according to GB/T 16483 and GB/T 17519



Posaconazole Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
7.0	2024/09/28	22497-00024	Date of first issue: 2014/10/16

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Posaconazole Injection Formulation					
Manufacturer or supplier's de	Manufacturer or supplier's details						
Company	:	MSD					
Address	:	199 Wenhai North Road HEDA, Hangzhou - Zhejiang Province - CHINA 310018					
Telephone	:	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	:	Pharmaceutical Not applicable					

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance Colour Odour	:	Aqueous solution Colorless to pale yellow odourless			
May cause an allergic skin reaction. May cause damage to organs through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.					
GHS Classification Skin sensitisation	:	Category 1			
Specific target organ toxicity - repeated exposure	:	Category 2			
Short-term (acute) aquatic hazard	:	Category 3			
Long-term (chronic) aquatic hazard	:	Category 3			

GHS label elements

according to GB/T 16483 and GB/T 17519



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Hazar	d pictograms	:	
Signa	l word	: Warning	
Hazar	d statements	H373 May ca peated expos	use an allergic skin reaction. use damage to organs through prolonged or re- ure. I to aquatic life with long lasting effects.
Preca	utionary statements	P272 Contam the workplace P273 Avoid re	breathe mist or vapours. ninated work clothing should not be allowed out o e. elease to the environment. rotective gloves.
		P314 Get me P333 + P313 vice/ attentior	IF ON SKIN: Wash with plenty of water. dical advice/ attention if you feel unwell. If skin irritation or rash occurs: Get medical ad- n. Take off contaminated clothing and wash it befo
		Disposal: P501 Dispose disposal plant	e of contents/ container to an approved waste

Not classified based on available information.

Health hazards

May cause an allergic skin reaction. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards

Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
.betaCyclodextrin, sulfobutyl ethers, sodium	182410-00-0	>= 30 -< 50
salts		

according to GB/T 16483 and GB/T 17519



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P	osacoi	nazole		1'	71228-49-2	>= 1 -< 2.5			
4. FIR		DMEASURES							
G	General advice		:	vice immediately	·. ·	eel unwell, seek medical ad- cases of doubt seek medical			
lf	f inhale	d	:	If inhaled, remov					
Ir	In case of skin contact			Get medical attention. In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.					
Ir	n case	of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.					
lf	If swallowed		:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.					
а	Most important symptoms and effects, both acute and delayed			Diarrhoea Fever Headache Nausea Vomiting May cause an allergic skin reaction. May cause damage to organs through prolonged or repeated exposure.					
Ρ	Protection of first-aiders		:	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).					
		o physician	:	Treat symptoma	tically and support	rtively.			
5. FIR	EFIGH	ITING MEASURES							
S	Suitable extinguishing media : Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical								
	Jnsuital nedia	ble extinguishing	:	None known.					
	Specific ghting	hazards during fire-	:	Exposure to corr	bustion products	may be a hazard to health.			
	lazardo icts	ous combustion prod-	:	: Carbon oxides Sulphur oxides Metal oxides					

according to GB/T 16483 and GB/T 17519



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Specific extinguishing meth- ods		:	cumstances and Use water spray	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 do	
	al protective equipment efighters	:		e, wear self-contained breathing apparatus. tective equipment.	
6. ACCID	ENTAL RELEASE MEA	SUF	RES		
tive e	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).		
Envir	onmental precautions	:	 Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. 		
	ods and materials for inment and cleaning up	:	 Soak up with inert absorbent material. For large spills, provide dyking or other appropriate of ment to keep material from spreading. If dyked mate be pumped, store recovered material in appropriate of Clean up remaining materials from spill with suitable bent. Local or national regulations may apply to releases a posal of this material, as well as those materials and employed in the cleanup of releases. You will need to mine which regulations are applicable. Sections 13 and 15 of this SDS provide information r certain local or national requirements. 		

Handling

Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: Use only with adequate ventilation.
Advice on safe handling	: Do not get on skin or clothing.
	Do not breathe mist or vapours.
	Do not swallow.
	Avoid contact with eyes.
	Wash skin thoroughly after handling.
	 Use only with adequate ventilation. Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes.

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Avoidance of contact		:	 Handle in accordance with good industrial hygiene and sa practice, based on the results of the workplace exposure sessment Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to environment. Oxidizing agents 	
Stora	ge			
Conditions for safe storage Materials to avoid		:	Keep in properly labelled containers. Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents	
Packaging material		:	Unsuitable materi	al: 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		
Posaconazole	171228-49-2	TWA	300 µg/m3 (OEB 2)	Internal		
Engineering measures	technologies less quick con All engineerin design and op protect produ	to control airborr nnections). Ig controls should berated in accord cts, workers, and	controls and manufac ne concentrations (e.c d be implemented by dance with GMP princ d the environment. require special contai	g., drip- facility ciples to		
Personal protective equipme	nt					
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 Eye/face protection	: Wear safety of If the work en mists or aeros Wear a faces	Particulates type 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. Work uniform or laboratory coat. Chemical-resistant gloves				
Skin and body protection Hand protection Material	: Work uniform					
Hygiene measures	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work- ing place.					

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When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. 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	:	Aqueous solution
Colour	:	Colorless to pale yellow
Odour	:	odourless
Odour Threshold	:	No data available
рН	:	2.6
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1.15 g/cm ³
Solubility(ies) Water solubility	:	No data available

according to GB/T 16483 and GB/T 17519



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	ion coefficient: n- ol/water	: Not applicable	
Auto-	ignition temperature	: No data availa	ble
Deco	mposition temperature	: No data availa	ble
Visco Vis	sity scosity, kinematic	: No data availa	ble
Explo	sive properties	: Not explosive	
Oxidi	zing properties	: The substance	e or mixture is not classified as oxidizing.
Moleo	cular weight	: No data availa	ble
	cle characteristics cle size	: Not applicable	
0. STAB	ILITY AND REACTIVIT	Y	
	tivity nical stability ibility of hazardous reac	: Stable under n	as a reactivity hazard. formal conditions. strong oxidizing agents.
Cond Incom	itions to avoid npatible materials rdous decomposition ucts	None known.Oxidizing agerNo hazardous	nts decomposition products are known.
1. TOXIC	OLOGICAL INFORMA	TION	
Expo	sure routes	: Inhalation Skin contact Ingestion Eye contact	
	e toxicity lassified based on availa	able information.	
<u>Com</u>	ponents:		
	-Cyclodextrin, sulfobute oral toxicity	ityl ethers, sodium : LD50 (Rat): > 8	
II Posa	conazole:		
	conazole: e oral toxicity	: LD50 (Rat): > 5	5,000 mg/kg
		: LD50 (Rat): > 5 LD50 (Mouse):	

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Skin corrosion/irritation

Not classified based on available information.

Components:

Posaconazole:

Species Result	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Posaconazole:

Species	:	Rabbit
Result	:	Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:

Assessment

: Probability or evidence of skin sensitisation in humans

Posaconazole:

Test Type	: Magnusson-Kligman-Test
Exposure routes	: Skin contact
Species	: Guinea pig
Test Type Exposure routes Species Result	: negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Posaconazole:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosomal aberration Result: negative

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Geno	toxicity in vivo	:	Test Type: Micror Species: Mouse Cell type: Bone m Application Route Result: negative	narrow
Not cl	nogenicity assified based on avail ponents:	able	information.	
Posa Speci Applio	conazole: es cation Route sure time t	:	Rat oral (feed) 2 Years positive The mechanism o	or mode of action is not relevant in humans.
	cation Route sure time t	:	Mouse Oral 2 Years positive The mechanism o	or mode of action is not relevant in humans.
Not cl	oductive toxicity assified based on avail ponents: -Cyclodextrin, sulfob			alts:
Effect	s on fertility	:	Test Type: Fertilit Species: Rat Application Route Result: negative	y e: Intravenous injection
Effect ment	s on foetal develop-	:	Species: Rat	vo-foetal development e: Intravenous injection
	conazole: s on fertility	:		y/early embryonic development
			Species: Rat, ma General Toxicity	
			Test Type: Fertilit	y/early embryonic development

Test Type: Fertility/early embryonic development Species: Rat, female General Toxicity - Parent: NOAEL: 45 mg/kg body weight

according to GB/T 16483 and GB/T 17519



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Effects	s on foetal develop-	:	Result: negative Test Type: Embry Species: Rat, fem Application Route Developmental To Result: Fetotoxici Test Type: Embry Species: Rabbit, f	e: Oral oxicity: LOAEL: 29 mg/kg body weight ty, Malformations were observed. vo-foetal development female oxicity: LOAEL: 40 mg/kg body weight
Repro-	ductive toxicity - As-	:	Some evidence o	f adverse effects on development, based on
sessm	ent		animal experimen	ts.
STOT	- single exposure			

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Posaconazole:

	Exposure routes	:	Ingestion
	Exposure routes Target Organs	:	Adrenal gland, Bone marrow, Kidney, Liver, Reproductive
			organs, Nervous system
	Assessment	:	Causes damage to organs through prolonged or repeated
I			exposure.

Repeated dose toxicity

Components:

Posaconazole:

Species LOAEL Application Route Exposure time Target Organs	 Rat, female 5 mg/kg Oral 6 Months Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary
Species LOAEL Application Route Exposure time Target Organs	 Dog 3 mg/kg Oral 392 Days Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue
Species	: Monkey

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LOAEL Application Route Exposure time Target Organs	: 15 mg/kg : Oral : 1 Months : Bone marrow, A	drenal gland, Lymph nodes, Blood
Species LOAEL Application Route Exposure time Target Organs		Bone marrow, Kidney, Nervous system, gland, Testis, lymphoid tissue
Species LOAEL Application Route Exposure time Target Organs	: Monkey : 180 mg/kg : Oral : 12 Months : Blood, Gastroin	testinal tract, spleen
Species LOAEL Application Route Exposure time Target Organs	: Monkey : 8 mg/kg : Intravenous : 1 Months : Cardio-vascular	system, Lungs, Adrenal gland, Blood
Aspiration toxicity Not classified based on ava	ilable information.	
Experience with human ex Components:	cposure	

Posaconazole:

Ingestion

: Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritis, Diarrhoea, hypertension, neutropenia, electrolyte imbalance

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 220 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 96 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Selenastrum capricornutum (green algae)): > 100 mg/l Exposure time: 72 h

according to GB/T 16483 and GB/T 17519



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II

Posaconazole:		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.95 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0.276 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.509 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic tox-	:	1
icity) Toxicity to fish (Chronic tox- icity)	:	NOEC (Pimephales promelas (fathead minnow)): 0.206 mg/l Exposure time: 33 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.244 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
M-Factor (Chronic aquatic	:	1
toxicity) Toxicity to microorganisms	:	EC50 (Natural microorganism): > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Persistence and degradabili	ty	

Components:

Posaconazole:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 50 % Exposure time: 28 h Method: OECD Test Guideline 314
Stability in water	:	Degradation half life (DT50): > 30 d

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		1	Method: OECD T	est Guideline 111	
Bioad	ccumulative potential				
<u>Com</u>	ponents:				
Posa	conazole:				
Bioac	cumulation	E	Bioconcentration	macrochirus (Bluegill sunfish) factor (BCF): 20 est Guideline 305	
	ion coefficient: n- ol/water	:	og Pow: 4.15		
Mobi	lity in soil				
Com	ponents:				
Posa	conazole:				
	bution among environ- al compartments	: 1	og Koc: 5.52		
	r adverse effects ata available				

Disposal m	ethods
------------	--------

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number Proper shipping name Class Subsidiary risk Packing group Labels Environmentally hazardous		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no
IATA-DGR UN/ID No. Proper shipping name Class Subsidiary risk	:	Not applicable Not applicable Not applicable Not applicable

Packing group

Marine pollutant

Not applicable

Special precautions for user

National regulatory information

15. REGULATORY INFORMATION

Labels

according to GB/T 16483 and GB/T 17519



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Labe Pack aircra Pack	ing instruction (cargo	 Not applicable Not applicable Not applicable Not applicable 	
UN n Prope Class Subs Pack Labe EmS	idiary risk ing group	 Not applicable no 	
	sport in bulk according	-	RPOL 73/78 and the IBC Code
Natio	onal Regulations		
UN n Prope Class	944/12268 umber er shipping name s idiary risk	Not applicableNot applicableNot applicableNot applicableNot applicable	

Not applicable

Not applicable

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

:

:

: no

Regulations on earcry management of nazardous onen	lical3
Catalogue of Hazardous 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 Hazard Installations for Hazardous Cl 18218)	hemicals (GB : Not listed
Hazardous Chemicals for Priority Management under : SAWS	Not listed

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Regu	Ilations on Labour P	rotection in Workpla	ces where Toxic Substances are Used
Catal	ogue of Highly Toxic	Chemicals	: Not listed
	llation of Environme Export of Toxic Cher		the First Import of Chemicals and the Import
	a Severely Restricted Export	Toxic Chemicals for In	nport : Not listed
Requ	lation on the Admin	istration of Precurso	r Chemicals
-		on of Precursor Chemi	
Yang	stze River Protection	Law	
This	product does not cont	ain any dangerous che	emicals prohibited for inland river transport.
The c	components of this	product are reported	in the following inventories:
AICS		: not determined	
DSL		: not determined	ł
IECS	С	: not determined	ł
16. OTHE	R INFORMATION		
Revis	sion Date	: 2024/09/28	
	or information		

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

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 con-



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centration: 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.

CN / EN