

according to GB/T 16483 and GB/T 17519

# **Doxycycline Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
5.0	2024/09/28	6105661-00012	Date of first issue: 2020/07/06

### **1. PRODUCT AND COMPANY IDENTIFICATION**

Product name	:	Doxycycline Formulation				
Manufacturer or supplier's details						
Company	:	MSD				
Address	:	No. 485 Jing Tai Road Pu Tuo District - Shanghai - China 200331				
Telephone	:	+1-908-740-4000				
Emergency telephone number	:	86-571-87268110				
E-mail address	:	EHSDATASTEWARD@msd.com				
Recommended use of the chemical and restrictions on use						
Recommended use Restrictions on use	:	Veterinary product Not applicable				

### 2. HAZARDS IDENTIFICATION

### **Emergency Overview**

Appearance Colour Odour	:	powder light yellow No data available		
May be harmful if swallowed. Causes severe skin burns and eye damage. Very toxic to aquation life. Toxic to aquatic life with long lasting effects.				
GHS Classification				
Acute toxicity (Oral)	:	Category 5		
Skin corrosion/irritation	:	Category 1		
Serious eye damage/eye irri- tation	:	Category 1		
Short-term (acute) aquatic hazard	:	Category 1		
Long-term (chronic) aquatic hazard	:	Category 2		

### **GHS** label elements



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Haza	rd pictograms		¥2
Signa	al word	: Danger	•
Haza	rd statements	H314 Causes s H400 Very toxi	narmful if swallowed. severe skin burns and eye damage. c to aquatic life. aquatic life with long lasting effects.
Preca	autionary statements	P273 Avoid rel	in thoroughly after handling. ease to the environment. otective gloves/ protective clothing/ eye protec-
		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 P312 Call a PO	<ul> <li>P353 + P310 IF ON SKIN (or hair): Take off</li> <li>contaminated clothing. Rinse skin with water/</li> <li>diately call a POISON CENTER/ doctor.</li> <li>P310 IF INHALED: Remove person to fresh air</li> <li>fortable for breathing. Immediately call a</li> <li>TER/ doctor.</li> <li>P338 + P310 IF IN EYES: Rinse cautiously with</li> <li>ral minutes. Remove contact lenses, if present</li> <li>continue rinsing. Immediately call a POISON</li> <li>or.</li> <li>DISON CENTER/ doctor if you feel unwell.</li> <li>ntaminated clothing before reuse.</li> </ul>
		<b>Storage:</b> P405 Store loc	ked up.
		<b>Disposal:</b> P501 Dispose disposal plant.	of contents/ container to an approved waste

### Physical and chemical hazards

Not classified based on available information.

### Health hazards

May be harmful if swallowed. Causes severe skin burns and eye damage. Causes serious eye damage.



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#### **Environmental hazards**

Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

#### 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	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical</li> </ul>
If inhaled	<ul> <li>advice.</li> <li>If inhaled, remove to fresh air.</li> <li>If not breathing, give artificial respiration.</li> <li>If breathing is difficult, give oxygen.</li> </ul>
In case of skin contact	<ul> <li>Get medical attention immediately.</li> <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> </ul>
	Thoroughly clean shoes before reuse.
In case of eye contact	<ul> <li>In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.</li> <li>If easy to do, remove contact lens, if worn.</li> <li>Get medical attention immediately.</li> </ul>
If swallowed	<ul> <li>If swallowed, DO NOT induce vomiting.</li> <li>If vomiting occurs have person lean forward.</li> <li>Call a physician or poison control centre immediately.</li> <li>Rinse mouth thoroughly with water.</li> <li>Never give anything by mouth to an unconscious person.</li> </ul>
Most important symptoms and effects, both acute and delayed	<ul> <li>May be harmful if swallowed.</li> <li>Causes serious eye damage.</li> <li>Causes severe burns.</li> <li>Causes digestive tract burns.</li> </ul>
Protection of first-aiders	<ul> <li>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).</li> </ul>
Notes to physician	: Treat symptomatically and supportively.

#### **5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Water spray



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			Alcohol-resistant Carbon dioxide (C Dry chemical	
Unsu media	itable extinguishing a	:	None known.	
Spec fightir	ific hazards during fire- ng	:	concentrations, an potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a plosion hazard. pustion products may be a hazard to health.
Haza ucts	rdous combustion prod-	:	Carbon oxides	
Spec ods	ific extinguishing meth-	:	cumstances and t Use water spray t	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to de
	ial protective equipment efighters	:		e, wear self-contained breathing apparatus. tective equipment.
6. ACCID	ENTAL RELEASE MEAS	SUF	RES	
tive e	onal precautions, protec- quipment and emer- y procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t 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
Math	- de la se da siele fea		0	was up onillong and collect in quitchle con

Methods and materials for : containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable con- tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. 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.
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## 7. HANDLING AND STORAGE

#### Handling

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding
Local/Total ventilation	:	and bonding, or inert atmospheres.
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 as- sessment 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 environment.
Avoidance of contact	:	Oxidizing agents
Storage		
Conditions for safe storage	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Self-reactive substances and mixtures Organic peroxides Oxidizing agents Explosives
Packaging material	:	Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

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

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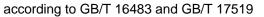


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Engir	neering measures	compound. All engineeri design and c	e engineering controls to minimize exposure to ing controls should be implemented by facility operated in accordance with GMP principles to ucts, workers, and the environment.
Perso	onal protective equip	ment	
Fil	iratory protection	sure assess ommended Particulates	
Eye/1	ace protection	If the work e mists or aero Wear a face	glasses with side shields or goggles. Invironment or activity involves dusty conditions, osols, wear the appropriate goggles. shield or other full face protection if there is a direct contact to the face with dusts, mists, or
Hand	and body protection protection aterial		n or laboratory coat. sistant gloves
Hygie	ene measures	eye flushing ing place. When using Wash contar The effective engineering appropriate industrial hys	to chemical is likely during typical use, provide systems and safety showers close to the work- do not eat, drink or smoke. minated clothing before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, giene monitoring, medical surveillance and the histrative controls.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	light yellow
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	1.5 - 3.5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable





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Eva	poration rate	:	Not applicable	
Flai	mmability (solid, gas)	:	May form explosiding or other me	ive dust-air mixture during processing, han- ans.
Flai	mmability (liquids)	:	Not applicable	
	per explosion limit / Upper nmability limit	:	No data available	9
	ver explosion limit / Lower nmability limit	:	No data available	9
Vap	oour pressure	:	Not applicable	
Rel	ative vapour density	:	Not applicable	
Rel	ative density	:	No data available	9
Der	nsity	:	No data available	9
	ubility(ies) Water solubility	:	No data available	9
	tition coefficient: n- anol/water	:	Not applicable	
	o-ignition temperature	:	No data available	9
Dec	composition temperature	:	No data available	9
	cosity Viscosity, kinematic	:	Not applicable	
Exp	losive properties	:	Not explosive	
Oxi	dizing properties	:	The substance o	r mixture is not classified as oxidizing.
Mol	ecular weight	:	No data available	9
	ticle characteristics ticle size	:	No data available	9

## **10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing, han-
tions		dling or other means.
		Can react with strong oxidizing agents.

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ersion .0	Revision Date: 2024/09/28		S Number: 05661-00012	Date of last issue: 2024/04/06 Date of first issue: 2020/07/06
Incor	litions to avoid npatible materials irdous decomposition ucts	:		ition.
1. TOXIC	COLOGICAL INFORMAT	101	1	
Expo	sure routes	:	Inhalation Skin contact Ingestion Eye contact	
	<b>e toxicity</b> be harmful if swallowed.			
Prod Acute	<u>uct:</u> e oral toxicity	:	Acute toxicity esti Method: Calculati	mate: 4,000 mg/kg on method
<u>Com</u>	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			
<u>Com</u>	ponents:			
<b>Doxy</b> Rem	<b>/cycline Hyclate:</b> arks	:	No data available May irritate skin.	
Caus	<b>ous eye damage/eye irri</b> ses serious eye damage.	tati	on	
	ponents:			
<b>Doxy</b> Rem	v <b>cycline Hyclate:</b> arks	:	No data available May irritate eyes.	





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#### Respiratory or skin sensitisation

### Skin sensitisation

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

:

### Components:

#### Doxycycline Hyclate:

Remarks

No data available May cause sensitisation by skin contact. May cause sensitisation of susceptible persons by skin contact or by inhalation of dust.

### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### **Doxycycline Hyclate:**

Genotoxicity in vitro	: Test Type: Chromosome aberration test in vitro Test system: Chinese hamster cells Result: Weakly positive Remarks: Based on data from similar materials
	Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster cells Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	: Test Type: In vivo micronucleus test Species: Mouse Application Route: Oral Result: negative Remarks: Based on data from similar materials

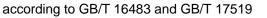
#### Carcinogenicity

Not classified based on available information.

#### 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)





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### **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.

### Experience with human exposure

#### Components:

# Doxycycline Hyclate:

General Information	: May cause
	Target Organs: Teeth
	Symptoms: Gastrointestinal disturbance
Skin contact	: Remarks: May cause photosensitisation.



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Furth	er information					
	oonents:					
Doxycycline Hyclate: Remarks			: Well tolerated in clinical use			
12. ECOL	OGICAL INFORMATI	ON				
Ecoto	oxicity					
Com	oonents:					
Doxy	cycline Hyclate:					
Toxic plants	ity to algae/aquatic	:	EC10 (Anabaena flos-aquae): 0.251 mg/l End point: Growth rate Exposure time: 72 h			
Ecoto	oxicology Assessme	nt				
Acute	aquatic toxicity	:	Very toxic to aq	uatic life.		
Chror	nic aquatic toxicity	:	Toxic to aquatic life with long lasting effects.			
	<b>stence and degradat</b> ata available	oility				
Bioad	ccumulative potentia	I				
Com	oonents:					
Partit	<b>cycline Hyclate:</b> ion coefficient: n- ol/water	:	log Pow: 0.02			
Mobi	<b>lity in soil</b> ata available					
	r adverse effects ata available					

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.



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#### 14. TRANSPORT INFORMATION

#### International Regulations

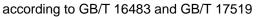
UNRTDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
		N.O.S.
		(Doxycycline Hyclate)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.		UN 3077
Proper shipping name	÷	Environmentally hazardous substance, solid, n.o.s.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

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **National Regulations**

<b>GB 6944/12268</b> UN number Proper shipping name	:	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Doxycycline Hyclate)
Class	:	9
Packing group	:	III
Labels	:	9
Marine pollutant	:	no





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

## **15. REGULATORY INFORMATION**

#### National regulatory information

### Law on the Prevention and Control of Occupational Diseases

#### **Regulations on Safety Management of Hazardous Chemicals**

Catalogue of Hazardou	is Chemicals	:	This product is not listed in the cata- logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de- termination.
Identification of Major H 18218)	Hazard Installations for Hazardo	us C	chemicals (GB : Not listed
Hazardous Chemicals SAWS	for Priority Management under	:	Not listed
Regulations on Labor	ur Protection in Workplaces w	here	e Toxic Substances are Used
Catalogue of Highly To	-	:	Not listed
and Export of Toxic C	-		Import of Chemicals and the Import
and Export		-	
Regulation on the Ad	ministration of Precursor Che	mic	als
Catalogue and Classifi	cation of Precursor Chemicals	:	Not listed
Yangtze River Protec	tion Law		
This product does not	contain any dangerous chemical	ls pr	ohibited for inland river transport.
The components of the	nis product are reported in the	e fol	lowing inventories:
AICS	: not determined		-
DSL	: not determined		
IECSC	: not determined		

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



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Revision Date	:	2024/09/28
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 Agen- 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.

Date format

#### : yyyy/mm/dd

#### 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 - 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

#### Disclaimer

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



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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.

CN / EN