

Aprepitant Formulation

Version 5.3	Revision Date: 28.09.2024		Number:)-00027	Date of last issue: 24.01.2024 Date of first issue: 09.10.2014				
SECTIO	N 1. IDENTIFICATION							
Pro	duct identifier	: A	prepitant Fo	ormulation				
	nufacturer or supplier							
Cor	mpany	: N	: MSD					
Ado	Iress	n	º 1500 – Di	nendador Antônio Loureiro Ramos, strito Industrial os – MG, Brazil 39404-620				
Tel	ephone	: +	55 (38) 322	9 7000				
Em	ergency telephone	: +	55 (38) 320	1 5670				
E-n	nail address	: E	HSDATAS ⁻	TEWARD@msd.com				
Ree	commended use of the	e chemica	I and restr	ictions on use				
	commended use		harmaceuti					
	strictions on use		ot applicab					
SECTIO	N 2. HAZARDS IDENT	IFICATIO	N					
GH	S Classification in acc	ordance	with ABNT	NBR 14725 Standard				
Spe	ecific target organ toxici eated exposure (Oral)							
	Long-term (chronic) aquatic hazard		ategory 1					
GH	S label elements in ac	cordance	with ABN	T NBR 14725 Standard				
Haz	zard pictograms	:						
Sig	Signal Word :		Warning					
Haz	Hazard Statements : H373 May cause damage to organs (Prostate, prolonged or repeated exposure if swallowed. H410 Very toxic to aquatic life with long lasting							
_	Precautionary Statements							
Pre	cautionary Statements	· P	revention:					

P273 Avoid release to the environment.

Response:

P314 Get medical advice/ attention if you feel unwell.



Version	Revision Date:	SDS Number:	Date of last issue: 24.01.2024
5.3	28.09.2024	20589-00027	Date of first issue: 09.10.2014

P391 Collect spillage.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. 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)
Aprepitant	170729-80-3	STOT RE, (Oral)(Prostate, Tes- tis) , 2 Aquatic Chronic, 1	>= 30 -< 50
Sucrose	57-50-1		>= 30 -< 50
Cellulose	9004-34-6		>= 10 -< 20

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. Get medical attention if symptoms occur.
In case of skin contact	:	Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact	:	If in eyes, rinse well with water. 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	:	May cause damage to organs through prolonged or repeated exposure if swallowed.
delayed		Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
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.



/ersion 5.3	Revision Date: 28.09.2024		9S Number: 589-00027	Date of last issue: 24.01.2024 Date of first issue: 09.10.2014			
me	dia						
	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.				
Ha uct	zardous combustion prod- s	:	: Carbon oxides Fluorine compounds Nitrogen oxides (NOx)				
Sp od:	ecific extinguishing meth- S	:	 Use extinguishing measures that are appropriate to loca cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe so. Evacuate area. 				
	ecial protective equipment fire-fighters	:		fire, wear self-contained breathing apparatus. protective equipment.			
SECTIC	ON 6. ACCIDENTAL RELE	ASI	EMEASURES				
tive	rsonal precautions, protec- e equipment and emer- ncy procedures	:	Follow safe ha	protective equipment. ndling advice (see section 7) and personal pment recommendations (see section 8).			
En	vironmental 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 spillage cannot be contained. 				
	thods and materials for ntainment and cleaning up	:	container for di Avoid dispersa with compress Dust deposits s surfaces, as th released into th Local or nation disposal of this employed in th determine whic Sections 13 an	l of dust in the air (i.e., clearing dust surfaces			

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



Aprepitant Formulation

Version 5.3	Revision Date: 28.09.2024	SDS Number: 20589-00027	Date of last issue: 24.01.2024 Date of first issue: 09.10.2014			
	Il/Total ventilation ce on safe handling	: Use only with Do not breath Do not swalld Avoid contac Avoid prolong Handle in acc practice, bas assessment Minimize dus Keep contain Keep away fr Take precaut	and bonding, or inert atmospheres. 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 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. Take care to prevent spills, waste and minimize release to the			
Hygiene measures		: If exposure to flushing syste place. When using of Wash contan The effective engineering of appropriate of industrial hyg	chemical is likely during typical use, provide eye ems and safety showers close to the working do not eat, drink or smoke. hinated clothing before re-use. operation of a facility should include review of controls, proper personal protective equipment, egowning and decontamination procedures, iene monitoring, medical surveillance and the strative controls.			
Cond	ditions for safe storage	 Keep in properly labeled containers. Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents 				
Mate	erials to avoid					

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis		
Aprepitant	170729-80-3	TŴA	0.2 mg/m3 (OEB 2)	Internal		
Sucrose	57-50-1	TWA	10 mg/m ³	ACGIH		
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH		
	compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.					
Personal protective equipr	nent					
Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.						
Filter type Hand protection	: Particulates ty					
	4 / 1	5				

Ingredients with workplace control parameters



Version 5.3	Revision Date: 28.09.2024		S Number: 589-00027	Date of last issue: 24.01.2024 Date of first issue: 09.10.2014	
М	aterial	:	Chemical-resistan	t gloves	
	Eye protection		: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty condition 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.		
	and body protection	EMIC	Work uniform or la	·	
	ical state	:	powder		
Color	r	:	colored		
Odor		:	odorless		
Odor	Threshold	:	No data available)	
pН		:	No data available	9	
Melti	ng point/freezing point	:	No data available	9	
Initial range	l boiling point and boiling e	:	No data available)	
Flash	n point	:	No data available)	
Evap	oration rate	:	No data available)	
Flam	mability (solid, gas)	:	May form explosi handling or other	ve dust-air mixture during processing, means.	
Flam	mability (liquids)	:	No data available)	
	er explosion limit / Upper nability limit	:	No data available)	
	er explosion limit / Lower nability limit	:	No data available		
Vapo	or pressure	:	No data available)	
Relat	tive vapor density	:	No data available)	
Relat	tive density	:	No data available)	
Dens	ity	:	No data available		
	bility(ies) /ater solubility	:	No data available)	
	tion coefficient: n- nol/water	:	No data available		



Aprepitant Formulation

Version 5.3	Revision Date: 28.09.2024	SDS Number: 20589-00027		Date of last issue: 24.01.2024 Date of first issue: 09.10.2014
Autoignition temperature Decomposition temperature			o data available o data available	-
Viscosity Viscosity, kinematic Explosive properties			o data available ot explosive	9
Oxidizing properties Molecular weight Minimum ignition energy		: No	ne substance o o data available 3 mJ	r mixture is not classified as oxidizing.
Particle characteristics Particle size		: No	o data available	9

SECTION 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, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	 Heat, flames and sparks. Avoid dust formation. Ovidiation agonte.
Incompatible materials Hazardous decomposition products	 Oxidizing agents No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : exposure	Inhalation Skin contact Ingestion Eye contact
Acute toxicity	
Not classified based on available	information.
Components:	
Aprepitant:	
Acute oral toxicity :	LD50 (Rat): > 2.000 mg/kg
	LD50 (Mouse): > 2.000 mg/kg
Acute toxicity (other routes of : administration)	LD50 (Rat): 800 - 2.000 mg/kg Application Route: Intraperitoneal

LD50 (Mouse): > 2.000 mg/kg Application Route: Intraperitoneal



ersion 3	Revision Date: 28.09.2024		OS Number: 589-00027	Date of last issue: 24.01.2024 Date of first issue: 09.10.2014
Sucr				
Acute	e oral toxicity	:	LD50 (Rat): 29.	700 mg/kg
Cellu	llose:			
Acute	e oral toxicity	:	LD50 (Rat): > 5	.000 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): > 5 Exposure time: Test atmospher	4 h
Acute	e dermal toxicity	:	LD50 (Rabbit):	> 2.000 mg/kg
	corrosion/irritation lassified based on ava	ailable	information.	
Com	ponents:			
Apre	pitant:			
Spec		:	Rabbit	
Meth Resu		:	Draize Test No skin irritatior	2
<u>Com</u>	ponents:			
Apre	pitant:			
Spec		:	Rabbit	
Resu Meth		:	No eye irritatior Draize Test	1
Resp	iratory or skin sensi	tizatio	n	
-	iratory or skin sensi sensitization	tizatio	n	
Skin	-			
Skin Not c Resp	sensitization lassified based on ava	ailable	information.	
Skin Not c Resp Not c	sensitization lassified based on ava	ailable	information.	
Skin Not c Resp Not c <u>Com</u>	sensitization lassified based on ava iratory sensitization lassified based on ava ponents:	ailable	information.	
Skin Not c Resp Not c <u>Com</u>	sensitization lassified based on ava iratory sensitization lassified based on ava ponents: pitant:	ailable	information.	le
Skin Not c Resp Not c <u>Com</u> Apre Rema	sensitization lassified based on ava iratory sensitization lassified based on ava ponents: pitant:	ailable ailable :	information. information. No data availab	le
Skin Not c Resp Not c Com Apre Rema Germ Not c	sensitization lassified based on ava piratory sensitization lassified based on ava ponents: pitant: arks	ailable ailable :	information. information. No data availab	le
Skin Not c Resp Not c Com Apre Rema Germ Not c <u>Com</u>	sensitization lassified based on availassified based on availassified based on availassified based on availant: ponents: pitant: arks n cell mutagenicity lassified based on availassified based on availassified based on available	ailable ailable :	information. information. No data availab	le

Remarks



Aprepitant Formulation

ersion .3	Revision Date: 28.09.2024	SDS Number: 20589-00027	Date of last issue: 24.01.2024 Date of first issue: 09.10.2014
		Result: nega	ative
			Chromosomal aberration a: Chinese hamster ovary cells ative
			Alkaline elution assay a: rat hepatocytes ative
		Test Type: i Test system Result: nega	i: human lymphoblastoid cells
Geno	toxicity in vivo	: Test Type: I Species: Mo Application Result: nega	Route: Oral
Sucr	ose:		
Geno	toxicity in vitro	: Test Type: I Result: nega	n vitro mammalian cell gene mutation test ative
Cellu	lose:		
Geno	toxicity in vitro	: Test Type: Result: nega	Bacterial reverse mutation assay (AMES) ative
		Test Type: I Result: nega	n vitro mammalian cell gene mutation test ative
Geno	toxicity in vivo	cytogenetic Species: Mo	buse Route: Ingestion
	nogenicity	voilable information	
	lassified based on av ponents:		
Speci Applie	cation Route sure time	: Mouse, mal : Oral : 106 weeks : >=1000 mg/	e ′kg body weight
Resu	lt	: positive	

: The mechanism or mode of action is not relevant in humans.

Application Route :	Mouse, female Oral
	106 weeks
Dose :	>= 500 mg/kg body weight



ersion .3	Revision Date: 28.09.2024		Number: 9-00027	Date of last issue: 24.01.2024 Date of first issue: 09.10.2014
Resul Rema			ositive he mechanism c	or mode of action is not relevant in humans.
	cation Route sure time t	: O : 10 : 20	louse ral 05 weeks 000 mg/kg body ositive he mechanism c	weight or mode of action is not relevant in humans.
Cellu	lose:			
	cation Route sure time	: Ir : 7:	at Igestion 2 weeks egative	
-	oductive toxicity assified based on availa	able inf	ormation.	
<u>Com</u>	oonents:			
Apre	oitant:			
Effect	s on fertility	S F	est Type: Fertilit pecies: Rat, mal ertility: NOAEL: esult: No effects	e and female 2.000 mg/kg body weight
Effect	s on fetal development	S D R T S A D	esult: No effects est Type: Develo pecies: Rabbit pplication Route evelopmental To	: Oral oxicity: NOAEL: 2.000 mg/kg body weight on fetal development. opment
Cellu	lose:			
Effect	s on fertility	S A	est Type: One-g pecies: Rat pplication Route esult: negative	eneration reproduction toxicity study : Ingestion
Effect	s on fetal development	S A	est Type: Fertilit pecies: Rat pplication Route esult: negative	y/early embryonic development : Ingestion
OT OT	cingle expecture			

STOT-single exposure

Not classified based on available information.



STOT-			Date of first issue: 09.10.2014
	repeated exposure		
May ca swallov		ans (Prostate, Testis) t	hrough prolonged or repeated exposure if
<u>Comp</u>	onents:		
Aprep	itant:		
Target Assess	Organs sment	 Prostate, Testi May cause dar exposure. 	s mage to organs through prolonged or repeated
Repea	ted dose toxicity		
Comp	onents:		
Aprep	itant:		
Specie		: Dog	
LOAEL		: >= 50 mg/kg	
	ation Route ure time	: Oral : 39 Weeks	
	organs	: Prostate, Testi	S
-	-		-
Specie		: Rat	
NOAE		: 125 mg/kg	
	ation Route ure time	: Oral : 27 Weeks	
	Organs	: Liver, Thyroid	
Specie	es	: Monkey	
NOAE		: 0,240 mg/kg	
	ation Route	: Intravenous	
	ure time	: 7 d	
Remar	ks	: No significant a	adverse effects were reported
Specie	es	: Rat, female	
LOAEL		: 125 mg/kg	
	ation Route	: Oral	
	ure time	: 106 Weeks	
Target	Organs	: Kidney	
Cellulo	ose:		
Specie		: Rat	
NOAE	—	: >= 9.000 mg/kg	g
	ation Route ure time	: Ingestion : 90 Days	
Слроза		. 30 Days	
Aspira	ation toxicity		
Not cla	assified based on ava	ailable information.	
Experi	ience with human e	exposure	
<u>Comp</u>	onents:		
Aprep			



ersion .3	Revision Date: 28.09.2024		9S Number: 589-00027	Date of last issue: 24.01.2024 Date of first issue: 09.10.2014	
Ingestic	Ingestion		: Symptoms: Headache, Fatigue, hiccups, constipation, anoroia, liver function change, Rash, Nausea, Diarrhea, hypoten- sion		
ECTION 12	2. ECOLOGICAL INFO	ORN	IATION		
Ecotox	icity				
<u>Compo</u>	nents:				
Aprepit	tant:				
Toxicity	to fish	:	Exposure time: 96 Method: OECD Te		
	to daphnia and other invertebrates	:	Exposure time: 48 Method: OECD Te		
Toxicity plants	to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD To		
			0,184 mg/l Exposure time: 72 Method: OECD Te		
Toxicity icity)	to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te		
	to daphnia and other invertebrates (Chron- ty)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te		
	or (Chronic aquatic	:	1		
toxicity) Toxicity	to microorganisms	:	EC50: > 100 mg/l Exposure time: 3 Test Type: Respir Method: OECD To Remarks: No toxio	h ation inhibition	
Cellulo	se:				
Toxicity		:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials	



/ersion 5.3	Revision Date: 28.09.2024		DS Number: 589-00027	Date of last issue: 24.01.2024 Date of first issue: 09.10.2014
Persi	stence and degradabi	lity		
Com	ponents:			
Apre	pitant:			
Biode	egradability	:	Result: not rapic Biodegradation: Exposure time: Method: OECD	50 %
Cellu	lose:			
Biode	egradability	:	Result: Readily	biodegradable.
Bioa	ccumulative potential			
Com	ponents:			
Apre	pitant:			
Bioac	cumulation	:	Bioconcentratio	nis macrochirus (Bluegill sunfish) n factor (BCF): 50,1 Test Guideline 305
	ion coefficient: n- ol/water	:	log Pow: 4,75	
Sucr	ose:			
	ion coefficient: n- ol/water	:	Pow: < 1	
Mobi	lity in soil			
Com	ponents:			
Apre	pitant:			
	bution among environ- al compartments	:	log Koc: 3,10	
Othe	r adverse effects			
No da	ata available			

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer.
Contaminated packaging	:	Dispose of in accordance with local regulations. 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

UNRTDG



Version 5.3	Revision Date: 28.09.2024		ast issue: 24.01.2024 irst issue: 09.10.2014
	l number oper shipping name	 UN 3077 ENVIRONMENTALLY HAZ N.O.S. (Aprepitant) 	ARDOUS SUBSTANCE, SOLID,
Pa La	ass cking group oels vironmentally hazardous	: 9 : III : 9 : yes	
UN	FA-DGR I/ID No. oper shipping name	 : UN 3077 : Environmentally hazardous (Aprepitant) 	substance, solid, n.o.s.
Pa La Pa	ass cking group oels cking instruction (cargo	: 9 : III : Miscellaneous : 956	
Pa ge	craft) cking instruction (passen- r aircraft) vironmentally hazardous	: 956 : yes	
UN	DG-Code I number oper shipping name	N.O.S.	ARDOUS SUBSTANCE, SOLID,
Pa La Em	ass cking group pels iS Code irine pollutant	(Aprepitant) : 9 : III : 9 : F-A, S-F : yes	

Transport in bulk according to Annex II of MARPOL 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. (Aprepitant)
Class Packing group Labels Hazard Identification Number	:	9 9 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.





Versi 5.3	ion	Revision Date: 28.09.2024		OS Number: 589-00027	_		of last issue: 24.01.2024 of first issue: 09.10.2014			
SECTION 15. REGULATORY INFORMATION										
Safety, health and environmental regulations/legislation specific for the substance or mixture										
	National List of Carcinogenic Agents for Humans - : Not applicable (LINACH)									
	Brazil. List of chemicals controlled by the Federal : Not applicable Police									
	The ingredients of this product are reported in the following inventories: AICS : not determined									
	DSL		:	not determined						
	IECSC		:	not determined						
SECTION 16. OTHER INFORMATION										
	Revisic Date fo	on Date ormat	:	28.09.2024 dd.mm.yyyy						
	Source compile	Further informationSources of key data used to ompile the Material Safety Data SheetInternal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/								
	Full tex ACGIH	xt of other abbreviation	ons :		res	hold	Limit Values (TLV)			

ACGIH / TWA : 8-hour, time-weighted average

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



Version	Revision Date:	SDS Number:	Date of last issue: 24.01.2024
5.3	28.09.2024	20589-00027	Date of first issue: 09.10.2014

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.

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