

Caspofungin Formulation

Version 7.0	Revision Date: 28.09.2024		S Number: 273-00027	Date of last issue: 06.07.2024 Date of first issue: 21.10.2014
SECTION	1. IDENTIFICATION			
Produ	uct identifier	:	Caspofungin Fo	ormulation
Manu	ifacturer or supplier's	s detai	ls	
Comp	bany	:	MSD	
Addre	ess	:	nº 1500 – Distri	idador Antônio Loureiro Ramos, to Industrial – MG, Brazil 39404-620
Telep	hone	:	+55 (38) 3229 7	7000
Emer	gency telephone	:	+55 (38) 3201 5	5670
E-ma	il address	:	EHSDATASTE	WARD@msd.com
Reco	mmended use of the	chem	ical and restrict	ions on use
	mmended use ictions on use	:	Pharmaceutical Not applicable	

SECTION 2. HAZARDS IDENTIFICATION

hazard

GHS Classification in accordance with ABNT NBR 14725 Stand					
Serious eye damage	:	Category 1			
Effects on or via lactation					
Short-term (acute) aquatic	:	Category 1			

Long-term (chronic) aquatic	:	Category 1
hazard		

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H318 Causes serious eye damage. H362 May cause harm to breast-fed children. H410 Very toxic to aquatic life with long lasting effects.
Precautionary Statements	:	Prevention:



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		P202 Do not h and understod P260 Do not b P263 Avoid co P264 Wash sh P270 Do not e P273 Avoid re	
	wat and CEI P30 atte		+ P338 + P310 IF IN EYES: Rinse cautiously with eral minutes. Remove contact lenses, if present b. Continue rinsing. Immediately call a POISON etor. IF exposed or concerned: Get medical advice/ spillage.

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.	Classification	Concentration (% w/w)
Caspofungin	179463-17-3	Eye Dam., 1 Lact. Aquatic Acute, 1 Aquatic Chronic, 1	>= 30 -< 50
Sucrose	57-50-1		>= 30 -< 50
Acetic acid	64-19-7	Flam. Liq., 3 Acute Tox. (Oral), 5 Skin Corr., 1A Eye Dam., 1	>= 1 -< 3

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	:	Get medical attention.
In case of skin contact	:	Wash with water and soap.
		Get medical attention.
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water
		for at least 15 minutes.
		If easy to do, remove contact lens, if worn.
		Get medical attention immediately.



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Mo	swallowed ost important symptoms d effects, both acute and layed	:			
Pr	otection 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).		
No	otes to physician	:		cally and supportively.	
SECTIO	ON 5. FIRE-FIGHTING ME	ASI	JRES		
Su	itable extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical		
	nsuitable extinguishing edia	:	None known.		
	ecific hazards during fire hting	:	concentrations, and potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. oustion products may be a hazard to health.	
Ha uc	azardous combustion prod- ts	:	Carbon oxides		
Sp od	ecific extinguishing meth- s	:	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	
	ecial protective equipment fire-fighters	:		e, wear self-contained breathing apparatus. ective equipment.	
SECTIO	ON 6. ACCIDENTAL RELE	AS	E 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	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces



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		surfaces, as th released into t Local or natior disposal of this employed in th determine whi Sections 13 ar	ed air). should not be allowed to accumulate on hese may form an explosive mixture if they are he atmosphere in sufficient concentration. hal regulations may apply to releases and s material, as well as those materials and items he cleanup of releases. You will need to ch regulations are applicable. hd 15 of this SDS provide information regarding r national requirements.
SECTION	7. HANDLING AND ST	ORAGE	
Tech	nical measures	causing an ex Provide adequ	ty may accumulate and ignite suspended dust blosion. late precautions, such as electrical grounding or inert atmospheres.
Local	/Total ventilation		adequate ventilation.
	e on safe handling	: Avoid contact Do not breathe Do not swallow Do not get in e	during pregnancy and while nursing. e dust. v. eyes.
		Wash skin tho Handle in acco practice, base assessment Keep containe Minimize dust Keep containe	ed or repeated contact with skin. roughly after handling. ordance with good industrial hygiene and safety d on the results of the workplace exposure r tightly closed. generation and accumulation. r closed when not in use. m heat and sources of ignition.
		Take precaution Do not eat, dri	onary measures against static discharges. nk or smoke when using this product. revent spills, waste and minimize release to the
Hygie	ene measures	: If exposure to flushing syster place. When using do	chemical is likely during typical use, provide eye ns and safety showers close to the working o not eat, drink or smoke. nated clothing before re-use.
Cond	litions for safe storage	: Keep in prope Keep tightly cl	rly labeled containers.
Mate	rials to avoid		ith the following product types:

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
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Casp	ofungin		179463-17-3	TWA	140 μg/m3 (OEB 2)	Internal			
Sucro	se		57-50-1	TWA	10 mg/m ³	ACGIH			
Acetio			64-19-7	LT	8 ppm 20 mg/m ³	BR OEL			
			Further informa	ation: Degree	of harmfulness: mediu	m			
				TWA	10 ppm	ACGIH			
				STEL	15 ppm	ACGIH			
∟ngii	neering measures	:	Minimize work Apply measur Ensure that du dust collectors designed in a	splace exposu es to prevent ust-handling s s, vessels, and manner to pre	a, especially in confined re concentrations. dust explosions. ystems (such as exhau d processing equipmer event the escape of dus eakage from the equip	ust ducts, ht) are st into the			
Perso	onal protective equip	ment	:						
Respiratory protection :			If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.						
	ter type protection	:	Combined particulates and organic vapor type						
Ma	aterial	:	Chemical-resi	stant gloves					
	emarks	:	on the concert time is not def For special ap resistance to o gloves with th breaks and at	tration specific ermined for the plications, we chemicals of the glove manuf the end of wo		akthrough oves often! the tective pefore			
Eye p	protection	:		stant goggles	protective equipment: must be worn. ır, wear:				
Skin a	and body protection	:	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).						

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	powder
Color	:	off-white
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	No data available



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	Melting	point/freezing point	:	No data available	9
	Initial boiling point and boiling range		:	No data available)
	Flash p	point	:	Not applicable	
	Evapoi	ration rate	:	Not applicable	
	Flamm	ability (solid, gas)	:	May form explosi handling or other	ve dust-air mixture during processing, means.
	Flamm	ability (liquids)	:	Not applicable	
		explosion limit / Upper ability limit	:	No data available)
		explosion limit / Lower ability limit	:	No data available	
	Vapor	pressure	:	Not applicable	
	Relativ	e vapor density	:	Not applicable	
	Relativ	e density	:	No data available	
	Density	/	:	No data available	
	Solubil Wa	ity(ies) ter solubility	:	No data available)
	Partitio octano	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	
	Viscos Visc	ity cosity, kinematic	:	Not applicable	
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance of	r mixture is not classified as oxidizing.
	Molecu	ılar weight	:	No data available	9
	Minimu	im ignition energy	:	100 - 300 mJ	
				30 - 100 mJ	
	Particle Particle	e characteristics e size	:	No data available	3



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SECTIO	N 10. STABILITY AND F	REACTIVITY				
Reactivity Chemical stability Possibility of hazardous reac- tions		: Stable unde - : May form e handling or	 Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents. 			
Inco	nditions to avoid ompatible materials cardous decomposition	Avoid dust : Oxidizing a	 Heat, flames and sparks. Avoid dust formation. Oxidizing agents No hazardous decomposition products are known. 			
pro	ducts					

Information on likely routes of exposure	:	Skin contact
onpoouro		Ingestion

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5.000 mg/kg
		Method: Calculation method

Eye contact

Components:

Caspofungin:		
Acute oral toxicity	:	LD50 (Mouse): > 2.000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Mouse): 19 mg/kg Application Route: Intravenous
		LD50 (Rat): 38 mg/kg Application Route: Intravenous
Sucrose:		
Acute oral toxicity	:	LD50 (Rat): 29.700 mg/kg
Acetic acid:		
Acute oral toxicity	:	LD50 (Rat): > 2.000 - 5.000 mg/kg Remarks: Based on data from similar materials
Acute inhalation toxicity	:	Assessment: Corrosive to the respiratory tract.
Acute dermal toxicity	:	LD50 (Rabbit): > 5.000 mg/kg Remarks: Based on data from similar materials



Not cl	corrosion/irritation		
	assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
Casp	ofungin:		
Speci Resul		: Rabbit : Mild skin irritati	on
Aceti	c acid:		
Speci Resul		: Rabbit : Corrosive after	3 minutes or less of exposure
	us eye damage/eye es serious eye damag		
	oonents:		
	ofungin:		
Speci	-	: Rabbit	
Resul		: Irreversible effe	•
Metho	Ja	: Bovine cornea	(BCOP)
	c acid:		
Speci Resul		: Rabbit : Irreversible effe	ects on the eve
	iratory or skin sensi	tization	
_	sensitization assified based on ava	ailable information.	
	iratory sensitization assified based on ava	ailable information.	
	cell mutagenicity		
	assified based on ava	ailable information.	
Comp	oonents:		
	ofungin:		
Geno	toxicity in vitro		omosomal aberration hinese hamster ovary cells e
		Test Type: Bac Result: negativ	eterial reverse mutation assay (AMES)
		Test Type: Alka Test system: ra Result: negativ	
			itro mammalian cell gene mutation test hinese hamster fibroblasts
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			Result: negative			
Ge	Genotoxicity in vivo		: Test Type: Chromosomal aberration Species: Mouse Cell type: Bone marrow Result: negative			
Su	icrose:					
Ge	enotoxicity in vitro	:	Test Type: In vitro Result: negative	o mammalian cell gene mutation test		
 Ac	cetic acid:					
	enotoxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)		
			Test Type: Chron Result: negative	nosome aberration test in vitro		
			Test Type: DNA o thesis in mamma Result: negative	lamage and repair, unscheduled DNA syn- ian cells (in vitro)		
			Result: equivocal	o mammalian cell gene mutation test on data from similar materials		
Ge	enotoxicity in vivo	:	cytogenetic assay Species: Rat			
			Result: negative	:: inhalation (vapor) on data from similar materials		
اا م	arcinogenicity					
	ot classified based on ava	ilahle	information			
	omponents:					
Ac	cetic acid:					
	pecies	:	Mouse			
	plication Route	÷	Skin contact			
	esult	:	32 weeks negative			
11	Jour		nogativo			
	eproductive toxicity ay cause harm to breast-f	ed chi	ldren			
	omponents:					
	aspofungin: fects on fertility		Test Type: Fertilit			
		•	Species: Rat, ma			



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				Parent: 5 mg/kg body weight s on fertility and early embryonic develop- ed.
Effect	Effects on fetal development		Species: Rat Application Route General Toxicity M Embryo-fetal toxic Symptoms: Abnor	ro-fetal development : Intravenous injection Maternal: LOAEL: 5 mg/kg body weight city.: NOAEL F1: 2 mg/kg body weight rmalities of the musculosketal system. xic effects and adverse effects on the off- cited.
			General Toxicity M Developmental To	: Intravenous injection Maternal: NOAEL: 3 mg/kg body weight oxicity: NOAEL F1: >= 6 mg/kg body weight xic effects and adverse effects on the off-
Repro sessn	oductive toxicity - As- nent	:	Studies indicating period	a hazard to babies during the lactation
Aceti	c acid:			
Effect	ts on fetal development	:	Test Type: Embry Species: Rat Application Route Result: negative	ro-fetal development : Ingestion
	-single exposure lassified based on availa	ble	information.	
	-repeated exposure			
	lassified based on availa	ble	information.	
Repe	ated dose toxicity			
<u>Com</u>	oonents:			
Speci NOAE LOAE Applic Expos	ΞL		Monkey 2 mg/kg 5 mg/kg Intravenous 27 Weeks daily Liver	
	EL cation Route sure time	:	Rat 1,8 mg/kg Intravenous 27 Weeks Swelling of tissue	

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Species NOAEL LOAEL Application Route Exposure time Number of exposures Symptoms		Rat 2 mg/kg 5 mg/kg Intravenous 14 Weeks daily Swelling of tissue
Acetic acid: Species NOAEL Application Route	:	Rat 290 mg/kg Ingestion
Exposure time	:	8 Weeks
Aspiration toxicity Not classified based on availal	hla	information
Components:		
Caspofungin: No aspiration toxicity classifica	atio	n
SECTION 12. ECOLOGICAL INFO	RN	ΙΑΤΙΟΝ
Ecotoxicity		
Components:		
Caspofungin:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 2,4 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 22,6 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0,1 mg/l Exposure time: 72 h
		NOEC (Pseudokirchneriella subcapitata (green algae)): 0,05 mg/l Exposure time: 72 h
M-Factor (Acute aquatic tox-	:	10
icity) Toxicity to fish (Chronic tox- icity)	:	NOEC (Pimephales promelas (fathead minnow)): 0,084 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0,67 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
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II				
M-Fac toxicity	tor (Chronic aquatic	:	1	
	y to microorganisms	:	EC50: > 127 mg/l Exposure time: 3 Test Type: Respir Method: OECD T	h ration inhibition
			NOEC: 38 mg/l Exposure time: 3 Test Type: Respir Method: OECD T	ation inhibition
Acetic	acid:			
Toxicit	y to fish	:	Exposure time: 96	hus mykiss (rainbow trout)): > 100 mg/l 3 h on data from similar materials
	y to daphnia and other c invertebrates	:	Exposure time: 48 Method: OECD T	
Toxicit plants	y to algae/aquatic	:	Exposure time: 72	ema costatum (marine diatom)): > 100 mg/l 2 h on data from similar materials
			Exposure time: 72	ema costatum (marine diatom)): > 1 mg/l 2 h on data from similar materials
	y to daphnia and other c invertebrates (Chron-	:	NOEC (Daphnia r Exposure time: 2	nagna (Water flea)): > 1 mg/l I d
	y to microorganisms	:	NOEC (Pseudom Exposure time: 16	onas putida): 1.150 mg/l S h
Persis	tence and degradabili	ity		
<u>Comp</u>	onents:			
Caspo	ofungin:			
Biodeg	gradability	:	Result: Not readily Biodegradation: 7 Exposure time: 28 Method: OECD T	71,9 %
Stabilit	ty in water	:	Degradation half	ife (DT50): 2,8 h
Acetic	acid:			
Biodeg	gradability	:	Result: Readily bi Biodegradation: 9 Exposure time: 20	96 %



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Bioa	ccumulative potentia	al		
Com	ponents:			
Partit	oofungin: ion coefficient: n- nol/water	: log Pow: -1	,6	
Sucr	ose:			
	ion coefficient: n- nol/water	: Pow: < 1		
Aceti	ic acid:			
	ion coefficient: n- nol/water	: log Pow: -0	,17	
Mobi	lity in soil			
No da	ata available			
Othe	r adverse effects			
No da	ata available			

SECTION 13. DISPOSAL CONSIDERATIONS

Waste from residues	Do not dispose of waste into sewer. Dispose of in accordance with local re	egulations.
Contaminated packaging	Empty containers should be taken to handling site for recycling or disposal If not otherwise specified: Dispose of	

SECTION 14. TRANSPORT INFORMATION

UNRTDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Caspofungin)
Class	:	9
Packing group	:	
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Caspofungin)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956



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	ger airc	g instruction (passen- craft) nmentally hazardous	:	956 yes	
	IMDG-(UN nur Proper		:	UN 3077 ENVIRONMENTA N.O.S. (Caspofungin)	ALLY HAZARDOUS SUBSTANCE, SOLID,
	Class		:	9	
		g group	:		
	Labels		:	9	
	EmS C		:	F-A, S-F	
	Marine	pollutant	:	yes	
	Transp	oort in bulk according	g to	Annex II of MARP	OL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

ANTT

UN number Proper shipping name	:	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Caspofungin)
Class	:	9
Packing group	:	
Labels	:	9
Hazard Identification Number	:	90

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

National List of Carcinogenic Agents for Humans - (LINACH)	:	Not applicable
Brazil. List of chemicals controlled by the Federal Police		Not applicable

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

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

SECTION 16. OTHER INFORMATION



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Date fo	ormat	: dd.mm.yyyy	
	er information		

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 Agency, 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.

Full text of other abbreviations

ACGIH BR OEL		USA. ACGIH Threshold Limit Values (TLV) Brazil. NR 15 - Unhealthy activities and operations
ACGIH / TWA ACGIH / STEL BR OEL / LT	:	8-hour, time-weighted average Short-term exposure limit Up to 48 hours /week

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration: ICAO - International Civil Aviation Organization: IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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



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

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