according to GB/T 16483 and GB/T 17519



## **Oxytetracycline Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	6008064-00012	Date of first issue: 2020/06/05

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

Product name	:	Oxytetracycline Solid 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 ch	em	ical 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		
Causes severe skin burns and eye damage. May cause an allergic skin reaction. May damage the unborn child. Very toxic to aquatic life with long lasting effects.				
GHS Classification				
Skin corrosion/irritation	:	Category 1		
Serious eye damage/eye irri- tation	:	Category 1		
Skin sensitisation	:	Category 1		
Reproductive toxicity	:	Category 1A		
Short-term (acute) aquatic hazard	:	Category 1		
Long-term (chronic) aquatic hazard	:	Category 1		

according to GB/T 16483 and GB/T 17519



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	<b>label elements</b> rd pictograms		
Signa	al word	: Danger	$\mathbf{v}$ $\mathbf{v}$ $\mathbf{v}$
Haza	rd statements	H317 May cau H360D May da	severe skin burns and eye damage. use an allergic skin reaction. amage the unborn child. ic to aquatic life with long lasting effects.
Preca	autionary statements	P202 Do not h and understoc P260 Do not b P264 Wash sh P272 Contam the workplace P273 Avoid re	oreathe dust. kin thoroughly after handling. inated work clothing should not be allowed out of lease to the environment. otective gloves/ protective clothing/ eye protec-
		Do NOT induc CENTER/ doc P303 + P361 - immediately a shower. Imme P304 + P340 - and keep com POISON CEN P305 + P351 - water for seve and easy to do CENTER/ doc P308 + P313 - attention. P333 + P313 - vice/ attention	<ul> <li>+ P353 + P310 IF ON SKIN (or hair): Take off</li> <li>II contaminated clothing. Rinse skin with water/ diately call a POISON CENTER/ doctor.</li> <li>+ P310 IF INHALED: Remove person to fresh air fortable for breathing. Immediately call a TER/ doctor.</li> <li>+ P338 + P310 IF IN EYES: Rinse cautiously wit ral minutes. Remove contact lenses, if present</li> <li>D. Continue rinsing. Immediately call a POISON tor.</li> <li>IF exposed or concerned: Get medical advice/</li> <li>If skin irritation or rash occurs: Get medical ad- .</li> <li>Take off contaminated clothing and wash it befor</li> </ul>
		<b>Storage:</b> P405 Store lo	cked up.
		<b>Disposal:</b> P501 Dispose	of contents/ container to an approved waste

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disposal plant.

#### Physical and chemical hazards

Not classified based on available information.

#### Health hazards

Causes severe skin burns and eye damage. Causes serious eye damage. May cause an allergic skin reaction. May damage the unborn child.

#### Environmental hazards

Very toxic to aquatic life. Very 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)
oxytetracycline	79-57-2	>= 70 -< 90

#### 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately.
		When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air.
		If not breathing, give artificial respiration.
		If breathing is difficult, give oxygen.
In case of skin contact		Get medical attention immediately. In case of contact, immediately flush skin with plenty of water
	•	for at least 15 minutes while removing contaminated clothing and shoes.
		Get medical attention immediately.
		Wash clothing before reuse.
		Thoroughly clean shoes before reuse.
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water
		for at least 15 minutes.
		If easy to do, remove contact lens, if worn.
		Get medical attention immediately.
If swallowed	:	If swallowed, DO NOT induce vomiting.
		If vomiting occurs have person lean forward.
		Call a physician or poison control centre immediately.
		Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms		May cause an allergic skin reaction.
and effects, both acute and	•	Causes serious eye damage.
delayed		May damage the unborn child.
-		

according to GB/T 16483 and GB/T 17519



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Prote	ction of first-aiders	:	and use the recor	tract burns. ers should pay attention to self-protection, nmended personal protective equipment
Notes	to physician	:		I for exposure exists (see section 8). cally and supportively.
5. FIREFIC	GHTING MEASURES			
Suital	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
Unsui media	table extinguishing	:	None known.	
Speci fightir	fic hazards during fire- Ig	:	concentrations, and 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.
Hazai ucts	dous combustion prod-	:	Carbon oxides	
Speci ods	fic extinguishing meth-	:	cumstances and t Use water spray t	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
	al protective equipment	:		e, wear self-contained breathing apparatus. rective equipment.

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
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

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		es, as these ma leased into the Local or nationa posal of this ma employed in the mine which reg Sections 13 and	ed air). hould not be allowed to accumulate on surfac- ay form an explosive mixture if they are re- atmosphere in sufficient concentration. al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.
7. HAND	LING AND STORAGE		
Han	dling		
	nnical measures	causing an exp Provide adequa	r may accumulate and ignite suspended dust losion. ate precautions, such as electrical grounding rinert atmospheres.
Loca	al/Total ventilation		illation is unavailable, use with local exhaust
Advi	ce on safe handling	: Do not get on s Do not breathe Do not swallow Do not get in ey Wash skin thord Handle in accor practice, based sessment Keep container Minimize dust g Keep container Keep away from Take precaution	dust. ves. bughly after handling. rdance with good industrial hygiene and safety on the results of the workplace exposure as-
Avoi	dance of contact	: Oxidizing agent	s
Stor	age		
Con	ditions for safe storage	Store locked up Keep tightly clo	
Mate	erials to avoid	: Do not store wit	th the following product types: bstances and mixtures des
Pack	kaging material	: Unsuitable mate	erial: None known.

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#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS	S-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
oxytetracycline	79-5	57-2	TWA	500 µg/m3 (OEB 2)	Internal
	Furt	her informa	ation: DSEN	. ,	
			Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Engineering measures	cor All des	npound. engineerin sign 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 equipre	nent				
Respiratory protection	sur om	e assessm mended gi	ent demonstrat uidelines, use re	tilation is not availabl es exposures outside espiratory protection.	
Filter type Eye/face protection	: We If th mis We pot	<ul> <li>Particulates type</li> <li>Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty condition 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.</li> </ul>			
Skin and body protection Hand protection	: Wo	rk uniform	or laboratory co	bat.	
Material	: Ch	emical-resi	stant gloves		
Hygiene measures	eye ing Wh Cor wor Wa	flushing s place. en using d ntaminated rkplace. sh contam	ystems and saf o not eat, drink I work clothing s inated clothing	should not be allowed	the work-
				acility should include personal protective economic actions and protective economic actions and the second structure action acti	

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance :
--------------

Colour

: light yellow

use of administrative controls.

appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

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Odou	ır	:	No data availabl	e		
Odou	ur Threshold	:	No data availabl	e		
рН		:	1.5 - 3.0			
Melti	ng point/freezing point	:	No data availabl	e		
Initia range	l boiling point and boiling e	:	No data availabl	e		
Flash	n point	:	Not applicable			
Evap	oration rate	:	Not applicable			
Flam	mability (solid, gas)	:	May form explos dling or other me	ive dust-air mixture during processing, han- eans.		
Flam	mability (liquids)	:	Not applicable			
	er explosion limit / Upper nability limit	:	No data availabl	e		
	er explosion limit / Lower nability limit	:	No data availabl	e		
Vapo	our pressure	:	Not applicable			
Relat	tive vapour density	:	Not applicable			
Relat	tive density	:	No data available			
Dens	sity	:	No data availabl	e		
	bility(ies) /ater solubility	:	No data availabl	e		
	tion coefficient: n- nol/water	:	No data availabl	e		
	-ignition temperature	:	No data availabl	e		
Decc	omposition temperature	:	No data availabl	e		
Visco Vi	osity iscosity, kinematic	:	Not applicable			
Explo	osive properties	:	Not explosive			
Oxidi	izing properties	:	The substance c	r mixture is not classified as oxidizing.		

according to GB/T 16483 and GB/T 17519



ersion .0	Revision Date: 2024/09/28		S Number: 08064-00012	Date of last issue: 2024/04/06 Date of first issue: 2020/06/05				
Moleo	cular weight	:	No data available	9				
	cle characteristics cle size	:	No data available					
0. STAB	ILITY AND REACTIVITY	,						
	tivity nical stability ibility of hazardous reac-		Stable under nor May form explos dling or other me	ive dust-air mixture during processing, han-				
	itions to avoid npatible materials	:	Heat, flames and Avoid dust forma	tion.				
	rdous decomposition	:	Oxidizing agents No hazardous decomposition products are known.					
1. TOXIC	OLOGICAL INFORMAT		I					
Expo	sure routes	:	Inhalation Skin contact Ingestion Eye contact					
	e toxicity lassified based on availa	ble i	nformation.					
Com	ponents:							
	etracycline: e oral toxicity	:	LD50 (Rat): 4,800	) mg/kg				
			LD50 (Mouse): 2, Remarks: Eviden	240 mg/kg ce of phototoxicity was observed				
Acute	e inhalation toxicity	:	Remarks: No data	a available				
Acute	e dermal toxicity	:	Remarks: No data available					
	Acute toxicity (other routes of administration)		LD50 (Rat): 4,840 Application Route					
			LD50 (Mouse): 3, Application Route					
	corrosion/irritation es severe burns.							

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Com	ponents:						
oxyte	etracycline:						
Rema	arks	:	No data available				
	ous eye damage/eye i ses serious eye damag		on				
	ponents:						
	etracycline:						
Rema		:	No data available				
Resp	piratory or skin sensi	tisatio	n				
-	sensitisation cause an allergic skin	reactio	on.				
-	<b>Respiratory sensitisation</b> Not classified based on available information.						
Com	ponents:						
oxyte	etracycline:						
Test Resu		:	Human repeat ins Sensitiser	sult patch test (HRIPT)			
	n cell mutagenicity classified based on ava	ilable	information.				
Com	ponents:						
	etracycline:						
	otoxicity in vitro	:	Test Type: Microb Result: negative	pial mutagenesis assay (Ames test)			
			Test Type: Mouse Metabolic activation Result: positive	e Lymphoma on: Metabolic activation			
				chromatid exchange assay nese hamster ovary cells			
			Test Type: Chrom Result: negative	nosomal aberration			
Genc	otoxicity in vivo	:	Test Type: Micror Species: Mouse Cell type: Bone m Application Route	narrow			

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ersion 0	Revision Date: 2024/09/28	SDS Number: 6008064-00012	Date of last issue: 2024/04/06 Date of first issue: 2020/06/05
II		Result: equive	ocal
		Test Type: in Species: Mou Application R Result: negat	se oute: Intraperitoneal injection
	cell mutagenicity -	: Weight of evic cell mutagen.	dence does not support classification as a gern
	<b>nogenicity</b> assified based on avai	lable information.	
<u>Comp</u>	oonents:		
Speci Applic	cation Route sure time	: Mouse : Oral : 104 weeks : negative	
Expos Resul	cation Route sure time t t Organs		l, Pituitary gland sm or mode of action may not be relevant in hu
Carcii ment	nogenicity - Assess-	: Weight of evid	dence does not support classification as a car-
-	oductive toxicity Jamage the unborn chi	ld.	
Comp	oonents:		
oxyte	tracycline:		
Effect	s on fertility	Species: Rat Application R Fertility: NOA Result: No eff	vo-generation reproduction toxicity study oute: Oral EL: 18 mg/kg body weight fects on fertility, No effect on reproduction capa cant adverse effects were reported
Effect ment	s on foetal develop-	Species: Rat Application R Embryo-foeta	nbryo-foetal development oute: Oral I toxicity: LOAEL: 48 mg/kg body weight nplantation loss., Skeletal malformations

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		Species: Rat Application Rout General Toxicity Embryo-foetal to Result: No terato	Maternal: LOAEL: 1,200 mg/kg body weight pxicity: NOAEL: 1,500 mg/kg body weight
		Species: Mouse Application Rout General Toxicity Embryo-foetal to Result: No terato	e: Oral Maternal: LOAEL: 1,325 mg/kg body weight exicity: NOAEL: 2,100 mg/kg body weight
		Species: Rabbit Application Rout Embryo-foetal to	ryo-foetal development te: Intramuscular oxicity: LOAEL: 41.5 mg/kg body weight antation loss., No foetal abnormalities
		Species: Dog Application Rout Embryo-foetal to	ryo-foetal development te: Intramuscular oxicity: LOAEL: 20.75 mg/kg body weight and visceral variations, Postimplantation loss.
Repro sessr	oductive toxicity - As- nent	: Positive evidenc human epidemic	e of adverse effects on development from plogical studies.
STOI	- single exposure		

### STOT - single exposure

Not classified based on available information.

#### **STOT - repeated exposure**

Not classified based on available information.

#### Repeated dose toxicity

### **Components:**

#### oxytetracycline:

Species LOAEL Application Route Exposure time Target Organs Remarks	:	Rat 198 mg/kg Oral 13 Weeks Bone No significant adverse effects were reported
	:	Mouse 7,990 mg/kg Oral

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	sure time et Organs arks	: :	13 Weeks Bone No significant adv	verse effects were reported
Expo	EL EL cation Route sure time et Organs		Dog 125 mg/kg 250 mg/kg Oral 12 Months Testis Significant toxicity	<i>r</i> observed in testing
Expo	EL		Rat 40 mg/kg 100 mg/kg Intraperitoneal 14 Days Kidney	
Not c Expe	ration toxicity lassified based on availa rience with human exp ponents:			
oxyte Inges	etracycline: tion	:		ointestinal disturbance, tooth discoloration use birth defects.
Ecote	OGICAL INFORMATIOI oxicity ponents:	N		
	etracycline: ity to fish	:	Exposure time: 9	ipes (Japanese medaka)): 110 mg/l 6 h est Guideline 203
	ity to daphnia and other tic invertebrates	:	Exposure time: 4 Method: OECD T EC50 (Daphnia n Exposure time: 4	est Guideline 202 nagna (Water flea)): 669 mg/l
   Toxic	ity to algae/aquatic	:	EC50 (Anabaena	): 0.032 mg/l

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plants	;		Exposure time: 72	2 h			
			NOEC (Anabaen Exposure time: 72				
	ctor (Acute aquatic tox-	:	10				
	ctor (Chronic aquatic	:	10				
toxicit Toxici	y) ity to microorganisms	:	EC50: 17.9 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209				
			NOEC: 0.2 mg/l Exposure time: 3 Test Type: Respi Method: OECD T				
	stence and degradabil Ita available	ity					
	cumulative potential						
	i <b>ty in soil</b> Ita available						
	adverse effects ata available						
13. DISPO	SAL CONSIDERATION	IS					
Dispo	osal methods						
	e from residues minated packaging	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved wa				
Conta		•	dling site for recy				
14. TRANS	SPORT INFORMATION						
Interr	national Regulations						
	<b>TDG</b> umber er shipping name	:	UN 3077 ENVIRONMENT/ N.O.S.	ALLY HAZARDOUS SUBSTANCE, SOLID,			
Class	Class		(oxytetracycline) : 9				

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Label	ng group s onmentally hazardous	: III : 9 : yes	
ΙΑΤΑ	-DGR		
UN/IE Prope	) No. er shipping name	: UN 3077 : Environmenta (oxytetracycl	ally hazardous substance, solid, n.o.s.
Label Packi	ng group s ng instruction (cargo	: 9 : III : Miscellaneou : 956	
ger ai	ft) ng instruction (passen- rcraft) onmentally hazardous	: 956 : yes	
UN n	<b>-Code</b> umber er shipping name	: UN 3077 : ENVIRONME N.O.S. (oxytetracycli	NTALLY HAZARDOUS SUBSTANCE, SOLID,
Label EmS	ng group s	: 9 : III : 9 : F-A, S-F : yes	
	sport in bulk according		ARPOL 73/78 and the IBC Code
	nal Regulations		
UN n	<b>944/12268</b> umber er shipping name	N.O.S.	NTALLY HAZARDOUS SUBSTANCE, SOLID,
Label	ng group	(oxytetracycl : 9 : III : 9 : no	ii i⊂ <i>)</i>
	ial precautions for use	r	
The tr based Sheet	ransport classification(s) d upon the properties of	provided herein a the unpackaged m cations may vary b	re for informational purposes only, and solely aterial as it is described within this Safety Data by mode of transportation, package sizes, and v

### **15. REGULATORY INFORMATION**

### National regulatory information Law on the Prevention and Control of Occupational Diseases

according to GB/T 16483 and GB/T 17519



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					~		
	-	i <b>tions on Safety Man</b> gue of Hazardous Che	-		s Che	en	nicals 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.
	Identific 18218)	cation of Major Hazard	d Ins	tallations for Hazar	dous	C	hemicals (GB : Not listed
	Hazard SAWS	ous Chemicals for Pri	ority	Management unde	er :		Not listed
11	Regula	tions on Labour Pro	tect	ion in Workplaces	s whe	re	Toxic Substances are Used
	Catalog	gue of Highly Toxic Cl	nemi	cals	:		Not listed
		tion of Environment port of Toxic Chemi			e Firs	t I	mport of Chemicals and the Import
	China S and Ex	Severely Restricted To port	oxic	Chemicals for Impo	ort :	:	Not listed
	Regula	tion on the Adminis	trati	on of Precursor C	hemi	Ca	als
	Catalog	gue and Classification	of F	Precursor Chemical	s :		Not listed
	Yangtz	e River Protection L	aw				
	This pr	oduct does not contai	n an	y dangerous chemi	icals p	orc	bhibited for inland river transport.
		mponents of this pr			the fo	<b>)</b>	owing inventories:
	DSL		:	not determined			
	AICS		:	not determined			
	IECSC		:	not determined			
16. C	THER	INFORMATION					
	Revisio	n Date	:	2024/09/28			
	Furthe	r information					
		s of key data used to e the Safety Data	:		arch re	es	ata from raw material SDSs, OECD sults and European Chemicals Agen- /
		where changes have b ent by two vertical line		made to the previo	ous ve	rs	ion are highlighted in the body of this

Date format : yyyy/mm/dd

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#### 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 - Verv Persistent and Verv 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 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