

Doxycycline Formulation

Version 5.0	Revision Date: 28.09.2024		S Number: 05684-00011	Date of last issue: 30.09.2023 Date of first issue: 06.07.2020		
SECTION 1. IDENTIFICATION						
Product identifier		:	Doxycycline For	Doxycycline Formulation		
Manu	facturer or supplier's	s deta	ils			
Comp	Company		MSD	MSD		
Address		:	Rua Coronel Bento Soares, 530 Cruzeiro - Sao Paulo - Brazil CEP 12730-340			
Telep	Telephone		908-740-4000			
Emer	Emergency telephone		1-908-423-6000			
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 in accordance with ABNT NBR 14725 Standard

Acute toxicity (Oral)	:	Category 5
Skin corrosion	:	Category 1
Serious eye damage	:	Category 1
Short-term (acute) aquatic hazard	:	Category 1
Long-term (chronic) aquatic hazard	:	Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H303 May be harmful if swallowed. H314 Causes severe skin burns and eye damage. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects.



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Precautionary Statements			ease to the environment. tective gloves/ protective clothing/ eye protec-
		tor if you feel u P301 + P330 + Do NOT induce CENTER/ doct P303 + P361 + immediately all shower. Immed P304 + P340 + and keep comf POISON CENT P305 + P351 + water for sever and easy to do CENTER/ doct	 P331 + P310 IF SWALLOWED: Rinse mouth. vomiting. Immediately call a POISON P353 + P310 IF ON SKIN (or hair): Take off contaminated clothing. Rinse skin with water or diately call a POISON CENTER/ doctor. P310 IF INHALED: Remove person to fresh air ortable for breathing. Immediately call a TER/ doctor. P338 + P310 IF IN EYES: Rinse cautiously with al minutes. Remove contact lenses, if present Continue rinsing. Immediately call a POISON or.
		Storage: P405 Store loc	ked up.

Other hazards which do not result in classification

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.	Classification	Concentration (% w/w)
Doxycycline Hyclate		Acute Tox. (Oral), 4 Aquatic Acute, 1 Aquatic Chronic, 2	>= 50 -< 70

SECTION 4. FIRST AID MEASURES

General advice	In the case of accident or if you feel unwell, seek in advice immediately. When symptoms persist or in all cases of doubt se advice.	
If inhaled	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.	
In case of skin contact	In case of contact, immediately flush skin with plen	nty of water



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In cas	se of eye contact	:	and shoes. Get medical atter Wash clothing be Thoroughly clean In case of contac for at least 15 min	n shoes before reuse. t, immediately flush eyes with plenty of wate
lf swa	If swallowed		Get medical atter If swallowed, DO If vomiting occurs Call a physician of Rinse mouth thor	ntion immediately. NOT induce vomiting. s have person lean forward. or poison control center immediately. roughly with water.
	important symptoms effects, both acute and red	:	Never give anyth May be harmful if Causes serious e Causes severe b Causes digestive	eye damage. urns.
Prote	Protection of first-aiders		First Aid respond and use the reco	lers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8).
	Notes to physician		• •	ically and supportively.
		430		
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide ((Dry chemical	
Unsu media	itable extinguishing a	:	None known.	
Spec fightir	ific hazards during fire ng	:	concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health.
Haza ucts	rdous combustion prod-	:	Carbon oxides	
Speci ods	ific extinguishing meth-	:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged containers from fire area if it is safe to c
	ial protective equipment	:		e, wear self-contained breathing apparatus.

for fire-fighters Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Use personal protective equipment.



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tive equipment and emer- gency procedures			Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).		
	Enviror	nmental 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 a Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1	dust in the air (i.e., clearing dust surfaces	

SECTION 7. HANDLING AND STORAGE

Technical measures	 Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	 Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling.
	 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the
Hygiene measures	 environment. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment,



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	itions for safe storage ials to avoid	 appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations Do not store with the following product types: 	
mater		Strong oxidizing	agents ostances and mixtures

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components		CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Doxycycline Hyclate		24390-14-5	TWA	OEL = 100 μg/m3 (OEB 2)	Internal
Engineering measures	:	compound. All engineerin design and op	g controls shou perated in accor	trols to minimize expo ld be implemented by dance with GMP prin d the environment.	facility
Personal protective equipm	ent				
Respiratory protection Filter type Hand protection	:	exposure ass	essment demor d guidelines, us	itilation is not availabl istrates exposures ou e respiratory protectio	tside the
Material	:	Chemical-res	istant gloves		
Eye protection	:	If the work en mists or aeros Wear a faces potential for d aerosols.	vironment or ac sols, wear the a hield or other fu irect contact to	e shields or goggles. tivity involves dusty c ppropriate goggles. Il face protection if the the face with dusts, m	ere is a
Skin and body protection	:	Work uniform	or laboratory co	pat.	
TION 9. PHYSICAL AND CH	EMI	CAL PROPER	TIES		
Physical state	:	powder			
Color	:	light yellow			

Odor :	No data available
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Odor Threshold : No data available



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	рН		:	1,5 - 3,5	
	Melting	point/freezing point	:	No data available	9
	Initial boiling point and boiling range Flash point		:	No data available	9
			:	Not applicable	
	Evapor	ration rate	:	Not applicable	
	Flammability (solid, gas)		:	May form explosi handling or other	ive dust-air mixture during processing, means.
	Flamm	ability (liquids)	:	Not applicable	
		explosion limit / Upper ability limit	:	No data available	9
		explosion limit / Lower ability limit	:	No data available	9
	Vapor	pressure	:	Not applicable	
	Relativ	e vapor density	:	Not applicable	
	Relativ	e density	:	No data available	9
	Density	ý	:	No data available	9
	Solubility(ies)				
		ter solubility	:	No data available	9
	Partitio octano	n coefficient: n- I/water	:	Not applicable	
	Autoigr	nition temperature	:	No data available	2
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ity cosity, kinematic	:	Not applicable	
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	ılar weight	:	No data available	9
	Particle Particle	e characteristics e size	:	No data available	9

SECTION 10. STABILITY AND REACTIVITY



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		vity cal stability ility of hazardous reac-	:	handling or other n	al conditions. e dust-air mixture during processing,
	Incom	ions to avoid patible materials dous decomposition cts	:		
SEC	CTION 1	11. TOXICOLOGICAL I	NFC	ORMATION	
	Inform exposi	ation on likely routes of ure	:	Inhalation Skin contact Ingestion Eye contact	
		toxicity			
	-	e harmful if swallowed.			
	Produ Acute	<u>ct:</u> oral toxicity	:	Acute toxicity estim Method: Calculation	
	Comp	onents:			
	Doxyc	cycline Hyclate:			
	-	oral toxicity	:	LD50 (Rat): 2.000 r	ng/kg
				LD50 (Mouse): 1.87	70 mg/kg
				LD50 (Dog): 500 m	g/kg
		toxicity (other routes of istration)	:	LD50 (Rat): 222 mg Application Route: I	
•		orrosion/irritation			
	<u>Comp</u>	onents:			
	Doxyc Remar	s ycline Hyclate: rks	:	No data available May irritate skin.	
		is eye damage/eye irri s serious eye damage.	tati	on	
	<u>Comp</u>	onents:			
I	Doxyc Remar	e ycline Hyclate: rks	:	No data available	

Symptoms Target Organs

Remarks



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		May irritate eye	S.
atory or skin sens	itizatio	n	
ensitization	- 1 - 1 - 1 -		
		information.	
-		information.	
onents:			
ycline Hyclate:			
ks	:	May cause sen May cause sen	sitization by skin contact. sitization of susceptible persons by skin con-
cell mutagenicity ssified based on av	ailable	information.	
onents:			
ycline Hyclate:			
oxicity in vitro	:	Test system: Cl Result: Weakly	omosome aberration test in vitro ninese hamster cells positive d on data from similar materials
		Test system: Cl Result: negative	
			d on data from similar materials
oxicity in vivo	:	Species: Mouse	te: Oral
	ensitization ssified based on av atory sensitization ssified based on av onents: ycline Hyclate: ks cell mutagenicity ssified based on av onents: ycline Hyclate:	ensitization ssified based on available atory sensitization ssified based on available onents: ycline Hyclate: ks : cell mutagenicity ssified based on available onents: ycline Hyclate: oxicity in vitro :	ssified based on available information. atory sensitization ssified based on available information. onents: ycline Hyclate: ks : No data available May cause sense May cause sense tact or by inhala cell mutagenicity ssified based on available information. onents: ycline Hyclate: pxicity in vitro : Test Type: Chroc Test system: Chroc Result: Weakly Remarks: Based Test Type: In vir Test system: Chroc Result: Weakly Remarks: Based pxicity in vivo : Test Type: In vir Species: Mouse Application Rou

Uterus (including cervix)Benign tumor(s)

females

:



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Not cl	oductive toxicity assified based on availa ponents:	able	information.	
Doxy	cycline Hyclate:			
Effect	s on fetal development	:	Species: Rat, fem Application Route General Toxicity Result: No advers Test Type: Fertilit Species: Rat, ma Application Route General Toxicity Symptoms: male	e: Oral Maternal: NOAEL: 250 mg/kg body weight se effects. ty/early embryonic development le e: Oral Maternal: NOAEL: 50 mg/kg body weight reproductive effects v and developmental toxicity tests did not

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Doxycycline Hyclate:		
General Information	:	May cause Target Organs: Teeth Symptoms: Gastrointestinal disturbance
Skin contact	:	Remarks: May cause photosensitization.
Further information		
Components:		
Doxycycline Hyclate:		



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Rema	arks	: Well to	lerated in	clinical use
SECTION	12. ECOLOGICAL INI	ORMATION		
Ecot	oxicity			
Com	ponents:			
Doxy	vcycline Hyclate:			
Toxic plants	ity to algae/aquatic s	End po	Anabaen bint: Grow ure time:	
Ecot	oxicology Assessmer	t		
Acute	e aquatic toxicity	: Very to	oxic to aqu	uatic life.
Chro	nic aquatic toxicity	: Toxic to	o aquatic	life with long lasting effects.
	istence and degradab ata available	ility		
Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Partit	vcycline Hyclate: tion coefficient: n- nol/water	: log Pov	w: 0,02	
	i lity in soil ata available			
	r adverse effects ata available			
SECTION	13. DISPOSAL CONS	IDERATION	5	
Disp	osal methods			
-	e from residues			of waste into sewer.
Conta	aminated packaging	: Empty	containe	cordance with local regulations. rs should be taken to an approved waste

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number Proper shipping name		UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
		(Doxycycline Hyclate)

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.



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Labe	ing group	:	9 III 9 yes	
UN/II Prope	er shipping name	:	UN 3077 Environmentally h (Doxycycline Hyd	nazardous substance, solid, n.o.s. Slate)
Labe	ing group ls ing instruction (cargo	:	9 III Miscellaneous 956	
ger a	ing instruction (passen- ircraft) onmentally hazardous	:	956 yes	
UN n	3-Code umber er shipping name	:	UN 3077 ENVIRONMENTA N.O.S. (Doxycycline Hyc	ALLY HAZARDOUS SUBSTANCE, SOLID,
Labe EmS	ing group	:	9 III 9 F-A, S-F yes	
	sport in bulk according			OL 73/78 and the IBC Code
Dom	estic regulation			
	F umber er shipping name	:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, SOLID,
Labe	ing group	:	(Doxycycline Hyd 9 III 9 90	אמוכן
-	ial precautions for use		vided herein ere fe	r informational purposes only, and solely

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - : Not applicable (LINACH)



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Brazil. Police	List of chemicals contr	rolled by the Federal	: Not applicable
The ir AICS	ngredients of this proc	duct are reported in : not determined	the following inventories:
DSL		: not determined	
IECSC	2	: not determined	

SECTION 16. OTHER INFORMATION

Revision Date	:	28.09.2024
Date format	:	dd.mm.yyyy

Further information

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

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 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 - Transporta-



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tion 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 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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