

Version 2.1	Revision Date: 30.09.2023		S Number: 40884-00013	Date of last issue: 04.04.2023 Date of first issue: 23.02.2018	
SECTION	1. IDENTIFICATION				
Produ	Product name		Dexamethasone Solid Formulation		
Manu	afacturer or supplier's	s deta	ils		
Comp	Company		MSD		
Addre	Address		Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP		
Telep	Telephone		908-740-4000		
Emer	Emergency telephone		1-908-423-6000		
E-ma	E-mail address		EHSDATASTEWARD@msd.com		
Reco	mmended use of the	chem	ical and restriction	ons on use	
	mmended use ictions on use	:	Veterinary produ Not applicable	ict	

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Long-term (chronic) aquatic : hazard	Category 3
GHS label elements Hazard Statements :	H412 Harmful to aquatic life with long lasting effects.
Precautionary Statements :	Prevention: P273 Avoid release to the environment.
	Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture		
Components				
Chemical name			CAS-No.	Concentration (% w/w)



Hazardous combustion prod- :

ucts

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Stard	ch		9005-25-8	>= 30 -< 50			
	amethasone		50-02-2	>= 0,25 -< 0,3			
SECTION	I 4. FIRST AID MEASUF	RES					
Gene	eral advice	advice immed	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.				
lf inh	aled		nove to fresh air.				
In ca	se of skin contact	 Get medical attention. In case of contact, immediately flush skin with soap and ple of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. 					
In ca	se of eye contact		se well with water.	develope and paraiete			
lf sw	allowed	: If swallowed, Get medical a	 Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. 				
	important symptoms effects, both acute and ved	: Contact with the skin.					
	ection of first-aiders	: First Aid resp and use the r	 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). 				
Note	s to physician		matically and suppo				
SECTION	I 5. FIRE-FIGHTING ME	ASURES					
	able extinguishing media	Alcohol-resist Carbon dioxid Dry chemical	de (CO2)				
Unsu medi	uitable extinguishing	: None known.					
	cific hazards during fire	concentration	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a				

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 do
		Remove undamaged containers from fire area if it is safe to do

Carbon oxides

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

so. Evacuate area.

SAFETY DATA SHEET



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for fir	e-fighters		Use personal prot	ective equipment.	
SECTION	6. ACCIDENTAL RELE	AS	E MEASURES		
tive e	Personal precautions, protec- tive equipment and emer- gency procedures		: Use personal protective equipment. Follow safe handling advice (see section 7) and persona protective equipment recommendations (see section 8).		
Envir	onmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages	
	Methods and materials for containment and cleaning up		container for disper Avoid dispersal of with compressed Dust deposits sho surfaces, as these released into the Local or national in disposal of this m employed in the c determine which in Sections 13 and 1	dust in the air (i.e., clearing dust surfaces	

SECTION 7. HANDLING AND STORAGE

Technical measures	using an explosi ovide adequate	ay accumulate and ignite suspended dust on. precautions, such as electrical grounding ert atmospheres.
Local/Total ventilation	•	ion is unavailable, use with local exhaust
Advice on safe handling	o not get on skin o not breathe dus o not swallow. void contact with andle in accordan actice, based on seessment eep container tigl inimize dust gene eep container clo eep away from he ake precautionar	eyes. hee with good industrial hygiene and safety the results of the workplace exposure
Conditions for safe storage	ep tightly closed	beled containers. I. e with the particular national regulations.
Materials to avoid		ne following product types:



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		Strong oxidizing Self-reactive su Organic peroxic Explosives Gases	ubstances and mixtures

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis			
Starch	9005-25-8		10 mg/m ³	AR OEL			
			classifiable as a huma				
		TWA	10 mg/m ³	ACGIH			
Dexamethasone	50-02-2	TWA	10 µg/m3 (OEB 3)	Internal			
		formation: Skin	1 0 µg, (0 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0				
		Wipe limit	100 µg/100 cm ²	Internal			
ingineering measures : All engineering controls should be implemented by fadesign and operated in accordance with GMP princip protect products, workers, and the environment. Containment technologies suitable for controlling con are required to control at source and to prevent migrathe compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.							
Personal protective equipn							
Respiratory protection	exposure	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.					
Filter type Hand protection		Particulates type					
Material	: Chemica	Chemical-resistant gloves					
Remarks Eye protection	: Wear sat If the wo mists or Wear a f	Consider double gloving. 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.					
Skin and body protection	: Work un Additiona task beir disposat Use app contamir	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 contaminated clothing.					
Hygiene measures	: If exposu eye flush	contaminated clothing. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place					

working place.



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			Wash contaminat The effective ope engineering contr appropriate degov	ot eat, drink or smoke. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, wning and decontamination procedures, monitoring, medical surveillance and the tive controls.
ECTION	9. PHYSICAL AND CH	EMIC	CAL PROPERTIES	S
Appe	arance	:	powder	
Color		:	white	
Odor		:	No data available	9
Odor	Threshold	:	No data available	9
рН		:	No data available	9
Meltir	ng point/freezing point	:	No data available	9
Initial range	boiling point and boiling	:	No data available	9
Flash	point	:	Not applicable	
Evap	oration rate	:	Not applicable	
Flam	mability (solid, gas)	:	May form explos handling or other	ive dust-air mixture during processing, means.
Flam	mability (liquids)	:	No data available	9
	r explosion limit / Upper nability limit	:	No data available	2
	r explosion limit / Lower nability limit	:	No data available	9
Vapo	r pressure	:	Not applicable	
Relat	ive vapor density	:	Not applicable	
Relat	ive density	:	No data available	9
Dens	ity	:	No data available	e
	bility(ies) ater solubility	:	No data available	e
	ion coefficient: n-	:	Not applicable	
	ol/water gnition temperature	:	No data available	9



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Decor	nposition temperature	:	No data available	e
	sity cosity, kinematic sive properties	:	Not applicable Not explosive	
Oxidizing properties Molecular weight Particle size		: : :	The substance o No data available No data available	-

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	Stable ur May form handling	ified as a reactivity hazard. nder normal conditions. n explosive dust-air mixture during processing, or other means. t with strong oxidizing agents.
Conditions to avoid		nes and sparks. st formation.
Incompatible materials	Oxidizing	agents
Hazardous decomposition products		dous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact
		Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Starch:

Acute oral toxicity	:	LD50 (Rat): > 5.000 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 2.000 mg/kg
Dexamethasone:		
Acute oral toxicity	:	LD50 (Rat): > 2.000 mg/kg
		LD50 (Mouse): > 6.500 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 14 mg/kg Application Route: Subcutaneous





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Skin c	corrosion/irritation			
Not cla	assified based on ava	ailable	information.	
<u>Comp</u>	onents:			
Dexar	methasone:			
Specie Result		:	Rabbit Mild skin irritation	
	us eye damage/eye	irritati		
	assified based on ava			
<u>Comp</u>	onents:			
Starch	h:			
Specie	es	:	Rabbit	
Result	t	:	No eye irritation	
Dexar	nethasone:			
Specie		:	Rabbit	
Result	t	:	Mild eye irritation	
Respi	ratory or skin sensi	tizatio	n	
Skin s	sensitization			
Not cla	assified based on ava	ailable	information.	
	ratory sensitization			
Not cla	assified based on ava	ailable	information.	
Comn	onents:			
<u>comp</u>				
Starch				
Starch Test T	h: ype	:	Maximization Tes	t
Starch Test T Route	h: ype s of exposure	:	Skin contact	t
Starch Test T	h: ype s of exposure es	:		t
Starch Test T Route Specie Result	h: ype s of exposure es t	:	Skin contact Guinea pig	t
Starch Test T Route Specie Result	h: ype s of exposure es	:	Skin contact Guinea pig negative	t
Starch Test T Route Specie Result Germ Not cla	h: Type s of exposure es t cell mutagenicity	:	Skin contact Guinea pig negative	t
Starch Test T Route Specie Result Germ Not cla	h: ype s of exposure es t cell mutagenicity assified based on ava conents:	:	Skin contact Guinea pig negative	t
Starch Test T Route Specie Result Germ Not cla <u>Comp</u> Starch	h: ype s of exposure es t cell mutagenicity assified based on ava conents:	:	Skin contact Guinea pig negative information. Test Type: Bacter	t rial reverse mutation assay (AMES)
Starcl Test T Route Specie Result Germ Not cla Comp Starcl	h: Type s of exposure es t cell mutagenicity assified based on ava ponents: h:	:	Skin contact Guinea pig negative information.	
Starci Test T Route Specie Result Germ Not cla Comp Starci Genot	h: Type s of exposure es t cell mutagenicity assified based on ava ponents: h:	:	Skin contact Guinea pig negative information. Test Type: Bacter	
Starch Test T Route Specie Result Germ Not cla Comp Starch Genot	h: Type s of exposure es t cell mutagenicity assified based on ava conents: h: coxicity in vitro	:	Skin contact Guinea pig negative information. Test Type: Bacter Result: negative	



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				Result: negative	
	Genoto	oxicity in vivo	:	Test Type: Micror Species: Mouse Application Route Result: negative	
		ogenicity ssified based on availa	ıble	information.	
	-	ductive toxicity ssified based on availa	ble	information.	
	Compo	onents:			
		ethasone: on fetal development	:		
				•	: Intramuscular oxicity: NOAEL: 0,025 mg/kg body weight evelopmental abnormalities.
					: Intramuscular oxicity: LOAEL: >= 0,062 mg/kg body weight evelopmental abnormalities.
				•	: Subcutaneous oxicity: LOAEL: >= 0,02 mg/kg body weight nd visceral variations ., Retardations.
	Reprod sessme	luctive toxicity - As- ent	:	May damage the	unborn child.
		single exposure ssified based on availa	ble	information.	
		repeated exposure ssified based on availa	ble	information.	
	Compo	onents:			
		ethasone:			
		of exposure Organs ment	:		mune system, thymus gland ge to organs through prolonged or repeated



Versi 2.1	on	Revision Date: 30.09.2023	DS Number: 40884-00013	Date of last issue: 04.04.2023 Date of first issue: 23.02.2018
I	Repeat	ed dose toxicity		
<u>(</u>	Compo	onents:		
	Starch	-		
1 / E		- tion Route ire time	 Rat >= 2.000 mg/kg Skin contact 28 Days OECD Test Guide	line 410
I	Dexam	ethasone:		
1 / E	Exposu	- tion Route ire time Organs	 Rat 0,0015 mg/kg Oral 7 d Liver Significant toxicity	observed in testing
L / E	Exposu	tion Route ire time Organs		and, thymus gland observed in testing
L / E	Exposu	tion Route ire time Organs	 Rat 0,125 mg/kg Oral 6 Weeks Adrenal gland Significant toxicity	observed in testing
L / E	Exposu	tion Route ire time Organs	 Rat 0,4 mg/kg Oral 3 Months Immune system Significant toxicity	observed in testing
L / E	Exposu	tion Route ire time Organs	 Dog 8 mg/kg Oral 3 Months Immune system Significant toxicity	observed in testing
	Asnira	tion toxicity		

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Dexamethasone:



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Ingestion		: Target Organs: Immune system Target Organs: Adrenal gland Target Organs: Bone Symptoms: muscle weakness		
CTION 1	2. ECOLOGICAL INFO	ORN	IATION	
Ecoto	xicity			
Comp	onents:			
Dexan	nethasone:			
	y to daphnia and other c invertebrates	:	Exposure time: 4	nagna (Water flea)): > 56 mg/l 8 h est Guideline 202
Toxicit plants	y to algae/aquatic	:	mg/l Exposure time: 7	chneriella subcapitata (green algae)): > 9,2 2 h est Guideline 201
			mg/l Exposure time: 7	rchneriella subcapitata (green algae)): 9,2 2 h est Guideline 201
Toxicit icity)	y to fish (Chronic tox-	:	Exposure time: 3	es promelas (fathead minnow)): 0,033 mg, 2 d est Guideline 210
	tor (Chronic aquatic	:	1	
toxicity Toxicit	y to microorganisms	:	EC50: > 1.000 m Exposure time: 3 Test Type: Respi Method: OECD T	ĥ
			NOEC: 1.000 mg Exposure time: 3 Test Type: Respi Method: OECD T	h
Persis	tence and degradabil	ity		
Comp	onents:			
	nethasone: gradability	:	Result: Not readi Biodegradation: Exposure time: 3 Method: OECD T	50 %



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Bioa	occumulative potential				
Com	ponents:				
Dexa	amethasone:				
	tion coefficient: n- nol/water	: log Pow: 1,83			
	ility in soil lata available				
	er adverse effects lata available				
SECTION	13. DISPOSAL CONS	DERATIONS			
-	osal methods				
Was	te from residues		of waste into sewer.		
Cont	aminated 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 INFO	ORMATION	-		
Inter	national Regulations				
• • • • • •	TDG regulated as a dangerou	s good			
	A-DGR regulated as a dangerou	s good			
	G-Code regulated as a dangerou	s good			
	applicable for product as	-	POL 73/78 and the IBC Code		
-	cial precautions for use applicable	er			
SECTION	15. REGULATORY IN	FORMATION			
Safe mixt		nental regulations/le	gislation specific for the substance or		
Arge Regi	ntina. Carcinogenic Sub stry.	stances and Agents	: Not applicable		
	trol of precursors and est aration of drugs.	sential chemicals for th	ne : Not applicable		

The ingredients of this product are reported in the following inventories: AICS : not determined



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DSL		:	not determined	
IECS	SC	:	not determined	
SECTION	I 16. OTHER INFORMA	ΓΙΟΙ	N	
-	sion Date format	:	30.09.2023 dd.mm.yyyy	
Furt	her information			
com	ces of key data used to bile the Material Safety Sheet	:		data, data from raw material SDSs, OECD arch results and European Chemicals Agen- ropa.eu/
Full	text of other abbreviati	ons		
ACG AR C		:		eshold Limit Values (TLV) ational Exposure Limits
	IH / TWA DEL / CMP	:	8-hour, time-weig TLV (Threshold L	
Lanc Carc Stan x% r ENC x% g tem; - Int Equi centr cal S Marit ganis centr Letha n.o.s Conc	I of Brazil; ASTM - America inogen, Mutagen or Re- dardisation; DSL - Domer- response; ELx - Loading S - Existing and New C growth rate response; EF GLP - Good Laboratory ernational Air Transport pment of Ships carrying ration; ICAO - Internation Substances in China; IM time Organization; ISHL sation for Standardizatio ration to 50 % of a test p al Dose); MARPOL - In s Not Otherwise Specific centration; NO(A)EL - Not	ricar pro- pro- stic pra- (G - Pra- (C - Pra- (C - Da (C - Da (C - (C	a Society for the T ductive Toxicant; Substances List (C e associated with ical Substances (Emergency Respo- ctice; IARC - Intern sociation; IBC - I ngerous Chemicals Civil Aviation Orgar - International Ma dustrial Safety and ECI - Korea Exist ilation; LD50 - Letta ational Conventior Nch - Chilean Noi oserved (Adverse)	s; ANTT - National Agency for Transport by esting of Materials; bw - Body weight; CMR - DIN - Standard of the German Institute for Canada); ECx - Concentration associated with x% response; EmS - Emergency Schedule; Japan); ErCx - Concentration associated with onse Guide; GHS - Globally Harmonized Sys- ational Agency for Research on Cancer; IATA nternational Code for the Construction and s in Bulk; IC50 - Half maximal inhibitory con- tization; IECSC - Inventory of Existing Chemi- ritime Dangerous Goods; IMO - International d Health Law (Japan); ISO - International Or- ing Chemicals Inventory; LC50 - Lethal Con- nal Dose to 50% of a test population (Median of or the Prevention of Pollution from Ships; m; NO(A)EC - No Observed (Adverse) Effect Effect Level; NOELR - No Observable Effect - National Toxicology Program; NZIoC - New

Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System



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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 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.

AR / Z8