

Carbimazole Formulation

Vers 5.0	sion	Revision Date: 2024/07/06		S Number: 8652-00016	Date of last issue: 2024/05/16 Date of first issue: 2019/03/22				
1. P	1. PRODUCT AND COMPANY IDENTIFICATION								
	Product	name	:	Carbimazole For	mulation				
	Other m	eans of identification	:	Vidalta 15 (A011) VIDALTA 15 MG					
	Manufa	cturer or supplier's d	letai	ls					
	Compar	ıy	:	MSD					
	Address	3	:	126 E. Lincoln Av Rahway, New Je	venue rsey U.S.A. 07065				
	Telepho	ne	:	908-740-4000					
	Emerge	ncy telephone number	· :	1-908-423-6000					
	E-mail a	address	:	EHSDATASTEW	ARD@msd.com				
	Recom	mended use of the cl	nemi	ical and restrictio	ons on use				
		nended use ions on use	:	Veterinary produce Not applicable	ct				

2. HAZARDS IDENTIFICATION

GHS Classification		
Reproductive toxicity	:	Category 1A
Specific target organ toxicity - repeated exposure (Dermal)	:	Category 2 (Thyroid, Adrenal gland, Testis)
Long-term (chronic) aquatic hazard	:	Category 2
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H360 May damage fertility or the unborn child. H373 May cause damage to organs (Thyroid, Adrenal gland, Testis) through prolonged or repeated exposure in contact with



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		skin. H411 Toxic to	aquatic life with long lasting effects.
Preca	autionary statements	P202 Do not h and understoo P260 Do not b P273 Avoid re	breathe dust. lease to the environment. otective gloves/ protective clothing/ eye protec-
		Response: P308 + P313 I attention. P391 Collect s	F exposed or concerned: Get medical advice/
		Storage: P405 Store loo	cked up.
		Disposal: P501 Dispose disposal plant.	of contents/ container to an approved waste
Dust		not result in classification can lead to mechanication	l 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 -< 60
Carbimazole	22232-54-8	>= 10 -< 25
Talc	14807-96-6	< 10

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.
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.



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lf s an de Pr	swallo ost im nd effe elayed	portant symptoms cts, both acute and	: : :	If in eyes, rinse w Get medical atten If swallowed, DO Get medical atten Rinse mouth thor May damage ferti May cause damage exposure in conta Contact with dust the skin. Dust contact with First Aid responde and use the recor when the potentia	shoes before reuse. ell with water. tion if irritation develops and persists. NOT induce vomiting. tion. oughly with water. lity or the unborn child. ge to organs through prolonged or repeated
5. FIRE	EFIGH	TING MEASURES			
Ur me Sp	Suitable extinguishing media Unsuitable extinguishing media Specific hazards during fire- fighting		:	concentrations, a	CO2) dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a
				potential dust exp Exposure to comb	bustion products may be a hazard to health.
Ha uc		ous combustion prod-	:	Carbon oxides	
Sr od		extinguishing meth-	:	cumstances and t Use water spray t Remove undamag so.	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 equipment for firefighters		:		e, wear self-contained breathing apparatus. rective equipment.
6. ACC		TAL RELEASE MEAS	SUF	RES	
tiv	ve equ	al precautions, protec- ipment and emer- rocedures	:	Follow safe handl	ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).





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				cannot be contair	ned.	
		ds and materials for iment and cleaning up	:	tainer for disposa Avoid dispersal o with compressed Dust deposits sho es, as these may leased into the at Local or national posal of this mate employed in the o mine which regula Sections 13 and	f dust in the air (i.e., clearing dust surfaces	
7. H	ANDLIN	NG AND STORAGE				
	Technical measures		:	causing an explo	nay accumulate and ignite suspended dust sion. precautions, such as electrical grounding nert atmospheres.	
	Local/T	otal ventilation	:	If sufficient ventila ventilation.	ation is unavailable, use with local exhaust	
	Advice	on safe handling	:	 Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and practice, based on the results of the workplace exposur sessment Keep container tightly closed. 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 		
	Conditi	ons for safe storage	:	Store locked up. Keep tightly close		
	Materia	als to avoid	:		nce with the particular national regulations. the following product types: agents	

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

•	-	•			
Components		CAS-No.	Value type	Control parame-	Basis



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		(Form of exposure)	ters / Permissible concentration			
Cellulose	9004-34-6	NAB	10 mg/m3	ID OEL		
		TWA	10 mg/m3	ACGIH		
Carbimazole	22232-54-8	TWA	20 µg/m3 (OEB 3)	Internal		
		Wipe limit	200 µg/100 cm ²	Internal		
Talc	14807-96-6	NAB (Res- pirable par- ticulate mat- ter)	2 mg/m3	ID OEL		
	enough data to	Further information: Not classified as carcinogenic to humans. No enough data to classify these materials as carcinogenic to hu- mans or animals				
		TWA (Res- pirable par- ticulate mat- ter)	2 mg/m3	ACGIH		

Engineering measures :		All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face con- tainment devices). Minimize open handling.	
Personal protective equipme	nt		
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.	
Filter type Hand protection	:	Particulates type	
Material	:	Chemical-resistant gloves	
Remarks Eye protection	:	Consider double gloving. 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	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.	
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work- ing place.	





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When using do not eat, drink or smoke. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	tablet, powder
Colour	:	pink
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n- octanol/water	:	Not applicable



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Decc Visc V Expl Oxid Mole Parti	-ignition temperature omposition temperature osity iscosity, kinematic osive properties izing properties ecular weight cle characteristics cle size	 No data avai No data avai Not applicable Not explosive The substance No data avai No data avai No data avai 	lable e ce or mixture is not classified as oxidizing. lable
Read Cher Poss tions Cond	ditions to avoid mpatible materials ardous decomposition	 Not classified Stable under May form exp dling or other Can react with Heat, flames Avoid dust for Oxidizing age 	th strong oxidizing agents. and sparks. rmation.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion
		Eye contact

Acute toxicity

Not classified based on available information.

Components:

Cellulose:		
Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg



Acute derm Talc: Acute oral t Skin corro	toxicity lation toxicity nal toxicity toxicity psion/irritation ed based on ava	::	icity LD50 (Mouse): & Remarks: Based Remarks: No da Remarks: No da LD50 (Rat): > 5, Remarks: Based	e substance or mixture has no acute oral to 360 mg/kg 3 on data from similar materials ta available ta available
Carbimazo Acute oral t Acute inhal Acute derm Talc: Acute oral t Skin corro Not classifie Componer Carbimazo Remarks Talc:	toxicity lation toxicity nal toxicity toxicity psion/irritation ed based on ava	::	Assessment: The icity LD50 (Mouse): & Remarks: Based Remarks: No da Remarks: No da LD50 (Rat): > 5, Remarks: Based	e substance or mixture has no acute oral to 360 mg/kg d on data from similar materials ta available ta available 000 mg/kg
Acute oral t Acute inhal Acute derm Talc: Acute oral t Skin corro Not classific <u>Componer</u> Carbimazo Remarks Talc:	toxicity lation toxicity nal toxicity toxicity psion/irritation ed based on ava	::	Assessment: The icity LD50 (Mouse): & Remarks: Based Remarks: No da Remarks: No da LD50 (Rat): > 5, Remarks: Based	e substance or mixture has no acute oral to 360 mg/kg d on data from similar materials ta available ta available 000 mg/kg
Acute derm Talc: Acute oral t Skin corro Not classific <u>Componer</u> Carbimazo Remarks Talc:	nal toxicity toxicity psion/irritation ed based on ava	:	Remarks: Based Remarks: No da Remarks: No da LD50 (Rat): > 5, Remarks: Based	d on data from similar materials ta available ta available 000 mg/kg
Acute derm Talc: Acute oral t Skin corro Not classific <u>Componer</u> Carbimazo Remarks Talc:	nal toxicity toxicity psion/irritation ed based on ava	:	Remarks: No da LD50 (Rat): > 5, Remarks: Based	ta available 000 mg/kg
Talc: Acute oral to Skin corro Not classifie Componer Carbimazo Remarks Talc:	toxicity sion/irritation ed based on ava	:	LD50 (Rat): > 5, Remarks: Based	000 mg/kg
Acute oral f Skin corro Not classific <u>Componer</u> Carbimazo Remarks Talc:	sion/irritation ed based on ava		Remarks: Based	
Skin corro Not classifie <u>Componer</u> Carbimazo Remarks Talc:	sion/irritation ed based on ava		Remarks: Based	
Not classifi Componer Carbimazo Remarks Talc:	ed based on ava	ailable	information.	
Componer Carbimazo Remarks Talc:		ailable	information.	
Carbimazo Remarks Talc:	nts:			
Remarks				
Talc:	ole:		NI 1 / 111	
		:	No data available	e
Species Result				
rtoount		:	Rabbit No skin irritation	
		•		
-	/e damage/eye i			
	ed based on ava	ailable	information.	
<u>Componer</u>				
Carbimazo Remarks	ole:	:	No data availabl	٩
		•		
Talc:				
Species Result		:	Rabbit No eye irritation	
I Vesuit		•	No eye imation	
Respirator	ry or skin sensi	tisatic	on	
Skin sensi Not classifi	itisation ed based on ava	ailable	information.	
Respirator				



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<u>Com</u>	ponents:		
Carb	imazole:		
Rema	arks	: No data ava	ailable
Talc:			
	sure routes	: Skin contac	xt
Spec Resu		: Humans : negative	
Germ	cell mutagenicity		
Not c	lassified based on av	ailable information.	
<u>Com</u>	ponents:		
Cellu			
Geno	toxicity in vitro	: Test Type: Result: neg	Bacterial reverse mutation assay (AMES) ative
		Test Type: Result: neg	In vitro mammalian cell gene mutation test ative
Geno	toxicity in vivo	cytogenetic Species: M	ouse Route: Ingestion
II Carbi	imazole:		
Geno	toxicity in vitro	Result: pos	Chromosome aberration test in vitro itive Based on data from similar materials
Geno	toxicity in vivo	cytogenetic Species: M Application Result: equ	Route: Subcutaneous
		cytogenetic Species: M Application Result: neg	ouse Route: Subcutaneous
Talc:			
Geno	toxicity in vitro		DNA damage and repair, unscheduled DNA syn- ammalian cells (in vitro)



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I			Result: negative	
Geno	otoxicity in vivo	:	Test Type: Chrom Species: Rat Application Route Result: negative	nosome aberration test in vitro : Ingestion
Carci	inogenicity			
Not c	lassified based on avai	lable	information.	
Com	ponents:			
Cellu	llose:			
	cation Route sure time	:	Rat Ingestion 72 weeks negative	
Carb	imazole:			
Speci Applio Resu Rema	cation Route It	:	Mouse Oral positive Based on data fro	om similar materials
Spec Applie Resu Rema	cation Route It	:	Rat Oral positive Based on data fro	om similar materials
Talc:				
	cation Route sure time	:	Mouse inhalation (dust/m 2 Years negative	ist/fume)
-	oductive toxicity			
-	damage fertility or the u	Inpor	n child.	
	<u>ponents:</u>			
Cellu IEffect	l lose: ts on fertility		Test Tune: One a	eneration reproduction toxicity study
LIEC		•	Species: Rat Application Route Result: negative	eneration reproduction toxicity study
Effect ment	ts on foetal develop-	:	Test Type: Fertilit Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion



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Carbimazole:

Reproductive toxicity - As- sessment	:	May damage fertility or the unborn child.
Talc:		
Effects on foetal develop- ment	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Thyroid, Adrenal gland, Testis) through prolonged or repeated exposure in contact with skin.

Components:

Carbimazole:

Exposure routes	: Skin contact
Target Organs	: Thyroid, Adrenal gland, Testis
Target Organs Assessment	: May cause damage to organs through prolonged or repeated
	exposure.

Repeated dose toxicity

Components:

Cellulose:

Species	: Rat
NOAEL	: >= 9,000 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

Carbimazole:

Species	:	Rat
LÖAEL	:	0.5 mg/kg
Application Route	:	Intraperitoneal
Exposure time	:	15 Days
Target Organs	:	Thyroid

:	Rat
:	1.35 mg/kg
:	Oral
:	8 Weeks
:	Thyroid, Testis
	:



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Not c	ration toxicity lassified based on availa rience with human exp					
<u>Com</u>	oonents:					
Carbi	i mazole: tion	:	Symptoms: Rash	, hearing loss, Headache, Nausea, hair loss		
2. ECOL	OGICAL INFORMATION	N				
Ecoto	oxicity					
<u>Com</u>	oonents:					
Cellu	lose:					
Toxic	ity to fish	:	Exposure time: 4	tipes (Japanese medaka)): > 100 mg/l 8 h on data from similar materials		
Carbi	imazole:					
Toxic	ity to fish	:	Exposure time: 9 Method: OECD T	es promelas (fathead minnow)): > 120 mg/l 6 h ēst Guideline 203 on data from similar materials		
	ity to daphnia and other ic invertebrates	:	Exposure time: 4 Method: OECD T	nagna (Water flea)): 0.43 mg/l 8 h Test Guideline 202 on data from similar materials		
			LC50 (Americam Exposure time: 9 Remarks: Based			
Toxic plants	ity to algae/aquatic	:	mg/l Exposure time: 7	chneriella subcapitata (green algae)): > 100 2 h on data from similar materials		
			mg/l Exposure time: 7	rchneriella subcapitata (green algae)): 25 2 h on data from similar materials		
	ctor (Acute aquatic tox-	:	1			
	ctor (Chronic aquatic	:	1			
toxicit Toxic	ty) ity to microorganisms	:	: EC50: > 1,000 mg/l Exposure time: 3 h			



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		NOEC: > 1,000 m Exposure time: 3 Test Type: Respir	on data from similar materials g/l h
	Γ alc: Γoxicity to fish	LC50 (Brachydan Exposure time: 24	io rerio (zebrafish)): > 100,000 mg/l l h
II F	Persistence and degradabil		
	Components:		
	Cellulose: Biodegradability	Result: Readily bi	odegradable.
ר ת ר	Bioaccumulative potential No data available Mobility in soil No data available Other adverse effects		
1	No data available		
13. D	ISPOSAL CONSIDERATION		
١	Disposal methods Waste from residues Contaminated packaging	Empty containers dling site for recyc	ordance with local regulations. should be taken to an approved waste han-
14. TI	RANSPORT INFORMATION		
I	nternational Regulations		
L F C F	JNRTDG JN number Proper shipping name Class Packing group Labels	UN 3077 ENVIRONMENTA N.O.S. (Carbimazole) 9 III 9	ALLY HAZARDOUS SUBSTANCE, SOLID,
	Environmentally hazardous	yes	





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		:	(Carbimazole)	azardous substance, solid, n.o.s.
Labels	g instruction (cargo	:	9 III Miscellaneous 956	
ger air	g instruction (passen- craft) nmentally hazardous	:	956 yes	
IMDG- UN nu Proper		:	UN 3077 ENVIRONMENTA N.O.S. (Carbimazole)	ALLY HAZARDOUS SUBSTANCE, SOLID,
Labels EmS C		: : : : : : : : : : : : : : : : : : : :	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.

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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable



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Restri	icted substances				:	Not applicable
Regu Mater		of Ti	ade No. 7 of 2022	2 on	Di	stribution and Control of Hazardo
•••	of hazardous materials ol, Annex I	subj	ect to distribution	and	:	Not applicable
	of hazardous materials bl, Annex II	subj	ect to distribution	and	:	Not applicable
	components of this pro	oduo	-	the f	ol	lowing inventories:
AICS		:	not determined			
DSL		:	not determined			
IECS	С	:	not determined			
OTHE	R INFORMATION					
Revis	ion Date	:	2024/07/06			
Furth	er information					
	ces of key data used to ile the Safety Data t	:		arch	re	lata from raw material SDSs, OECE sults and European Chemicals Age "/
	where changes have b nent by two vertical line		made to the previ	ous v	er	sion are highlighted in the body of th
Date	format	:	yyyy/mm/dd			
Full to	ext of other abbreviati	ons				
ACGI ID OE		:				Limit Values (TLV) Exposure Limits
	H / TWA EL / NAB	:	8-hour, time-weig Long term expos			
AIIC	- Australian Inventory		dustrial Chemica	ls; Al	١T	t T - National Agency for Transpo of Materials; bw - Body weight; C

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



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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.

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