

according to the Globally Harmonized System

# **Doxycycline Formulation**

Version 5.0	Revision Date: 28.09.2024		S Number: 05688-00011	Date of last issue: 30.09.2023 Date of first issue: 06.07.2020
1. PROD	UCT AND COMPANY ID	ENT	IFICATION	
Product name		:	Doxycycline Forr	nulation
Manufacturer or supplier's details				
Com	ipany	:	MSD	
Addı	ress	:	Briahnager - Off Wagholi - Pune -	Pune Nagar Road India 412 207
Tele	phone	:	+1-908-740-4000	)
Eme	rgency telephone numbe	r:	+1-908-423-6000	)

E-mail address	:	EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

#### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GIIS Classification	GHS	Classification
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GHS label elements Hazard pictograms	:	
Long-term (chronic) aquatic hazard	:	Category 2
Short-term (acute) aquatic hazard	:	Category 1
Serious eye damage/eye irri- tation	:	Category 1
Skin corrosion/irritation	:	Category 1
Acute toxicity (Oral)	:	Category 5

Signal word

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Hazaı	rd statements	H314 Causes s H400 Very toxic	armful if swallowed. evere skin burns and eye damage. c to aquatic life. aquatic life with long lasting effects.				
Precautionary statements		P264 Wash hai P273 Avoid rele P280 Wear pro	Prevention: P260 Do not breathe dust. P264 Wash hands thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protec- tion/ face protection.				
		Do NOT induce diately. P302 + P361 + all contaminate eral minutes. G P304 + P340 + and keep comfe help immediate P305 + P354 + with water for s sent and easy t help immediate	P338 + P316 IF IN EYES: Immediately rinse everal minutes. Remove contact lenses, if pre- o do. Continue rinsing. Get emergency medical ly. ntaminated clothing before reuse.				
		<b>Storage:</b> P405 Store lock <b>Disposal:</b> P501 Dispose of disposal plant.	ked up. of contents/ container to an approved waste				

#### Other hazards which do not result in classification

May form explosive dust-air mixture during processing, handling or other means.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Doxycycline Hyclate	24390-14-5	>= 50 - < 70

#### 4. FIRST AID MEASURES

General advice

: 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

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I	If inhale	d	:	advice. If inhaled, remove				
			If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.					
	In case of skin contact			<ul> <li>In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.</li> <li>Get medical attention immediately.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>				
l	In case	of eye contact	:					
I	If swallo	wed	:	If swallowed, DO If vomiting occurs Call a physician o Rinse mouth thore	NOT induce vomiting. have person lean forward. r poison control centre immediately.			
;		portant symptoms cts, both acute and	:	May be harmful if Causes serious ey Causes severe bu	swallowed. ye damage. urns.			
		on of first-aiders	<ul> <li>Causes digestive tract burns.</li> <li>First Aid responders should pay attention to self-pro and use the recommended personal protective equi when the potential for exposure exists (see section)</li> </ul>		ers should pay attention to self-protection, nmended personal protective equipment I for exposure exists (see section 8).			
	Notes to physician 5. FIREFIGHTING MEASURES		:	I reat symptomation	cally and supportively.			
		extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical				
	Unsuital media	ble extinguishing	:	None known.				
	Specific fighting	hazards during fire-	:	concentrations, ar potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. oustion products may be a hazard to health.			
	Hazardo ucts	ous combustion prod-	:	Carbon oxides				
	Specific ods	extinguishing meth-	:	cumstances and t Use water spray to	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			
:	Special	protective equipment	:	In the event of fire	e, wear self-contained breathing apparatus.			

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efighters	U	se personal prot	ective equipment.
ENTAL RELEASE MEAS	SURES	3	
onal precautions, protec- quipment and emer- / procedures	Fo	ollow safe handl	ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
onmental precautions	Pr Re Lo	event further least etain and dispose ocal authorities s	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
ods and materials for inment and cleaning up	ta Av Di es lea Lo er m Se	iner for disposal void dispersal of th compressed ust deposits sho as these may ased into the ational osal of this mate inployed in the co ine which regula actions 13 and 1	dust in the air (i.e., clearing dust surfaces
ING AND STORAGE			
nical measures	ca Pr	using an explose ovide adequate	precautions, such as electrical grounding
/Total ventilation	: If sufficient ventilation is unavailable, use with local ex		
e on safe handling	: Do Do Do W Ha pr se Ke Ke Ke Ta Ta er	o not get on skir o not breathe du o not swallow. o not get in eyes ash skin thorou andle in accorda actice, based or essment eep container tig eep container cl eep away from h ake precautiona ake care to prev ovironment.	ust. ghly after handling. ance with good industrial hygiene and safety in the results of the workplace exposure as- ghtly closed. heration and accumulation. osed when not in use. heat and sources of ignition. ry measures against static discharges. ent spills, waste and minimize release to the
	28.09.2024 efighters ENTAL RELEASE MEAS anal precautions, protec- quipment and emer- procedures onmental precautions ods and materials for inment and cleaning up ING AND STORAGE hical measures (Total ventilation e on safe handling	28.09.2024       61056         efighters       Use         ENTAL RELEASE MEASURES       Indext and emer- or procedures       Indext and emer- or procedures         onmental precautions       Image: And Precautions       Image: And Precautions         ods and materials for inment and cleaning up       Image: State And With Data Endext and Precautions       Image: State Precautions         IMG AND STORAGE       Image: State Precautions       Image: State Precautions       Image: State Precautions         Incal measures       Image: State Precautions       Image: State Precautions       Image: State Precautions         Image: Total ventilation       Image: State Precautions       Image: State Precautions       Image: State Precautions         Image: Total ventilation       Image: State Precautions       Image: State Precautions       Image: State Precautions         Image: Total ventilation       Image: State Precautions       Image: State Precautions       Image: State Precautions         Image: Total ventilation       Image: State Precautions       Image: State Precautions       Image: State Precautions         Image: Total ventilation       Image: State Precautions       Image: State Precautions       Image: State Precautions         Image: Total ventilation       Image: State Precautions       Image: State Precautions       Image: State Precautions         Image: To	28.09.2024       6105688-00011         efighters       Use personal profection of the procedures         and precautions, protection of procedures       :       Use personal profection of the procedures         and materials procedures       :       Use personal profection of the procedures         and materials for inment and cleaning up       :       Avoid release to the prevent further lease to the prevent further lease to the prevent further lease cannot be contain         adds and materials for inment and cleaning up       :       Sweep up or vacuations the contain         bods and materials for inment and cleaning up       :       Sweep up or vacuations the contain         bods and materials for inment and cleaning up       :       Sweep up or vacuations the contain         bods and materials for inment and cleaning up       :       Sweep up or vacuations the contain of the posal of this mate employed in the container for disposal Avoid dispersal of with compressed Dust deposits shores, as these may leased into the atter to cal or national the posal of this mate employed in the container of the container of the posal of this mate employed in the container of causing an explose Provide adequate and bonding, or in the container of sufficient ventilation.         incal measures       :       Static electricity measures the posal of this material bonding, or in the sufficient ventilation.         incal wentilation       :       Do not get on skir Do not get on skir Do not swallow.         in on the posal of the posal of t

Conditions for safe storage : Keep in properly labelled containers.



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Mater	ials to avoid	: Do not store wi	sed. ance with the particular national regulations. th the following product types: ibstances and mixtures des

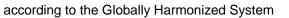
#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Components CAS-No. Value type Control parame-Basis ters / Permissible (Form of exposure) concentration Doxycycline Hyclate 24390-14-5 OEL = 100 TWA Internal µg/m3 (OEB 2) **Engineering measures** Use feasible engineering controls to minimize exposure to : compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Personal protective equipment

#### Components with workplace control parameters

reisonai protective equipin	ent	
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type Hand protection	:	Particulates type
Material	:	Chemical-resistant gloves
Eye 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.
Skin and body protection	:	Work uniform or laboratory coat.
Hygiene measures	:	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 contaminated 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.

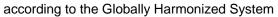
#### 9. PHYSICAL AND CHEMICAL PROPERTIES





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	Appear	ance	:	powder	
	Colour		:	light yellow	
	Odour		:	No data available	)
	Odour <sup>-</sup>	Threshold	:	No data available	
	рН		:	1.5 - 3.5	
	Melting	point/freezing point	:	No data available	)
	Initial be range	oiling point and boiling	:	No data available	
	Flash p	oint	:	Not applicable	
	Evapor	ation rate	:	Not applicable	
	Flamma	ability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.
	Flamma	ability (liquids)	:	Not applicable	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	Not applicable	
	Relative	e vapour density	:	Not applicable	
	Relative	e density	:	No data available	)
	Density	,	:	No data available	)
	Solubili Wat	ty(ies) er solubility	:	No data available	)
		n coefficient: n-	:	Not applicable	
	octanol Auto-ig	/water nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty osity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	r mixture is not classified as oxidizing.





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Moleo	cular weight	:	No data availabl	e
	cle characteristics cle size	:	No data availabl	e
0. STAB		(		
	tivity nical stability bility of hazardous reac-	:	Stable under nor May form explos dling or other me	ive dust-air mixture during processing, han-
Cond	itions to avoid	:	Heat, flames and	
Incompatible materials Hazardous decomposition products		:	Avoid dust forma Oxidizing agents No hazardous de	
1. TOXIC		ΓΙΟΝ	N	
Inforr expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
Acute	e toxicity			
May I	be harmful if swallowed.			
Prod				
Acute	e oral toxicity	:	Acute toxicity esti Method: Calculati	imate: 4,000 mg/kg ion method
Com	ponents:			
Doxy	cycline Hyclate:			
Acute	e oral toxicity	:	LD50 (Rat): 2,000	) mg/kg
			LD50 (Mouse): 1,	870 mg/kg
			LD50 (Dog): 500	mg/kg
	e toxicity (other routes of nistration)	:	LD50 (Rat): 222 r Application Route	
-	corrosion/irritation es severe burns.			
Com	ponents:			



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II		May irritate ski	n.
	ous eye damage/eye es serious eye dama		
Com	ponents:		
<b>Doxy</b> Rema	<b>rcycline Hyclate:</b> arks	: No data availa May irritate ey	
Resp	iratory or skin sens	itisation	
-	<b>sensitisation</b> lassified based on av	ailable information.	
•	<b>iratory sensitisatior</b> lassified based on av		
<u>Com</u>	ponents:		
<b>Doxy</b> Rema	<b>rcycline Hyclate:</b> arks		nsitisation by skin contact. nsitisation of susceptible persons by skin con-
	n cell mutagenicity lassified based on av	ailable information.	
Com	ponents:		
Doxy	cycline Hyclate:		
Geno	toxicity in vitro	Test system: C Result: Weakly	romosome aberration test in vitro Chinese hamster cells / positive ed on data from similar materials
		Test system: C Result: negativ	vitro mammalian cell gene mutation test Chinese hamster cells ve ed on data from similar materials
Gend	otoxicity in vivo	: Test Type: In v Species: Mous	<i>r</i> ivo micronucleus test se

#### Carcinogenicity

Not classified based on available information.

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#### Components:

#### **Doxycycline Hyclate:**

Species	: Rat
Application Route	: Oral
Species Application Route Exposure time	: 2 Years
	: 200 mg/kg body weight
Symptoms	: females
Target Organs	: Uterus (including cervix)
Symptoms Target Organs Remarks	: Benign tumor(s)
	<b>G</b> ( )

#### **Reproductive toxicity**

Not classified based on available information.

#### **Components:**

#### **Doxycycline Hyclate:**

Effects on foetal develop- ment	:	Test Type: Fertility/early embryonic development Species: Rat, females Application Route: Oral General Toxicity Maternal: NOAEL: 250 mg/kg body weight Result: No adverse effects
		Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Oral General Toxicity Maternal: NOAEL: 50 mg/kg body weight Symptoms: male reproductive effects
		Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Not classified based on available information.

#### **Repeated dose toxicity**

#### **Components:**

#### **Doxycycline Hyclate:**

Species NOAEL	:	Rat
NOAEL	:	25 mg/kg
Application Route	:	Oral
Exposure time	:	28 d
Symptoms	:	Thyroid effects

#### Aspiration toxicity

Not classified based on available information.



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-	rience with human ex	cpos	ure			
Com	ponents:					
Doxy	cycline Hyclate:					
	eral Information	:		eeth rointestinal disturbance ause photosensitisation.		
Furth	ner information					
Com	ponents:					
<b>Doxy</b> Rema	r <b>cycline Hyclate:</b> arks	:	Well tolerated in	clinical use		
12. ECOL	12. ECOLOGICAL INFORMATION					
Ecoto	oxicity					
Com	Components:					

### Doxycycline Hyclate:

Toxicity to algae/aquatic plants	:	EC10 ( Anabaena flos-aquae): 0.251 mg/l End point: Growth rate Exposure time: 72 h
Ecotoxicology Assessment		
Acute aquatic toxicity	:	Very toxic to aquatic life.
Chronic aquatic toxicity	:	Toxic to aquatic life with long lasting effects.
Persistence and degradabilit	у	
No data available		
Bioaccumulative potential		
Components:		
<u>Components:</u> Doxycycline Hyclate:		
	:	log Pow: 0.02
Doxycycline Hyclate: Partition coefficient: n-	:	log Pow: 0.02
<b>Doxycycline Hyclate:</b> Partition coefficient: n- octanol/water	:	log Pow: 0.02
Doxycycline Hyclate: Partition coefficient: n- octanol/water Mobility in soil	:	log Pow: 0.02
Doxycycline Hyclate: Partition coefficient: n- octanol/water Mobility in soil No data available	:	log Pow: 0.02



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#### 13. DISPOSAL CONSIDERATIONS

#### **Disposal methods**

Waste from residues	:	Do not dispose of waste into sewer.
		Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

#### International Regulations

UNRTDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Doxycycline Hyclate)
Class	:	9
Packing group	:	
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passen- ger aircraft)	:	956
Environmentally hazardous	:	yes
IMDG-Code		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
		(Doxycycline Hyclate)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data



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Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### **15. REGULATORY INFORMATION**

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

The components of	f this product are	reported in the	following inventories:
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AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

#### **16. OTHER INFORMATION**

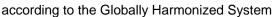
Revision Date	:	28.09.2024
Further information Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

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

Date format : dd.mm.yyyy

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substanc-





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es; (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.

IN / EN