according to GB/T 16483 and GB/T 17519



# Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
5.0	2024/09/28	5727281-00013	Date of first issue: 2020/04/27

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

Product name	:	Amoxicillin Trihydrate Formulation					
Manufacturer or supplier's de Company	etai :	i <b>ls</b> 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 white to off-white No data available
May cause allergy or asthma s life with long lasting effects.	ym	ptoms or breathing difficulties if inhaled. Very toxic to aquatic
GHS Classification		
Respiratory sensitisation	:	Category 1
Short-term (acute) aquatic hazard	:	Category 1
Long-term (chronic) aquatic hazard	:	Category 1
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger

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Hazar	d statements	difficulties if inh	se allergy or asthma symptoms or breathing naled. ic to aquatic life with long lasting effects.
Preca	utionary statements		eathing dust. ease to the environment. spiratory protection.
		keep comfortal	
		<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 cause allergy or asthma symptoms or breathing difficulties if inhaled.

#### **Environmental hazards**

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

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

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

#### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	>= 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.
II IIIIaeu	·	

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		lf b		ive artificial respiration. cult, give oxygen.	
In ca	ase of skin contact	: Wa	sh with water a		
In ca	ase of eye contact	: If in	eyes, rinse we	ell with water.	
lf sw	If swallowed		wallowed, DO	tion if irritation develops and persists. NOT induce vomiting. tion if symptoms occur.	
	t important symptoms effects, both acute and yed	: Ma ties Exc oth tive Con the	<ul> <li>Rinse mouth thoroughly with water.</li> <li>May cause allergy or asthma symptoms or breathing ties if inhaled.</li> <li>Excessive exposure may aggravate preexisting as other respiratory disorders (e.g. emphysema, brown tive airways dysfunction syndrome).</li> <li>Contact with dust can cause mechanical irritation the skin.</li> </ul>		
Prot	Protection of first-aiders		Dust contact with the eyes can lead to mechanical irritation. 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).		
Note	es to physician		Treat symptomatically and supportively.		
5. FIREF	IGHTING MEASURES				
Suita	able extinguishing media	Alc Cai	ter spray ohol-resistant f bon dioxide (C chemical		
Uns med	uitable extinguishing ia	: Noi	ne known.		
Speo fight	cific hazards during fire- ing	con pot	: Avoid generating dust; fine dust dispersed in air in sur concentrations, and in the presence of an ignition sou potential dust explosion hazard. Exposure to combustion products may be a hazard to		
Haza ucts	ardous combustion prod-	: Cai	bon oxides		
Spec ods	cific extinguishing meth-	cun Use Rei so.	nstances and t 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	
	cial protective equipment refighters			e, wear self-contained breathing apparatus. ective equipment.	

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#### 6. ACCIDENTAL RELEASE MEASURES

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	:	Surround spill with absorbents and place a damp covering over the area to minimise entry of the material into the air. Add excess liquid to allow the material to enter into solution. Soak up with inert absorbent material. 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. Clean up remaining materials from spill with suitable absor- bent. 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.

### 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 and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe dust.
		Do not swallow.
		Avoid contact with eyes.
		Avoid prolonged or repeated contact with skin.
		Handle in accordance with good industrial hygiene and safety
		practice, based on the results of the workplace exposure as- sessment
		Keep container tightly closed.
		Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease,

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Avoid	Avoidance of contact		<ul> <li>should consult their physician regarding working with tory irritants or sensitisers.</li> <li>Minimize dust generation and accumulation.</li> <li>Keep container closed when not in use.</li> <li>Keep away from heat and sources of ignition.</li> <li>Take precautionary measures against static discharge Take care to prevent spills, waste and minimize releatenvironment.</li> <li>Oxidizing agents</li> </ul>	
Stora	age			
Conditions for safe storage Materials to avoid		:	Keep tightly close Store in accordar	nce with the particular national regulations. the following product types:
Pack	aging material	:	Unsuitable mater	ial: 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				
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m3 (OEB 1)	Internal				
	Further inform	ation: RSEN						
Engineering measures	<ul> <li>Use feasible engineering controls to minimize exposure to compound.</li> <li>All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.</li> </ul>							
Personal protective equipme	nt							
Respiratory protection	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	: Particulates t	~ 1						
Eye/face protection	If the work er mists or aero Wear a faces	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 Hand protection	: Work uniform	or laboratory co	at.					
Material	: Chemical-res	istant gloves						
Hygiene measures	: If exposure to	If exposure to chemical is likely during typical use, provide						

### Components with workplace control parameters

according to GB/T 16483 and GB/T 17519



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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

Appearance	:	powder
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	4.5 - 6.5 (as aqueous solution)
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		

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Water solubility	: 0.3125 g/l partly soluble
Partition coefficient: n-	: Not applicable
octanol/water Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity Viscosity, kinematic	: Not applicable
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available
Particle characteristics Particle size	: No data available
STABILITY AND REACTIVITY	1
Reactivity Chemical stability Possibility of hazardous reac- tions	<ul> <li>Not classified as a reactivity hazard.</li> <li>Stable under normal conditions.</li> <li>May form explosive dust-air mixture during processing, har dling or other means.</li> <li>Can react with strong oxidizing agents.</li> </ul>
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials Hazardous decomposition products	<ul> <li>Avoid dust formation.</li> <li>Oxidizing agents</li> <li>No hazardous decomposition products are known.</li> </ul>
TOXICOLOGICAL INFORMA	ΓΙΟΝ
Exposure routes	: Inhalation Skin contact Ingestion Eye contact
Acute toxicity	
Not classified based on availa	ble information.
Components:	
Amoxicillin Trihydrate: Acute oral toxicity	: LD50 (Rat): > 8,000 mg/kg
	LD50 (Mai): > 10,000 mg/kg

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П			
		LD50 (Dog): >	• 3,000 mg/kg
	corrosion/irritation	ailable information.	
	ous eye damage/eye		
	lassified based on ava		
Resp	piratory or skin sensi	tisation	
-	sensitisation		
	lassified based on ava		
-	<b>iratory sensitisation</b> cause allergy or asthn		hing difficulties if inhaled.
Com	ponents:		
Amo	xicillin Trihydrate:		
Resu Rema			nsitisation by inhalation. on human evidence
	n cell mutagenicity lassified based on ava	ailable information.	
Com	ponents:		
Amo	xicillin Trihydrate:		
	otoxicity in vitro	: Test Type: Ba Result: negati	cterial reverse mutation assay (AMES) ve
Geno	otoxicity in vivo	: Test Type: Mi Species: Mou Result: negati	
		Test Type: Ro Species: Mou Result: negati	
11			

#### Carcinogenicity

Not classified based on available information.

## Reproductive toxicity

Not classified based on available information.

#### Components:

#### Amoxicillin Trihydrate:

Effects on fertility

: Test Type: Fertility

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ersion .0	Revision Date: 2024/09/28	SDS Number: 5727281-00013	Date of last issue: 2024/07/06 Date of first issue: 2020/04/27
Effects	s on foetal develop-	Result: Reduce Remarks: Not c Test Type: Ferti Species: Rat Application Rou Fertility: LOAEL Result: Reduce Remarks: Not c Test Type: Deve Species: Rat Application Rou Developmental Result: No emb Test Type: Deve Species: Mouse Application Rou Developmental Result: Some e based on anima Remarks: Not c Test Type: Deve Species: Rat Application Rou Developmental Result: Some e based on anima Remarks: Not c	: 200 mg/kg body weight d fertility lassified due to inconclusive data. lity te: Oral : 500 mg/kg body weight d fertility lassified due to inconclusive data. elopment te: Oral Toxicity: NOAEL: >= 1,000 mg/kg body weight ryo-foetal toxicity elopment te: Oral Toxicity: LOAEL: 200 mg/kg body weight vidence of adverse effects on development, al experiments. lassified due to inconclusive data. elopment
	- single exposure assified based on avai	lable information	
STOT	<ul> <li>repeated exposure assified based on avairable</li> </ul>		
	onents:		
	icillin Trihydrate:		
Rema	rks	: Not classified d	ue to inconclusive data.
Repea	ated dose toxicity		
<u>Comp</u>	onents:		
Amox	icillin Trihydrate:		

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Expos Rema Speci Applic	ation Route sure time rks		Rat Oral 6 Months No significant ac Dog Oral 6 Months	dverse effects were reported			
Rema		:	6 Months No significant adverse effects were reported				
•	ation toxicity						
	assified based on availa						
-	rience with human exp ponents:	osi	Ire				
	cicillin Trihydrate:	:	flatulence, skin i	sea, Vomiting, Abdominal pain, Diarrhoea, rash, Breathing difficulties produce an allergic reaction.			
ECOLO	OGICAL INFORMATIO	N					
	oxicity						
<u>Comp</u>	oonents:						
<u>Comr</u> Amox	-	:	Exposure time:	s auratus (goldfish)): 0.035 mg/l 96 h Test Guideline 203			
Comr Amox Toxici	oonents: xicillin Trihydrate: ty to fish ty to algae/aquatic	:	Exposure time:	96 h Test Guideline 203 gae): 530 mg/l			
Comr Amox Toxici	oonents: xicillin Trihydrate: ty to fish ty to algae/aquatic	:	Exposure time: Method: OECD NOEC (green al Exposure time:	96 h Test Guideline 203 gae): 530 mg/l 72 h coccus leopoliensis (blue-green algae)):			
Comr Amox Toxici	oonents: xicillin Trihydrate: ty to fish ty to algae/aquatic	:	Exposure time: Method: OECD NOEC (green al Exposure time: EC50 (Synecho 0.0022 mg/l Exposure time:	96 h Test Guideline 203 gae): 530 mg/l 72 h coccus leopoliensis (blue-green algae)): 96 h en algae): 0.0057 mg/l			
Comr Amox Toxici plants M-Fac icity)	oonents: xicillin Trihydrate: ty to fish ty to algae/aquatic	:	Exposure time: Method: OECD NOEC (green al Exposure time: EC50 (Synecho 0.0022 mg/l Exposure time: NOEC (blue-gree	96 h Test Guideline 203 gae): 530 mg/l 72 h coccus leopoliensis (blue-green algae)): 96 h en algae): 0.0057 mg/l			

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Persis	stence and degradabi	lity		
<u>Comp</u>	onents:			
Amox	icillin Trihydrate:			
Biodeç	gradability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD T	88 %
Bioac	cumulative potential			
<u>Comp</u>	onents:			
Amox	icillin Trihydrate:			
Bioaco	cumulation	:	Remarks: Bioacc	umulation is unlikely.
	on coefficient: n- bl/water	:	log Pow: -0.124 Method: OECD T	est Guideline 107
Mobili	ity in soil			
No dat	ta available			
Other	adverse effects			
<u>Comp</u>	onents:			
	<b>icillin Trihydrate:</b> ts of PBT and vPvB sment	:	Product does not	persistent, bioaccumulative, and toxic (PBT). contain substances which are very persis- accumulative (vPvB) at levels of 0.1% or
II 3. DISPO	SAL CONSIDERATIO	NS		
Dispo	sal 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,

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			N.O.S. (Amoxicillin Trihy	/drate)
	ass	:	9	
	acking group abels	÷	 9	
	nvironmentally hazardous	:	yes	
	-	•	,	
	A <b>TA-DGR</b> N/ID No.		UN 3077	
-	roper shipping name	:		nazardous substance, solid, n.o.s.
	opor omporing hamo	•	(Amoxicillin Trihy	
C	ass	:	9	
	acking group	:	III	
	abels	:	Miscellaneous	
	acking instruction (cargo rcraft)		956	
	acking instruction (passen-		956	
	er aircraft)	•		
	nvironmentally hazardous	:	yes	
IN	IDG-Code			
	N number	:	UN 3077	
Pi	roper shipping name	:	ENVIRONMENT	ALLY HAZARDOUS SUBSTANCE, SOLID,
			N.O.S.	
			(Amoxicillin Trihy	drate)
	ass	÷	9	
	acking group abels	÷	 9	
	mS Code	:	9 F-A, S-F	
	arine 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**

#### GB 6944/12268

UN number Proper shipping name	:	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
		N.O.S.
		(Amoxicillin Trihydrate)
Class	:	9
Packing group	:	
Labels	:	9
Marine pollutant	:	no

#### 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.

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

Law on the Prevention and Regulations on Safety Mana	gement of Hazar	dous Che	micals
Catalogue of Hazardous Cher	-	:	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 Hazard 18218)	Installations for H	azardous (	Chemicals (GB : Not listed
Hazardous Chemicals for Price SAWS	Hazardous Chemicals for Priority Management under SAWS		
Regulations on Labour Prot	ection in Workpl	aces wher	e Toxic Substances are Used
	Catalogue of Highly Toxic Chemicals		Not listed
Regulation of Environmenta and Export of Toxic Chemic		n the First	Import of Chemicals and the Import
China Severely Restricted To: and Export	kic Chemicals for	Import :	Not listed
Regulation on the Administ		or Chemic	als
	of Precursor Chen	nicals :	Not listed
Yangtze River Protection La		nicals :	Not listed
-	w		Not listed
-	<b>w</b> any dangerous cl	hemicals pi d in the fol	ohibited for inland river transport.
This product does not contain The components of this pro	<b>w</b> any dangerous cl <b>duct are reporte</b> d	hemicals pi <b>d in the fol</b> ed	ohibited for inland river transport.
This product does not contain <b>The components of this pro</b> AICS	<b>w</b> any dangerous cl <b>duct are reporte</b> : not determine	hemicals pi <b>d in the fol</b> ed ed	ohibited for inland river transport.
This product does not contain <b>The components of this pro</b> AICS DSL	w any dangerous cl duct are reported : not determine : not determine	hemicals pi <b>d in the fol</b> ed ed	ohibited for inland river transport.
This product does not contain <b>The components of this pro</b> AICS DSL IECSC	w any dangerous cl duct are reported : not determine : not determine	hemicals pi <b>d in the fol</b> ed ed	ohibited for inland river transport.
This product does not contain <b>The components of this pro</b> AICS DSL IECSC <b>5. OTHER INFORMATION</b>	w any dangerous cl duct are reported : not determine : not determine : not determine	hemicals pi <b>d in the fol</b> ed ed	ohibited for inland river transport.

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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 to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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CN/EN