

Version 7.1	Revision Date: 30.09.2023	-	9S Number: 56292-00023	Date of last issue: 04.04.2023 Date of first issue: 13.02.2018		
SECTION 1. IDENTIFICATION						
Product name		:	Benzylpenicillin	/ Streptomycin Sulphate Solid Formulation		
Manufacturer or supplier's de Company		deta :	ils MSD			
Address		:	Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP			
Telephone		:	908-740-4000	908-740-4000		
Emergency telephone		:	1-908-423-6000			
E-ma	il address	:	EHSDATASTEV	VARD@msd.com		
	mmended use of the	••				
	mmended use ictions on use	:	Veterinary produ Not applicable	ıct		

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Acute toxicity (Oral)	:	Category 4
Serious eye damage/eye irritation	:	Category 2B
Respiratory sensitization	:	Category 1
Skin sensitization	:	Category 1
Reproductive toxicity	:	Category 1A
Specific target organ toxicity - repeated exposure	:	Category 1 (Kidney, inner ear)
Short-term (acute) aquatic hazard	:	Category 1
Long-term (chronic) aquatic hazard	:	Category 1

GHS label elements



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Hazar	d pictograms		
Signal	Word	: Danger	
Hazar	d Statements	H320 Causes H334 May cau difficulties if in H360D May d H372 Causes prolonged or r	use an allergic skin reaction. eye irritation. use allergy or asthma symptoms or breathing
Preca	utionary Statements	P202 Do not h and understoo P260 Do not k P264 Wash sl P270 Do not e P272 Contam the workplace P273 Avoid re P280 Wear pr tion/ face prot	preathe dust. kin thoroughly after handling. eat, drink or smoke when using this product. inated work clothing should not be allowed out of lease to the environment. otective gloves/ protective clothing/ eye protec-
		CENTER/ doc P302 + P352 P304 + P340 keep comforta P305 + P351 for several min easy to do. Co P308 + P313 attention. P333 + P313 vice/ attention P337 + P313 tention. P342 + P311 POISON CEN	If eye irritation persists: Get medical advice/ at- If experiencing respiratory symptoms: Call a TER/ doctor. Take off contaminated clothing and wash it befor



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P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Benzylpenicillin	61-33-6	>= 50 -< 70
Streptomycin sulphate	3810-74-0	>= 30 -< 50

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 advice.
If inhaled	:	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	:	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.
In case of eye contact	:	
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	Harmful if swallowed. May cause an allergic skin reaction. Causes eye irritation. May cause allergy or asthma symptoms or breathing difficul- ties if inhaled. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.



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oti tiv Co				other respiratory of tive airways dysfu	ire may aggravate preexisting asthma and disorders (e.g. emphysema, bronchitis, reac- inction syndrome). can cause mechanical irritation or drying of	
Protection of first-aiders		:	and use the recor when the potentia	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).		
1	Notes t	o physician	:	Treat symptomati	cally and supportively.	
SECT	TION 5	. FIRE-FIGHTING ME	ASL	JRES		
\$	Suitable extinguishing media		:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical		
	Unsuita media	able extinguishing	: None known.			
	Specific fighting	c hazards during fire	 Avoid generating dust; fine dust dispersed in air in suffic concentrations, and in the presence of an ignition source potential dust explosion hazard. Exposure to combustion products may be a hazard to here 		nd in the presence of an ignition source is a losion hazard.	
	Hazard ucts	ous combustion prod-	:	Carbon oxides Metal oxides		
	Specific ods	c 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	

Special protective equipmentEvacuate area.for fire-fightersIn the event of fire, wear self-contained breathing apparatus.Use personal protective equipment.

SECTION 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 protective 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 minimize 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



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		released into the Clean up remain absorbent. Local or nationa disposal of this employed in the determine which Sections 13 and	ese may form an explosive mixture if they are e atmosphere in sufficient concentration. ning materials from spill with suitable al regulations may apply to releases and material, as well as those materials and items e cleanup of releases. You will need to h regulations are applicable. d 15 of this SDS provide information regarding national requirements.

SECTION 7. HANDLING AND STORAGE

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	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the
Conditions for safe storage	:	environment. Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases



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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Benzylpenicillin	61-33-6	TWA	600 µg/m3 (OEB 2)	Internal
	Further inform	ation: RSEN, DS		
		Wipe limit	100 µg/100 cm2	Internal
Streptomycin sulphate	3810-74-0	TWA	OEB 2 (>= 100 < 1,000 μg/m3)	Internal
	Further inform	ation: DSEN	· · · · ·	
Engineering measures	compound. All engineerir design and oj	g controls shoul	trols to minimize expo d be implemented by dance with GMP prind d the environment.	facility
Personal protective equipme	nt			
Respiratory protection Filter type Hand protection	 If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type 			
	: Chemical-res	istant gloves		
Eye protection	 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 Hygiene measures	aerosols. Work uniform or laboratory coat. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. 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.			

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

App	earance
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: powder



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	Color		:	white	
	Odor		:	odorless	
	Odor T	hreshold	:	No data available)
	рH		:	6,0 - 7,5 (aqueous suspen	ision)
	Melting	point/freezing point	:	No data available)
	Initial b range	oiling point and boiling	:	No data available	3
	Flash p	point	:	No data available	
	Evapor	ation rate	:	Not applicable	
	Flamma	ability (solid, gas)	:	May form explosi handling or other	ve dust-air mixture during processing, means.
	Flamm	ability (liquids)	:	Not applicable	
		explosion limit / Upper bility limit	:	No data available	3
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	oressure	:	Not applicable	
	Relativ	e vapor density	:	Not applicable	
	Relative	e density	:	No data available)
	Density	/	:	> 0,3 g/cm ³	
	Solubili Wat	ity(ies) er solubility	:	slightly soluble	
	Partitio octanol	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	
	Decom	position temperature	:	No data available)
	Viscosi Visc	ty cosity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidizii	ng properties	:	The substance of	r mixture is not classified as oxidizing.



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Molecular weight	:	No data available)				
Particle size	:	No data available)				
SECTION 10. STABILITY AND REACTIVITY							
Reactivity Chemical stability Possibility of hazar tions	: rdous reac- :	Stable under nor May form explosi handling or other	ve dust-air mixture during processing,				
Conditions to avoid	: b	Heat, flames and Avoid dust forma					
Incompatible mate Hazardous decom products		Oxidizing agents	composition products are known.				
SECTION 11. TOXICO	LOGICAL INF	ORMATION					
Information on like exposure	ly routes of :	Inhalation Skin contact Ingestion Eye contact					
Acute toxicity Harmful if swallow	ed.						
Product: Acute oral toxicity	:	Acute toxicity estine Method: Calculation	mate: 1.030 mg/kg on method				
Components:							
Benzylpenicillin:							
Acute oral toxicity	:	LD50 (Rat): 8.000	mg/kg				
		LD50 (Mouse): > :	5.000 mg/kg				
Acute toxicity (othe administration)	er routes of :	LD50 (Mouse): 3. Application Route					
		LD50 (Mouse): 32 Application Route					
Streptomycin sul	phate:						
Acute oral toxicity	:	LD50 (Hamster):	400 mg/kg				
		LD50 (Rat): 430 n	ng/kg				
		LD50 (Mouse): 25	i.000 mg/kg				

Remarks



Benzylpenicillin / Streptomycin Sulphate Solid Formulation

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	e toxicity (other routes of nistration)	,	e): 85 - 111 mg/kg oute: Intravenous
			e): 575 - 610 mg/kg oute: Intraperitoneal
			e): 500 - 600 mg/kg oute: Subcutaneous
		Application R	220 - 440 mg/kg oute: Intravenous owered blood pressure
			ey): 110 mg/kg oute: Intravenous
		Application R	ey): 30 - 70 mg/kg oute: Subcutaneous espiratory depression
Not c Seric	corrosion/irritation classified based on availa ous eye damage/eye irri		
	es eye irritation. ponents:		
Resu	otomycin sulphate: It	: Mild eye irrita	tion
Resp	piratory or skin sensitiz	ation	
Skin	sensitization cause an allergic skin rea		
•	biratory sensitization	symptoms or brea	thing difficulties if inhaled.
-	ponents:		
Benz	ylpenicillin:		
Test			node assay (LLNA)
	es of exposure	: Dermal	
Spec Resu		: Mouse : Weak sensitiz	zer
Test	Туре	: Maximization	Test
Rout	es of exposure	: Dermal	
Spec Resu		: Guinea pig : positive	
Pom			o from similar motorials

: Based on data from similar materials



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	Result Remarks		:	Strong sensitizer Based on human	experience.
Te R S	est Ty	of exposure	: :	Human repeat ins Dermal Humans Weak sensitizer	ult patch test (HRIPT)
Ν	lot clas	ell mutagenicity ssified based on availa ments:	ble	information.	
		penicillin:			
G		ell mutagenicity -	:	Weight of evidenc cell mutagen.	e does not support classification as a germ
S	trepto	mycin sulphate:			
	-	xicity in vitro	:	Test Type: Chrom Result: equivocal	nosomal aberration
G	Senoto	xicity in vivo	:	Test Type: Chrom Cell type: Human Result: negative	osomal aberration lymphocytes
		ogenicity ssified based on availa	hla	information	
		nents:			
S	trepto	mycin sulphate:			
A N	pecies pplica IOAEL tesult	tion Route	:	Rat Oral 5 mg/kg body wei negative	ght
	arcinc nent	genicity - Assess-	:	Weight of evidenc cinogen	e does not support classification as a car-
	-	l uctive toxicity mage the unborn child			
<u>C</u>	ompo	nents:			
		penicillin: on fertility	:	Test Type: Fertility Species: Mouse Result: No effects Test Type: Fertility	on fertility.
				rearrype. Feruing	у



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			Species: Rat Result: No effects	s on fertility.
			Test Type: Fertilit Species: Rabbit Result: No effects	
Effec	ts on fetal development	:	Test Type: Develor Species: Mouse Result: No effects	opment s on fetal development.
			Test Type: Develor Species: Rat Result: No effects	opment s on fetal development.
			Test Type: Devel Species: Rabbit Result: No effects	opment s on fetal development.
Strep	otomycin sulphate:			
-	ts on fertility	:	Species: Rat Application Route Fertility: LOAEL:	
Effec	ts on fetal development	:		
			Test Type: Develor Species: Rabbit Application Route Developmental To Result: No terato	e: Oral oxicity: NOAEL: 10 mg/kg body weight
Repro sessr	oductive toxicity - As- nent	:	May damage the	unborn child.
STO	Γ-single exposure			
Not c	lassified based on availa	able	information.	
	F-repeated exposure			
		idne	ey, inner ear) throug	gh prolonged or repeated exposure.
Com	ponents:			
Strep	otomycin sulphate:			
	et Organs ssment	:	Kidney, inner ear Causes damage	to organs through prolonged or repeated

exposure.



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Repe	eated dose toxicity		
<u>Com</u>	ponents:		
Strep	otomycin sulphate:		
	EL cation Route sure time	: Rat : 100 mg/ : Subcuta : 72 Days : No signi	neous
Expo		: Cat : 200 mg/ : Oral : 90 Days : inner ea	
Expo		: Dog : 44 mg/k : Intramus : 14 Days : inner ea	scular
Expo Targe		: Dog : 50 - 100 : Intramus : 20 Days : inner ea : ataxia	scular
Expo	EL	: Monkey : 50 mg/k : 100 mg/ : Intramus : 5 Days : Liver, Ki	kg scular
	EL cation Route sure time	: Rat : 5 mg/kg : Oral : 2 y : No signi	ficant adverse effects were reported
Expo Targe		: Monkey : 25 mg/k : Subcuta : 66 Days : Blood, L : anemia	neous

Aspiration toxicity

Not classified based on available information.



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Expe	rience with human e	xposure				
<u>Com</u>	ponents:					
Benz	ylpenicillin:					
Inhala	ation	: Symptoms: Allergic reactions, Abdominal pain, bron- chospasm, skin rash				
Strep	tomycin sulphate:					
Inhala	ation	: Target Organs: Symptoms: hea Target Organs: Symptoms: hea	ring loss Kidney			
Skin	contact	: Symptoms: skir	•			
SECTION	12. ECOLOGICAL IN	IFORMATION				
Ecoto	oxicity					

Components:

Benzylpenicillin:		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 hrs Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 3,6 mg/l Exposure time: 48 hrs Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201
		NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201
		EC50 (blue-green algae): 0,74 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201
		NOEC (blue-green algae): 0,14 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201
M-Factor (Acute aquatic tox- icity)	:	1
Toxicity to microorganisms	:	EC50: > 500 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209



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			NOEC: 5 mg/l Exposure time: 3 Test Type: Resp Method: OECD	
Strep	otomycin sulphate:			
	ity to daphnia and other tic invertebrates	:	Exposure time: 4	nagna (Water flea)): 487 mg/l 8 h Fest Guideline 202
	Toxicity to algae/aquatic plants		EC50 (Microcyst Exposure time: 7 Method: ISO 869	
			Exposure time: 7	um capricornutum (green algae)): 0,133 mg/l '2 h Fest Guideline 201
	ctor (Acute aquatic tox-	:	100	
	ity to daphnia and other tic invertebrates (Chron- icity)	:	Exposure time: 2	magna (Water flea)): 32 mg/l 1 d Fest Guideline 211
M-Fa toxici	ctor (Chronic aquatic ty)	:	100	
Persi	istence and degradabil	ity		
Com	ponents:			
	gradability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD	70,10 %
Bioa	ccumulative potential			
Com	ponents:			
Partit	otomycin sulphate: ion coefficient: n- iol/water	:	log Pow: -3,2	
	lity in soil ata available			
	r adverse effects ata available			



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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		
UNRTDG UN number Proper shipping name	: E N	N 3077 NVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, .O.S. Streptomycin sulphate, Benzylpenicillin)
Class Packing group Labels Environmentally hazardous	: 9 : II : 9	
IATA-DGR UN/ID No. Proper shipping name	: E	N 3077 nvironmentally hazardous substance, solid, n.o.s. Streptomycin sulphate, Benzylpenicillin)
Class Packing group Labels Packing instruction (cargo aircraft)	: 9 : III : M	
Packing instruction (passen- ger aircraft) Environmentally hazardous		56 es
IMDG-Code UN number Proper shipping name	: E N	N 3077 NVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, .O.S.
Class Packing group Labels EmS Code Marine pollutant	: 9 : II : 9 : F	

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

Not applicable for product as supplied.

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



or

Benzylpenicillin / Streptomycin Sulphate Solid Formulation

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

SECTION 15. REGULATORY INFORMATION

Safety, health and environme mixture	ent	al regulations/legisla	atio	n specific for the substance of
Argentina. Carcinogenic Substa Registry.	ano	ces and Agents	:	Not applicable
Control of precursors and esse preparation of drugs.	enti	al chemicals for the	:	Not applicable
The ingredients of this produ	ıct	are reported in the f	ollo	wing inventories:
AICS	:	not determined		
DSL	:	not determined		

IECSC	:	not determined

SECTION 16. OTHER INFORMATION

: 30.09.2023 : dd.mm.yyyy	

Further information

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;



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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

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 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.

AR / Z8