

Vers 2.1	ion	Revision Date: 2023/09/30		S Number: 3219-00013	Date of last issue: 2023/04/04 Date of first issue: 2018/02/23				
1. PI	1. PRODUCT AND COMPANY IDENTIFICATION								
	Produc	t name	:	Dexamethasone	Solid Formulation				
	Manufa	acturer or supplier's c	letai	ls					
	Compa	ny	:	MSD					
	Address		:		venue ersey U.S.A. 07065				
	Teleph	one	:	908-740-4000					
	Emerge	ency telephone number	r:	1-908-423-6000					
	E-mail	address	:	EHSDATASTEW	/ARD@msd.com				
	Recom	mended use of the cl	nem	ical and restriction	ons on use				
		mended use tions on use	:	Veterinary produ Not applicable	ct				

2. HAZARDS IDENTIFICATION

GHS Classification Long-term (chronic) aquatic hazard	:	Category 3
GHS label elements		
Hazard pictograms Signal word Hazard statements	::	None None 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS



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Subst	tance / Mixture	: Mixture				
Com	ponents					
Cherr	nical name		CAS-No.	Concentration (% w/w)		
Starc	h		9005-25-8	>= 30 -< 60		
Dexa	methasone		50-02-2	>= 0.25 -< 0.3		
FIRST	AID MEASURES					
Gene	eral advice	vice immedia	tely.	feel unwell, seek medical ad- I cases of doubt seek medical		
lf inha	aled	: If inhaled, rer Get medical a	nove to fresh air. attention.			
In cas	se of skin contact	of water. Remove cont Get medical a Wash clothing	aminated clothing			
In cas	se of eye contact	 If in eyes, rinse well with water. Get medical attention if irritation develops and persists. 				
lf swa	allowed	: If swallowed, Get medical a	DO NOT induce v	omiting.		
Most	important symptoms effects, both acute and	the skin.		echanical irritation or drying of lead to mechanical irritation.		
and e	ner					
and e delay	ed ction of first-aiders	: First Aid resp and use the r	onders should pay ecommended pers	attention to self-protection, sonal protective equipment exists (see section 8).		

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire- fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides
Specific extinguishing meth-	:	Use extinguishing measures that are appropriate to local cir-



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ods			Use water spray t	the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do
	cial protective equipment refighters	:		e, wear self-contained breathing apparatus. tective equipment.
6. ACCID	ENTAL RELEASE MEA	SUI	RES	
tive	onal precautions, protec- equipment and emer- cy procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t recommendations (see section 8).
Envi	Environmental 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		Sweep up or vacuum up spillage and collect in suitable tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surf with compressed air). Dust deposits should not be allowed to accumulate on es, as these may form an explosive mixture if they are leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and posal of this material, as well as those materials and its employed in the cleanup of releases. You will need to co mine which regulations are applicable. Sections 13 and 15 of this SDS provide information reg certain local or national requirements.	
7. HAND	LING AND STORAGE			
Tech	nnical measures	:	causing an explose Provide adequate and bonding, or ir	precautions, such as electrical grounding nert atmospheres.
1	Tatal vantilation		10 - 00 - 1	

Local/Total ventilation

Advice on safe handling : Do not get on skin or clothing.

ventilation.

- Do not breathe dust. Do not swallow.
 - 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 assessment

: If sufficient ventilation is unavailable, use with local exhaust

Keep container tightly closed.

Minimize dust generation and accumulation.

Keep container closed when not in use.



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 Take precautionar Take care to preve environment. Keep in properly la Keep tightly closed Store in accordance Do not store with t 	d. ce with the particular national regulations. he following product types:
	Keep away from h Take precautionar Take care to preve environment. Keep in properly la Keep tightly closed Store in accordance

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Starch	9005-25-8	NAB	10 mg/m3	ID OEL
		o classify these r	fied as carcinogenic t materials as carcinog	
		TWA	10 mg/m3	ACGIH
Dexamethasone	50-02-2	TWA	10 µg/m3 (OEB 3)	Internal
	Further inform	nation: Skin		
		Wipe limit	100 µg/100 cm ²	Internal

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. 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 con- tainment devices). Minimize open handling.
Personal protective equipme	ent	
Respiratory protection Filter type Hand protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type
Material	:	Chemical-resistant gloves
Remarks Eye protection	:	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.



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Skin and body protection		Additional bod task being per posable suits)	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially					
Hygiene measures		: If exposure to eye flushing sy ing place. When using do Wash contami The effective of engineering co appropriate de industrial hygie	chemical is likely during typical use, provide ystems and safety showers close to the work- o not eat, drink or smoke. nated clothing before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the strative controls.					
9. PHYSIC	AL AND CHEMICAL I	PROPERTIES						
Арреа	arance	: powder						

Appearance	•	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable



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R	Relative density		No data available	9
D	ensity	:	No data available	2
S	olubility(ies) Water solubility	:	No data available	9
	Partition coefficient: n- octanol/water		Not applicable	
-	uto-ignition temperature	:	No data available	9
D	ecomposition temperature	:	No data available	9
V	iscosity Viscosity, kinematic	:	Not applicable	
E	xplosive properties	:	Not explosive	
0	xidizing properties	:	The substance o	r mixture is not classified as oxidizing.
Μ	lolecular weight	:	No data available	9
P	article size	:	No data available	9

10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	: :	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Components:

Starch:



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Acute	oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg
Acute	e dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg
Dexa	methasone:			
Acute	oral toxicity	:	LD50 (Rat): > 2,0	00 mg/kg
			LD50 (Mouse): >	6,500 mg/kg
	toxicity (other routes of histration)	:	LD50 (Rat): 14 m Application Route	
Skin	corrosion/irritation			
	assified based on availa	ble	information.	
<u>Com</u>	oonents:			
	methasone:			
Speci Resu		÷	Rabbit Mild skin irritation	
	us eye damage/eye irri lassified based on availa			
Not c <u>Com</u> Starc Speci	lassified based on availa <u>conents:</u> h: es		information. Rabbit	
Not c <u>Com</u> Starc	lassified based on availa <u>conents:</u> h: es		information.	
Not c Com Starc Speci Resu	lassified based on availa <u>conents:</u> h: es it methasone:		information. Rabbit No eye irritation	
Not c <u>Com</u> Starc Speci Resu	lassified based on availa <u>conents:</u> h: es It methasone: es		information. Rabbit	
Not c <u>Com</u> Starc Speci Resu Dexa Speci Resu	lassified based on availa <u>conents:</u> h: es It methasone: es	ble : :	information. Rabbit No eye irritation Rabbit Mild eye irritation	
Not c Com Starc Speci Resu Dexa Speci Resu Resu	lassified based on availa <u>conents:</u> h: es it methasone: es it	ble : :	information. Rabbit No eye irritation Rabbit Mild eye irritation	
Not c Com Starc Speci Resu Dexa Speci Resu Resp Skin	lassified based on availa <u>conents:</u> h: es it methasone: es it iratory or skin sensitisa	ble : : atic	information. Rabbit No eye irritation Rabbit Mild eye irritation	
Not c Com Starc Speci Resu Dexa Speci Resu Resp Skin Not c Resp	lassified based on availa <u>conents:</u> h: es It methasone: es It iratory or skin sensitisa sensitisation lassified based on availa iratory sensitisation	ble : : atic	information. Rabbit No eye irritation Rabbit Mild eye irritation on information.	
Not c Com Starc Speci Resu Dexa Speci Resu Resu Skin Not c Resp Not c	lassified based on availa <u>conents:</u> h: es It methasone: es It iratory or skin sensitist sensitisation lassified based on availa iratory sensitisation lassified based on availa	ble : : atic	information. Rabbit No eye irritation Rabbit Mild eye irritation on information.	
Not c Com Starc Speci Resu Dexa Speci Resu Resu Resu Not c Resp Not c Com	lassified based on availa <u>conents:</u> h: es It methasone: es It iratory or skin sensitist sensitisation lassified based on availa iratory sensitisation lassified based on availa <u>conents:</u>	ble : : atic	information. Rabbit No eye irritation Rabbit Mild eye irritation on information.	
Not c Com Starc Speci Resu Dexa Speci Resu Resp Skin Not c Resp Not c Com	lassified based on availa <u>conents:</u> h: es It methasone: es t iratory or skin sensitisa sensitisation lassified based on availa iratory sensitisation lassified based on availa bonents: h:	ble : : atic	information. Rabbit No eye irritation Rabbit Mild eye irritation on information.	
Not c Com Starc Speci Resu Dexa Speci Resu Resu Resu Resu Resu Resu Not c Com Starc Starc	lassified based on availa <u>conents:</u> h: es it methasone: es it iratory or skin sensitisation lassified based on availation lassified based on availation based on availation	ble : : atic	information. Rabbit No eye irritation Rabbit Mild eye irritation on information. information.	t
Not c Com Starc Speci Resu Dexa Speci Resu Resu Resu Resu Resu Resu Not c Com Starc Starc	lassified based on availa <u>conents:</u> h: es it methasone: es it iratory or skin sensitisation lassified based on availa iratory sensitisation lassified based on availa <u>conents:</u> h: Type sure routes es	ble : : atic	information. Rabbit No eye irritation Rabbit Mild eye irritation on information.	t



ersion 1	Revision Date: 2023/09/30	SDS Num 2533219-		Date of last issue: 2023/04/04 Date of first issue: 2018/02/23
	n cell mutagenicity lassified based on ava	ilable informa	ation.	
Com	ponents:			
Starc	:h:			
Geno	toxicity in vitro		Гуре: Bacte lt: negative	rial reverse mutation assay (AMES)
Dexa	methasone:			
Geno	toxicity in vitro		Гуре: Bacte lt: negative	rial reverse mutation assay (AMES)
		Test s	Type: in vitro system: mou t: negative	o assay use lymphoma cells
Geno	toxicity in vivo	Speci Applic	Type: Micro es: Mouse cation Route It: negative	nucleus test e: Oral
	i nogenicity lassified based on ava	ilable informa	ation.	
-	oductive toxicity			
	lassified based on ava	ilable informa	ation.	
<u>Com</u>	ponents:			
	methasone:			
Effec ment	ts on foetal develop-	Speci Applic Devel	opmental T	opment e: Subcutaneous oxicity: LOAEL: 6 mg/kg body weight levelopmental abnormalities, Cleft palate
		Applic Devel	opmental T	e: Intramuscular oxicity: NOAEL: 0.025 mg/kg body weight levelopmental abnormalities
		Applic		e: Intramuscular oxicity: LOAEL: >= 0.062 mg/kg body weig
				levelopmental abnormalities



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Repro sessr	oductive toxicity - As- nent	: May damage th	e unborn child.
	- single exposure lassified based on avai	lable information.	
	- repeated exposure lassified based on avai		
Com	ponents:		
Expo Targe	methasone: sure routes et Organs ssment		Immune system, thymus gland hage to organs through prolonged or repeated
Repe	ated dose toxicity		
<u>Com</u>	ponents:		
	ies EL cation Route sure time	: Rat : >= 2,000 mg/kg : Skin contact : 28 Days : OECD Test Gu	
Dexa	methasone:		
Speci NOAI Applic Expos	ies EL cation Route sure time et Organs	: Rat : 0.0015 mg/kg : Oral : 7 d : Liver : Significant toxic	sity observed in testing
Expo	EL cation Route sure time et Organs		gland, thymus gland ity observed in testing
Expo	EL cation Route sure time et Organs	: Rat : 0.125 mg/kg : Oral : 6 Weeks : Adrenal gland : Significant toxic	sity observed in testing
Speci LOAE		: Rat : 0.4 mg/kg	



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	Exposi	ation Route ure time Organs ks	:	Oral 3 Months Immune system Significant toxicity	v observed in testing
	Exposi	- ation Route ure time Organs		Dog 8 mg/kg Oral 3 Months Immune system Significant toxicity	v observed in testing
	-	tion toxicity			
		ssified based on availa			
	Experience with human expo		osu	ire	
		onents:			
	Dexam Ingesti	nethasone: on	:	Target Organs: In Target Organs: Ad Target Organs: Bo Symptoms: muscl	drenal gland one
12. E	ECOLO	GICAL INFORMATION	N		
	Ecoto	kicity			
	Compo	onents:			
	Dexam	nethasone:			
		y to daphnia and other c invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
	Toxicit <u>y</u> plants	y to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD To	
				NOEC (Pseudokir mg/l Exposure time: 72 Method: OECD Te	
	Toxicity	y to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te	
	M-Fact toxicity	or (Chronic aquatic)	:	1	



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Toxic	ity to microorganisms	:		
			NOEC: 1,000 m Exposure time: 3 Test Type: Resp Method: OECD	
Persi	stence and degradabi	ility		
<u>Com</u>	ponents:			
Dexa	methasone:			
Biode	egradability	:	Biodegradation: Exposure time:	
Bioad	ccumulative potential			
Com	ponents:			
Partit	methasone: ion coefficient: n- ol/water	:	log Pow: 1.83	
	lity in soil ata available			
	r adverse effects ata available			
3. DISPC	SAL CONSIDERATIO	NS		
Dispo	osal methods			
-	e from residues	:		of waste into sewer.
Conta	aminated packaging	:	Empty container dling site for rec	cordance with local regulations. 's should be taken to an approved waste han- ycling or disposal. specified: Dispose of as unused product.
4. TRAN	SPORT INFORMATIO	N		
Interi	national Regulations			
	umber er shipping name	:	Not applicable Not applicable Not applicable	



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	ary risk g group	: Not applie	
Labels	9 9. ° ° P	: Not appli	
Class Subsidi Packing Labels Packing aircraft Packing	No. shipping name ary risk g group g instruction (cargo) g instruction (passen-	 Not applie 	cable cable cable cable cable cable
Class Subsidi Packing Labels EmS C	Code nber shipping name ary risk g group	 Not applie 	cable cable cable cable cable cable
	ort in bulk according		f MARPOL 73/78 and the IBC Code
-	I precautions for use	r	

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable



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Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

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

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

16. OTHER INFORMATION

Revision Date	:	2023/09/30
Further information		
Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Date format	:	yyyy/mm/dd
Full text of other abbreviatio	ns	
ACGIH ID OEL	:	USA. ACGIH Threshold Limit Values (TLV) Indonesia. Occupational Exposure Limits
ACGIH / TWA ID OEL / NAB	:	8-hour, time-weighted average Long term exposure limit

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



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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; 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

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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