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SECTION 1. IDENTIFICATION

Product name Other means of identification		Amoxicillin Trihydrate / Potassium Clavulanate Formulation No data available					
Manufacturer or supplier's o	deta	ails					
Company name of supplier	:	Merck & Co., Inc					
Address	:	126 E. Lincoln Avenue					
		Rahway, New Jersey U.S.A. 07065					
Telephone	:	908-740-4000					
Emergency telephone	:	1-908-423-6000					
E-mail address	:	EHSDATASTEWARD@merck.com					
Recommended use of the c	Recommended use of the chemical and restrictions on use						

	•	
Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

	GHS classification in accordance with the Hazardous Products Regulations Respiratory sensitization : Sub-category 1A				
GHS label elements Hazard pictograms	:				
Signal Word	:	Danger			
Hazard Statements	:	H334 May cause allergy or asthma symptoms or breathing diffi- culties if inhaled.			
Precautionary Statements	:	Prevention: P261 Avoid breathing mist or vapors. P284 Wear respiratory protection.			
		Response: P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a doc- tor.			
		Disposal: P501 Dispose of contents and container to an approved waste disposal plant.			



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Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

oomponomo			
Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Amoxicillin Trihydrate	No data availa- ble	61336-70-7	>= 14.6264 - <= 17.8767
Aluminum tristearate	Octadecanoic acid, aluminum salt (3:1)	637-12-7	>= 2.02 - <= 2.4689
Benzyl alcohol	Benzenemetha- nol	100-51-6	>= 0.9091 - <= 1.1111

SECTION 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical
If inhaled	:	advice. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
In case of skin contact	:	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis,
Protection of first-aiders	:	reactive airways dysfunction syndrome). 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).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2)
		Dry chemical
Unsuitable extinguishing	:	None known.



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t f	fighting	c hazards during fire ous combustion prod-	:	Exposure to comb Carbon oxides Metal oxides Nitrogen oxides (N	oustion products may be a hazard to health.	
Specific extinguishing meth- ods Special protective equipment for fire-fighters		:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.			
SEC	TION 6	ACCIDENTAL RELE	ASE	E MEASURES		
t	Personal precautions, protec- tive equipment and emer- gency procedures			Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).		
ł	Environmental precautions		:	Prevent spreading oil barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g., by containment or se of contaminated wash water. should be advised if significant spillages	
	Methods and materials for containment and cleaning up		:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked ma can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and it employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regar certain local or national requirements.		

SECTION 7. HANDLING AND STORAGE

: See Engineering measures under EXPOSURE
CONTROLS/PERSONAL PROTECTION section.
: Use only with adequate ventilation.
: Avoid breathing mist or vapors. Do not swallow.

SAFETY DATA SHEET according to the Hazardous Products Regulations



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		Handle in accord practice, based assessment Keep containe Already sensit to asthma, alle should consult respiratory irrit	with eyes. ed or repeated contact with skin. ordance with good industrial hygiene and safety d on the results of the workplace exposure r tightly closed. ized individuals, and those susceptible ergies, chronic or recurrent respiratory disease, their physician regarding working with ants or sensitizers. revent spills, waste and minimize release to the
Condi	tions for safe storage	Keep tightly cl	
Materials to avoid			dance with the particular national regulations. ith the following product types: ig agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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	nation: RSEN		
Aluminum tristearate	637-12-7	TWA	10 mg/m ³	CA AB OEL
		TWA (Res- pirable)	1 mg/m ³ (Aluminum)	CA BC OEL
		TWAEV	10 mg/m ³	CA QC OEL
		TWA (Inhal- able)	10 mg/m ³	CA BC OEL
		TWA (Res- pirable)	3 mg/m ³	CA BC OEL
		TWAEV (respirable dust)	5 mg/m³	CA QC OEL
		TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH
		TWA (Respirable particulate matter)	1 mg/m³ (Aluminum)	ACGIH

Ingredients with workplace control parameters



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Engineering measures		:	Use appropriate engineering controls and manufacturi technologies to control airborne concentrations (e.g., o less quick connections). All engineering controls should be implemented by fac design and operated in accordance with GMP principle protect products, workers, and the environment. Laboratory operations do not require special containm			
Perso	nal protective equipm	ent				
Respiratory protection		:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside th recommended guidelines, use respiratory protection. Combined particulates and organic vapor type			
Hand protection Material		:	Chemical-resistant gloves			
Eye protection		:	If the work environ mists or aerosols, Wear a faceshield	ses with side shields or goggles. Inment or activity involves dusty conditions, wear the appropriate goggles. If or other full face protection if there is a t contact to the face with dusts, mists, or		
	nd body protection ne measures	:	Work uniform or la If exposure to che eye flushing syste working place. When using do no Wash contaminat The effective oper engineering contr appropriate degov	emical is likely during typical use, provide ems and safety showers close to the ot eat, drink or smoke. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, whing and decontamination procedures, monitoring, medical surveillance and the		

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Color	:	cream
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available

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	Flash p	point	:	No data available)
	Evapor	ation rate	:	No data available	9
	Flamm	ability (solid, gas)	:	Not applicable	
	Flamm	ability (liquids)	:	No data available)
		explosion limit / Upper ability limit	:	No data available	
		explosion limit / Lower ability limit	:	No data available	
	Vapor	pressure	:	Not applicable	
	Relativ	e vapor density	:	No data available)
	Relativ	e density	:	No data available)
	Density	/	:	0.900 - 1.100 g/c	m ³
	Solubil Wat	ity(ies) ter solubility	:	No data available	9
		n coefficient: n-	:	No data available	
	octano Autoigr	nition temperature	:	No data available	
	Decom	position temperature	:	No data available)
	Viscosi Visc	ity cosity, kinematic	:	No data available	9
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	ılar weight	:	No data available	9
	Particle Particle	e characteristics e size	:	No data available	9

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.
tions		
Conditions to avoid	:	None known.



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	npatible materials rdous decomposition icts	:	Oxidizing ager No hazardous	nts decomposition products are known.
SECTION	11. TOXICOLOGICAL	. INF	ORMATION	
Inhala Skin o Inges	contact	s of	exposure	
Acute	e toxicity			
Not c	lassified based on avai	lable	information.	
Prod	uct:			
Acute	e oral toxicity	:	Acute toxicity e Method: Calcul	stimate: > 2,000 mg/kg ation method
Acute	inhalation toxicity	:	Acute toxicity e Exposure time: Test atmosphe Method: Calcul	re: dust/mist
Com	oonents:			
Amo	kicillin Trihydrate:			
Acute	e oral toxicity	:	LD50 (Rat): > 8	8,000 mg/kg
			LD50 (Mouse):	> 10,000 mg/kg
			LD50 (Dog): > 3	3,000 mg/kg
Alum	inum tristearate:			
Acute	oral toxicity	:		ale): > 2,000 mg/kg d on data from similar materials
Acute	inhalation toxicity	:		4 h
Benz	yl alcohol:			
Acute	oral toxicity	:	LD50 (Rat): 1,6	i20 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 4 Exposure time: Test atmosphe Method: OECD	4 h



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Skin corrosion/irritation

Not classified based on available information.

Components:

Aluminum tristearate:

Species Method Remarks	 reconstructed human epidermis (RhE) OECD Test Guideline 439 Based on data from similar materials 	
Result	: No skin irritation	
Benzyl alcohol:	. Dekkit	

Species	: Rabbit
Method	: OECD Test Guideline 404
Species Method Result	: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Aluminum tristearate:

Species :	Rabbit
Result :	No eye irritation
Method :	OECD Test Guideline 405
Species:Result:Method:Remarks:	Based on data from similar materials

Benzyl alcohol:

Species : Result : Method :	Rabbit
Result :	Irritation to eyes, reversing within 21 days
Method :	OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

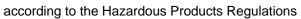
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

Amoxicillin Trihydrate:

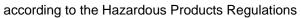
	:	Sensitizer
Remarks	:	May cause sensitization by inhalation.
		largely based on human evidence

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Alumi	num tristearate:							
Test Type Routes of exposure Species Method Result Remarks			 Local lymph node assay (LLNA) Skin contact Mouse OECD Test Guideline 429 negative Based on data from similar materials 					
Benzy	l alcohol:							
Test T	ype s of exposure es d		Maximization Tes Skin contact Guinea pig OECD Test Guide negative					
	cell mutagenicity assified based on avail	able	information.					
<u>Comp</u>	onents:							
Amox	icillin Trihydrate:							
Genot	oxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)				
Genot	oxicity in vivo	:	Test Type: Micror Species: Mouse Result: negative Test Type: Roder Species: Mouse Result: negative	nucleus test nt dominant lethal test (germ cell) (in vivo)				
Alumi	num tristearate:							
	oxicity in vitro	:	Method: OECD T Result: negative Remarks: Based	on data from similar materials				
			Method: OECD To Result: negative	rial reverse mutation assay (AMES) est Guideline 471 on data from similar materials				
Genot	oxicity in vivo	:	cytogenetic assay Species: Rat Application Route Method: OECD T Result: negative	: Ingestion				





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П				
	yl alcohol:			
	otoxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
Genc	otoxicity in vivo	:	cytogenetic assay Species: Mouse	nalian erythrocyte micronucleus test (in vivo y) e: Intraperitoneal injection
	inogenicity classified based on availa	able	information.	
<u>Com</u>	ponents:			
Benz	yl alcohol:			
	cation Route sure time od	:	Mouse Ingestion 103 weeks OECD Test Guide negative	eline 451
Not c	oductive toxicity classified based on availa	able	information.	
	ponents:			
	xicillin Trihydrate: ts on fertility		Test Type: Fertilit	N .
LICC		•	Species: Rat	
			Result: Reduced	200 mg/kg body weight
			Result: Reduced	e: Oral 500 mg/kg body weight
Effec	ts on fetal development	:	Test Type: Develor Species: Rat Application Route Developmental To Result: No embry	e: Oral oxicity: NOAEL: >= 1,000 mg/kg body weight
			Test Type: Devel Species: Mouse	opment

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			Result: Some evic based on animal Remarks: Not clas	oxicity: LOAEL: 200 mg/kg body weight dence of adverse effects on development, experiments. ssified due to inconclusive data.
			Result: Reduced weight gain.	
Alum	ninum tristearate:			
Effec	ts on fertility	:	Species: Rat Application Route Method: OECD To Result: negative	
Effec	ts on fetal development	:	Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion on data from similar materials
Benz	yl alcohol:			
Effec	ts on fertility	:	Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion on data from similar materials
Effec	ts on fetal development	:	Test Type: Embry Species: Mouse Application Route Result: negative	ro-fetal development : Ingestion
	F-single exposure lassified based on availa	able	information.	
STO	F-repeated exposure lassified based on availa			
	ponents:	IDIG		
	xicillin Trihvdrate:			

Amoxicillin Trihydrate:

Remarks

: Not classified due to inconclusive data.

according to the Hazardous Products Regulations



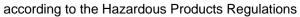
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Repe	ated dose toxicity				
Comp	oonents:				
Amox	cicillin Trihydrate:				
	cation Route sure time	: Rat : Oral : 6 Months : No significar	at adverse effects were reported		
Speci Applic Expos Rema	cation Route sure time	: Dog : Oral : 6 Months : No significar	Oral		
Alum	inum tristearate:				
	EL cation Route sure time	: Rat : >= 5,000 mg : Ingestion : 90 Days : Based on da	/kg ta from similar materials		
Benz	yl alcohol:				
	EL cation Route sure time	: 28 Days	ust/mist/fume) Guideline 412		
•	ation toxicity assified based on avai	ilable information.			
Expe	rience with human ex	cposure			
Comp	oonents:				
Amox	cicillin Trihydrate:				
Inges	tion	flatulence, sl	Nausea, Vomiting, Abdominal pain, Diarrhea, kin rash, Breathing difficulties ay produce an allergic reaction.		
SECTION	12. ECOLOGICAL IN	FORMATION			
Ecoto	oxicity				
Com	oonents:				
	cicillin Trihydrate:				
	ty to fish	Exposure tin	sius auratus (goldfish)): 0.035 mg/l ne: 96 h CD Test Guideline 203		



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	oxicity to algae/aquatic ants	:	NOEC (green alg Exposure time: 72	
			EC50 (Synechoco 0.0022 mg/l Exposure time: 96	occus leopoliensis (blue-green algae)): S h
			NOEC (blue-gree Exposure time: 72	n algae): 0.0057 mg/l 2 h
AI	uminum tristearate:			
Ec	cotoxicology Assessment			
Ac	cute aquatic toxicity	:	Toxic effects can	not be excluded
Cł	nronic aquatic toxicity	:	Toxic effects canr	not be excluded
Be	enzyl alcohol:			
Тс	oxicity to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): 460 mg/l 5 h
	oxicity to daphnia and other juatic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD T	
	oxicity to algae/aquatic ants	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD T	
			NOEC (Pseudokin mg/l Exposure time: 72 Method: OECD T	
ac	oxicity to daphnia and other juatic invertebrates (Chron- toxicity)		NOEC (Daphnia r Exposure time: 2 Method: OECD T	
Pe	ersistence and degradabil	ity		
<u>Co</u>	omponents:			
	noxicillin Trihydrate:			
Bi	odegradability	:	Result: Readily bi	odegradable.

: Result: Readily biodegradable.
Biodegradation: 88 %
Exposure time: 28 d
Method: OECD Test Guideline 301B





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	Benzyl alcohol: Biodegradability		: Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d	
Bioad	ccumulative potential			
<u>Com</u>	oonents:			
	cicillin Trihydrate:	:	Remarks: Bioacc	umulation is unlikely.
	ion coefficient: n- ol/water	: log Pow: -0.124 Method: OECD Test Guideline 107		est Guideline 107
Partiti	yl alcohol: ion coefficient: n- ol/water	:	log Pow: 1.05	
	l ity in soil ata available			
Other	r adverse effects			
<u>Com</u>	oonents:			
Resu	kicillin Trihydrate: Its of PBT and vPvB esment	:	Product does not	persistent, bioaccumulative, and toxic (PBT). contain substances which are very persis- accumulative (vPvB) at levels of 0.1% or

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal 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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. 	

SECTION 14. TRANSPORT INFORMATION

International Regulations



ersion D	Revision Date: 07/06/2024	SDS Number: 8845222-00012	Date of last issue: 04/06/2024 Date of first issue: 07/13/2021
Labels	ng group s nmentally hazardous	: 9 : III : 9 : yes	
IATA- I UN/ID	DGR	: UN 3082	ly hazardous substance, liquid, n.o.s.
Labels	ig instruction (cargo	: 9 : III : Miscellaneous : 964	
Packir ger air	instruction (passen-	: 964 : yes	
IMDG- UN nu Proper		: UN 3082 : ENVIRONMEN N.O.S. (Amoxicillin Tri	NTALLY HAZARDOUS SUBSTANCE, LIQUID,
Labels EmS (: 9 : III : 9 : F-A, S-F : yes	nyurate)
Trans	port in bulk according	to Annex II of MA	RPOL 73/78 and the IBC Code
•	plicable for product as	supplied.	
Dome	stic regulation		
TDG UN nu Propei	mber r shipping name	N.O.S.	NTALLY HAZARDOUS SUBSTANCE, LIQUID
Labels ERG ((Amoxicillin Tr : 9 : III : 9 : 171 : yes(Amoxicillir	
Speci a The tra	al precautions for use	r provided herein are	e for informational purposes only, and solely

based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:



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AICS		: not determined	
DSL		: not determined	
IECS	C	: not determined	

SECTION 16. OTHER INFORMATION

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Full text of other abbreviations						
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)				
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)				
CA BC OEL	:	Canada. British Columbia OEL				
CA QC OEL	:	Québec. Regulation respecting occupational health and safe- ty, Schedule 1, Part 1: Permissible exposure values for air- borne contaminants				
ACGIH / TWA	:	8-hour, time-weighted average				
CA AB OEL / TWA	:	8-hour Occupational exposure limit				
CA BC OEL / TWA	:	8-hour time weighted average				
CA QC OEL / TWAEV	:	Time-weighted average exposure value				

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 Recom-



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mendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material 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/
Revision Date Date format	-	07/06/2024 mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

CA / Z8