo ink, please contact your ven-
		dor.
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parlian major-accident hazards involving dangerous substances. Not applicable		t and of the Council on the control of

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

AICS

: not determined



# **Dexamethasone (0.28%) Formulation**

Version 3.0	Revision Date: 06.04.2024		te of last issue: 14.12.2023 te of first issue: 10.03.2020
DSL		not determined	
IECS	C	not determined	
	nical safety assessme al Safety Assessment ha	ot been carried out.	
SECTION	16: Other informati		
Other	information		have been made to the previous version body of this document by two vertical
Full to	ext of H-Statements		
H302 H319 H332 H360 H373	D	Harmful if swallowed. Causes serious eye in Harmful if inhaled. May damage the unbo May cause damage to exposure if swallowed	orn child. o organs through prolonged or repeated
H410		•	fe with long lasting effects.
Full to	ext of other abbreviati	5	
Acute Aquat Eye Ir Repr. STOT	ic Chronic rit.	Acute toxicity Long-term (chronic) ac Eye irritation Reproductive toxicity Specific target organ t	quatic hazard oxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; 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 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



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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; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

#### Further information

Sources of key data used to :	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data	eChem Portal search results and European Chemicals Agen-
Sheet	cy, http://echa.europa.eu/

**Classification procedure:** 

Calculation method

#### **Classification of the mixture:**

Aquatic Chronic 3 H412

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

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.

NO / EN