

Ceftolozane / Tazobactam Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
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1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name	:	Ceftolozane / Tazobactam Injection Formulation	
Supplier's company name, ac Company name of supplier		ess and phone number MSD	
Address	:	Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory	
Telephone	:	048-588-8411	
E-mail address	:	EHSDATASTEWARD@msd.com	
Emergency telephone number	:	+1-908-423-6000	

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product Respiratory sensitisation : Category 1				
Specific target organ toxicity - repeated exposure	:	Category 2 (Kidney, Liver)		
Short-term (acute) aquatic hazard	:	Category 1		
Long-term (chronic) aquatic hazard	:	Category 1		
GHS label elements				
Hazard pictograms	:			
Signal word	:	Danger		
Hazard statements	:	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H373 May cause damage to organs (Kidney, Liver) through		



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			peated exposure.
Pr	ecautionary statements	Prevention: P260 Do not br P273 Avoid rele	
		keep comfortab	
		Disposal: P501 Dispose o disposal plant.	of contents/ container to an approved waste
Ot	her hazards which do no	t result in classificat	ion
lin	portant symptoms and out es of the emergency as- med	Contact with du the skin.	th the eyes can lead to mechanical irritation. st can cause mechanical irritation or drying of sive dust-air mixture during processing, han-

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Ceftolozane	689293-68-3	>= 40 - < 50	
Tazobactam	89786-04-9	>= 10 - < 20	

dling or other means.

4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
In case of skin contact	:	Get medical attention. In case of contact, immediately flush skin with soap and plenty of water.



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In cas If swa Most and e delaye	se of eye contact Illowed important symptoms ffects, both acute and	Get medical at If in eyes, rinse Get medical at If swallowed, I Get medical at Rinse mouth tt May cause alle ties if inhaled. May cause da exposure. Excessive exp other respirato tive airways dy Contact with d the skin. Dust contact w First Aid respor and use the re- when the pote	ttention if symptoms occur. e well with water. ttention if irritation develops and persists. DO NOT induce vomiting. ttention if symptoms occur. horoughly with water. ergy or asthma symptoms or breathing difficul- mage to organs through prolonged or repeated osure may aggravate preexisting asthma and ory disorders (e.g. emphysema, bronchitis, reac- vsfunction syndrome). ust can cause mechanical irritation or drying of with the eyes can lead to mechanical irritation. onders should pay attention to self-protection, broommended personal protective equipment ntial for exposure exists (see section 8). natically and supportively.
	GHTING MEASURES		

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire- fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Metal oxides Chlorine compounds Nitrogen oxides (NOx)
Specific extinguishing meth- ods	:	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.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Use personal protective equipment.



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	quipment and emer-			ling advice (see section 7) and personal pro- t recommendations (see section 8).
Envirc	onmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
	ods and materials for inment and cleaning up	:	over the area to n Add excess liquid Soak up with iner Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the at Clean up remaining bent. Local or national posal of this mate employed in the of mine which regula Sections 13 and	h absorbents and place a damp covering ninimise entry of the material into the air. It to allow the material to enter into solution. t absorbent material. f dust in the air (i.e., clearing dust surfaces air). Duld not be allowed to accumulate on surfac- form an explosive mixture if they are re- mosphere in sufficient concentration. Ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- ations are applicable. 15 of this SDS provide information regarding ational 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 Advice on safe handling	 Use only with adequate ventilation. 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 assessment Keep container tightly closed. Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira- tory irritants or sensitisers. Minimize dust generation and accumulation. Keep container closed when not in use. 	



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	vidance of contact viene measures	Take pre Take car environm Oxidizing If expose flushing place. When us Wash co The effec engineer appropria industria	
Sto	rage		
Cor	nditions for safe storage	Keep tig	properly labelled containers. htly closed. accordance with the particular national regulations.
Mat	erials to avoid	: Do not s	rore with the following product types: xidizing agents
Pac	kaging material	: Unsuitab	le material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work en-
vironment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Reference concentration / Permissible con- centration	Basis		
Ceftolozane	689293-68-3	TWA	1000 µg/m3 (OEB 1)	Internal		
	Further informa	Further information: DSEN, RSEN				
		Wipe limit	100 µg/100 cm ²	Internal		
Tazobactam	89786-04-9	TWA	250 µg/m3 (OEB 2)	Internal		
	Further information: RSEN					
		Wipe limit	100 µg/100 cm2	Internal		

Engineering measures	:	Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.



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Personal protective equipment

:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type
:	Chemical-resistant gloves
	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.
	:

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
Lower explosion limit and uppe Upper explosion limit / Up- per flammability limit		xplosion limit / flammability limit No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Decomposition temperature	:	No data available
рН	:	No data available
Evaporation rate	:	No data available



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Au	to-ignition temperature	:	No data available	9
Vis	scosity Viscosity, kinematic	:	No data available	9
So	lubility(ies) Water solubility	:	No data available)
	rtition coefficient: n- tanol/water	:	No data available	
Va	pour pressure	:	No data available)
De	ensity and / or relative densi Relative density	ity :	No data available)
	Density	:	No data available	
Re	lative vapour density	:	No data available)
Ex	plosive properties	:	Not explosive	
Ox	idizing properties	:	The substance o	r mixture is not classified as oxidizing.
Мо	blecular weight	:	No data available)
Pa	rticle characteristics Particle size	:	No data available)

10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials Hazardous decomposition	:	Oxidizing agents No hazardous decomposition products are known.
products	•	

11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion



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Eye contact

Acute toxicity

Not classified based on available information.

Components:

Acute toxicity (other routes of : administration)	LD50 (Rat): > 2,000 mg/kg Application Route: Intravenous
	LD50 (Mouse): > 1,500 mg/kg Application Route: Intravenous
	LD50 (Dog): > 2,000 mg/kg Application Route: Intravenous
Tazobactam:	
Acute oral toxicity :	LD50 (Rat): > 5,000 mg/kg
	LD50 (Mouse): > 5,000 mg/kg
Acute toxicity (other routes of : administration)	LD50 (Rat): > 5,000 mg/kg Application Route: Intravenous
	LD50 (Mouse): > 5,000 mg/kg Application Route: Intravenous
	LD50 (Dog): > 5,000 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

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

:

Components:

Ceftolozane:

Test Type	
Species	

Maximisation Test Guinea pig



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Resu	lt	: Sensitise	r
	bactam:		
Resu	It	: Sensitise	ſ
	n cell mutagenicity lassified based on ava	ilable informatio	٦.
<u>Com</u>	ponents:		
Cefto	olozane:		
Geno	toxicity in vitro	: Test Type Result: ne	e: Bacterial reverse mutation assay (AMES) egative
		Test Type Result: ne	e: Chromosome aberration test in vitro egative
		Test Type Result: po	e: In vitro mammalian cell gene mutation test ositive
		Test Type Result: ne	e: In vitro mammalian cell gene mutation test egative
Geno	Genotoxicity in vivo	: Test Type cytogene Species: Result: ne	Mouse
Tazo	bactam:		
Geno	toxicity in vitro	: Test Type Result: ne	e: Bacterial reverse mutation assay (AMES) egative
			e: In vitro mammalian cell gene mutation test em: mouse lymphoma cells ositive
			e: Chromosome aberration test in vitro em: Chinese hamster fibroblasts egative
Geno	toxicity in vivo	cytogene Species:	



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II			Result: negative	
			Test Type: Unsch mammalian liver Species: Mouse Result: negative	neduled DNA synthesis (UDS) test with cells in vivo
	nogenicity	labla	information.	
	lassified based on avai oductive toxicity	lable	information.	
•	lassified based on avai	lable	information.	
Com	oonents:			
	lozane:			
Effect	s on fertility	:	Species: Rat Application Route	y/early embryonic development e: Intravenous injection 1,000 mg/kg body weight s on fertility
Effect ment	s on foetal develop-	:	Species: Mouse Application Route Developmental To	vo-foetal development e: Intravenous injection oxicity: NOAEL: 2,000 mg/kg body weight nificant adverse effects were reported
			Species: Rat Application Route Developmental To	yo-foetal development e: Intravenous injection oxicity: NOAEL: 1,000 mg/kg body weight nificant adverse effects were reported
Tazol	bactam:			
Effect	s on fertility	:	Species: Rat Application Route	y/early embryonic development e: Intraperitoneal injection 640 mg/kg body weight
Effect ment	s on foetal develop-	:	Species: Rat Application Route Developmental To	yo-foetal development e: Intraperitoneal injection oxicity: NOAEL: 40 mg/kg body weight n early embryonic development
			Species: Rat Application Route	/o-foetal development e: Intravenous injection oxicity: NOAEL: 3,000 mg/kg body weight



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		Result: No ef	fects on foetal development
Not c	Γ - single exposure lassified based on ava Γ - repeated exposure		
Mayo	cause damage to organ		rough prolonged or repeated exposure.
	ponents: Ilozane:		
Targe	et Organs ssment	: Kidney : May cause da exposure.	amage to organs through prolonged or repeated
Targe	bactam: et Organs ssment	: Liver : May cause da exposure.	amage to organs through prolonged or repeated
Repe	ated dose toxicity		
Com	ponents:		
Speci NOAI Appli Expo Targe		: Rat : 1,000 mg/kg : Intravenous : 28 days : Kidney : No adverse e	ffects
		: Dog : 300 mg/kg : 28 days : Kidney	
Tazo	bactam:		
Expo		: Rat : 40 mg/kg : Intraperitonea : 6 Months : Liver	al
	EL	: Dog : 40 mg/kg : 80 mg/kg : Intraperitonea : 6 Months	al



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Targe	et Organs	: Liver	
-	ration toxicity classified based on avai	ailable information.	
-	rience with human e	exposure	
<u>Com</u>	ponents:		
Cefto	blozane: stion		arrhoea, Fever, Headache, Nausea, Skin irrita- estinal discomfort
Tazo	bactam:		
Inhala	ation	: Remarks: May ing difficulties	r cause allergy or asthma symptoms or breath- if inhaled.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ceftolozane:		
Toxicity to algae/aquatic plants		EC50 (Anabaena flos-aquae): 0.0401 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Anabaena flos-aquae): 0.0018 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic tox- icity)	:	10
Toxicity to fish (Chronic tox- icity)	:	NOEC (Pimephales promelas (fathead minnow)): 10 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
		NOEC (Daphnia magna (Water flea)): 9.6 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	10
Toxicity to microorganisms	:	EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209



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			NOEC: 560 m Exposure time Test Type: Re Method: OECI	
II Tazoł	pactam:			
	ty to algae/aquatic	:	Exposure time	ena flos-aquae): 0.96 mg/l : 72 h D Test Guideline 201
			Exposure time	ena flos-aquae): 0.44 mg/l : 72 h D Test Guideline 201
	ctor (Acute aquatic tox-	:	1	
icity) Toxici icity)	ty to fish (Chronic tox-	:	Exposure time	hales promelas (fathead minnow)): 10.6 mg/l : 32 d D Test Guideline 210
	ty to daphnia and other ic invertebrates (Chron- city)	:	Exposure time	ia magna (Water flea)): 9.6 mg/l : 21 d D Test Guideline 211
Toxici	ty to microorganisms	:		
II Persi:	stence and degradabili	ty		
	oonents:			
Cefto	lozane:			
Biode	gradability	:		adily biodegradable. D Test Guideline 301D
	bactam: gradability	:		adily biodegradable. D Test Guideline 301D



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Bioad	ccumulative potential		
Com	ponents:		
Cefto	olozane:		
	ion coefficient: n- ol/water	: log Pow: -().21
Tazo	bactam:		
	ion coefficient: n- iol/water	: log Pow: -().63
Mobi	lity in soil		
Com	ponents:		
Cefto	olozane:		
	bution among environ- al compartments	: log Koc: 3. Method: O	3 ECD Test Guideline 106
Tazo	bactam:		
	bution among environ- al compartments	: log Koc: 0.	87
	rdous to the ozone lay	/er	
Othe	r adverse effects		
No da	ata available		
13. DISPC	SAL CONSIDERATIO	NS	
Disp	osal methods		
-	e from residues		in accordance with local regulations.
Conta	aminated packaging	dling site for	tainers should be taken to an approved waste han- or recycling or disposal. wise specified: Dispose of as unused product.
14. TRAN	SPORT INFORMATIO		
Interi	national Regulations		
UNR			
	umber er shipping name	: UN 3077 : ENVIRONI N.O.S.	MENTALLY HAZARDOUS SUBSTANCE, SOLID,
Class		(Ceftoloza	ne, Tazobactam)

: 9 : III : 9

Class

Labels

Packing group



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Envir	onmentally hazardous	:	yes	
UN/IE	-DGR D No. er shipping name	:	UN 3077 Environmentally h (Ceftolozane, Ta:	azardous substance, solid, n.o.s. zobactam)
Label	ng group s ng instruction (cargo	: : :	9 III Miscellaneous 956	
ger ai	ng instruction (passen- ircraft) onmentally hazardous	:	956 yes	
UN n	6-Code umber er shipping name	:	UN 3077 ENVIRONMENTA N.O.S. (Ceftolozane, Taz	ALLY HAZARDOUS SUBSTANCE, SOLID,
Label EmS	ng group	:	9 III 9 F-A, S-F yes	obaolamy

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code : 171

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.



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Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture Not applicable Harmful Substances Required Permission for Manufacture Not applicable Substances Prevented From Impairment of Health Not applicable Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act Not applicable



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Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission) Not applicable Specific Narcotic or Psychotropic Raw Material (Export / Import permission) Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER 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



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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

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.

JP / EN