

according to the Globally Harmonized System

### **Cimetidine Formulation**

Version 2.1	Revision Date: 30.09.2023		S Number: 2352-00010	Date of last issue: 04.04.2023 Date of first issue: 03.05.2019				
1. PROD	1. PRODUCT AND COMPANY IDENTIFICATION							
Pro	duct name	:	Cimetidine Formulation					
Mai	nufacturer or supplier's	s detai	ls					
	Company		MSD					
Adc	Address		Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207					
Tele	ephone	:	+1-908-740-40	000				
Em	ergency telephone numb	oer :	+1-908-423-60	000				
E-m	nail address	:	EHSDATASTE	WARD@msd.com				
Rec	commended use of the	chem	ical and restric	tions on use				
Rec	commended use	:	Pharmaceutica	al				

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

### 2. HAZARDS IDENTIFICATION

### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Liver, Kidney, Testis)
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H360D May damage the unborn child. H373 May cause damage to organs (Liver, Kidney, Testis) through prolonged or repeated exposure if swallowed.
Precautionary statements	:	<b>Prevention:</b> P203 Obtain, read and follow all safety instructions before use.

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P260 Do not breathe dust. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P318 IF exposed or concerned, get medical advice.

#### Storage:

P405 Store locked up.

### Disposal:

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

#### Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 40 %

#### 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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (%
		w/w)
cimetidine	51481-61-9	>= 30 - < 50
Cellulose	9004-34-6	>= 10 - < 20
Starch	9005-25-8	>= 1 - < 5
Magnesium stearate	557-04-0	>= 1 - < 5

#### 4. FIRST AID MEASURES

General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	<ul> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>
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. Rinse mouth thoroughly with water.



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Most important symptoms	:	May damage th			
and effects, both acute and delayed		<ul> <li>May cause damage to organs through prolonged or repeate exposure if swallowed.</li> <li>Contact with dust can cause mechanical irritation or drying the skin.</li> <li>Dust contact with the eyes can lead to mechanical irritation</li> <li>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).</li> </ul>			
Protection of first-aiders	:				
Notes to physician	:		atically and supportively.		
5. FIREFIGHTING MEASURES					
Suitable extinguishing media	:	Water spray Alcohol-resistar Carbon dioxide Dry chemical			
Unsuitable extinguishing media	:	None known.			
Specific hazards during fire- fighting	:	concentrations, potential dust e	ng dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a xplosion hazard. mbustion products may be a hazard to health.		
Hazardous combustion prod- ucts	<ul> <li>Carbon oxides</li> <li>Nitrogen oxides (NOx)</li> <li>Sulphur oxides</li> <li>Metal oxides</li> </ul>				
Specific extinguishing meth- ods	cumstances and the surrounding environ Use water spray to cool unopened contai				
Special protective equipment for firefighters	:		ire, wear self-contained breathing apparatus. rotective equipment.		
6. ACCIDENTAL RELEASE MEA	SUF	RES			
Personal precautions, protec- tive equipment and emer- gency procedures	:	Follow safe har	rotective equipment. Indling advice (see section 7) and personal pro- ent recommendations (see section 8).		
Environmental precautions	:	Prevent further Retain and disp	o the environment. leakage or spillage if safe to do so. loose of contaminated wash water. s should be advised if significant spillages ained.		
Methods and materials for containment and cleaning up	:	tainer for disposed Avoid dispersal with compressed	of dust in the air (i.e., clearing dust surfaces		
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		leased into the Local or nation posal of this n employed in the mine which re Sections 13 a	nay form an explosive mixture if they are re- e atmosphere in sufficient concentration. nal regulations may apply to releases and dis- naterial, as well as those materials and items ne cleanup of releases. You will need to deter- gulations are applicable. nd 15 of this SDS provide information regarding r national requirements.			
7. HAND	LING AND STORAGE					
Technical measures		causing an ex Provide adequ	uate precautions, such as electrical grounding			
Loca	al/Total ventilation		and bonding, or inert atmospheres. If sufficient ventilation is unavailable, use with local exhaust ventilation			
Adv	ice on safe handling	: Do not get on Do not breath Do not swallor Avoid contact Handle in acc practice, base sessment Keep containe Minimize dust Keep containe Keep away fro Take precauti	w.			
Con	ditions for safe storage	: Keep in prope Store locked u Keep tightly cl				
Mate	erials to avoid		vith the following product types:			

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
cimetidine	51481-61-9	TWA	1000 µg/m3 (OEB 1)	
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH



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			TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH		
Engin	neering measures	compound. All engineerin design and op	g controls shoul	trols to minimize e d be implemented dance with GMP p d the environment	by facility principles to		
Perso	onal protective equip	ment					
Filt	ratory protection ter type protection	sure assessm ommended gu					
	aterial	: Chemical-resi	Chemical-resistant gloves				
Eye p	Eye protection : Wear safety glasses with side shields or gogg If the work environment or activity involves du mists or aerosols, wear the appropriate gogg Wear a faceshield or other full face protection potential for direct contact to the face with du aerosols.			tivity involves dust opropriate goggles I face protection if	y conditions, s. there is a		
Skin a	and body protection	: Work uniform					
Hygie	ne measures	flushing syster place. When using d Wash contam The effective of engineering co appropriate de industrial hygi	ms and safety s o not eat, drink inated clothing l operation of a fa ontrols, proper p egowning and d	pefore re-use. acility should includ personal protective econtamination pr medical surveillar	the working de review of e equipment, ocedures,		

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	No data available
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

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	Flash p	point	:	Not applicable	
	Evapor	ation rate	:	Not applicable	
	Flamm	ability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- ans.
	Flamm	ability (liquids)	:	No data available	9
		explosion limit / Upper ability limit	:	No data available	9
		explosion limit / Lower ability limit	:	No data available	9
	Vapour	pressure	:	Not applicable	
	Relativ	e vapour density	:	Not applicable	
	Relativ	e density	:	No data available	9
	Density	/	:	No data available	9
	Solubili Wat	ity(ies) ter solubility	:	No data available	9
	Partitio octanol	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	Not applicable	
	Explosi	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	ılar weight	:	No data available	9
	Particle	e size	:	No data available	9

### 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac- tions	:	May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.



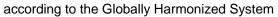
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lı F	ncompa	ons to avoid atible materials ous decomposition s	:		
11. TC	охісо	LOGICAL INFORMAT	101	1	
	nformat exposur	tion on likely routes of e	:	Inhalation Skin contact Ingestion Eye contact	
Ν	Acute to Not clas Compo	sified based on availa	ble	information.	
	cimetid				
Ą	Acute o	ral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
				LD50 (Mouse): 2,5	550 mg/kg
				LD50 (Hamster): >	> 4,000 mg/kg
	Acute to adminis	oxicity (other routes of tration)	:	LD50 (Rat): 106 m Application Route:	
				LD50 (Rabbit): 16 Application Route:	
				LD50 (Rat): 860 m Application Route:	
				LD50 (Mouse): 43 Application Route: Symptoms: Convu	Subcutaneous
c	Cellulo	se:			
A	Acute o	ral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
A	Acute in	halation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 h Test atmosphere:	า
Α	Acute d	ermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
	Starch: Acute of	ral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
A	Acute d	ermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
N	Magnes	sium stearate:			



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/ersion 2.1	Revision Date: 30.09.2023		S Number: 42352-00010		
Acute	oral toxicity	:	Assessment: Th icity	000 mg/kg Test Guideline 423 e substance or mixture has no acute oral tox- d on data from similar materials	
Acute	dermal toxicity	:	LD50 (Rabbit): > Remarks: Based	> 2,000 mg/kg d on data from similar materials	
-	corrosion/irritation assified based on ava	ailable	information.		
Comp	oonents:				
Magn	esium stearate:				
Speci Resul Rema	es t		Rabbit No skin irritation Based on data f	rom similar materials	
	Serious eye damage/eye irritation Not classified based on available information.				
<u>Comp</u>	oonents:				
Starc	h:				
Speci Resul		:	Rabbit No eye irritation		
Magn	esium stearate:				
Speci	es	:	Rabbit		
Resul Rema		:	No eye irritation Based on data f	rom similar materials	
Respi	iratory or skin sensi	tisatio	n		
-	sensitisation assified based on ava	ailable	information.		
-	iratory sensitisation assified based on ava		information.		
Comp	oonents:				
Starc	h:				
Test T Expos Speci Resul	sure routes es	:	Maximisation Te Skin contact Guinea pig negative	est	
	_		-		
-	esium stearate:	-	Movimication T	et.	
Test T	ype sure routes	:	Maximisation Te Skin contact	251	





ersion .1	Revision Date: 30.09.2023	SDS N 424235	umber: 52-00010	Date of last issue: 04.04.2023 Date of first issue: 03.05.2019				
Species Method Result Remarks		: OE : neg	<ul> <li>Guinea pig</li> <li>OECD Test Guideline 406</li> <li>negative</li> <li>Based on data from similar materials</li> </ul>					
	cell mutagenicity							
_	assified based on av	allable infor	mation.					
	oonents:							
	idine:	-	· <b>-</b>					
Geno	toxicity in vitro	: Tes Res	st Type: Bac sult: negative	terial reverse mutation assay (AMES) e				
			st Type: Chro sult: negative	omosomal aberration e				
		Tes	Test Type: unscheduled DNA synthesis assay Test system: rat hepatocytes Result: negative Test Type: unscheduled DNA synthesis assay Result: negative					
Cellu	lose:							
	toxicity in vitro		st Type: Bac sult: negative	terial reverse mutation assay (AMES) e				
			st Type: In vi sult: negative	tro mammalian cell gene mutation test e				
Geno	toxicity in vivo	cyto Spe App	: Test Type: Mammalian erythrocyte micronucleus test (in cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative					
Starc	h:							
	toxicity in vitro		st Type: Bac sult: negative	terial reverse mutation assay (AMES) e				
Magn	esium stearate:							
-	toxicity in vitro	Res	sult: negative	tro mammalian cell gene mutation test e d on data from similar materials				
		Met Res	thod: OECD sult: negative	omosome aberration test in vitro Test Guideline 473 e d on data from similar materials				
		Tes	st Type: Bac	terial reverse mutation assay (AMES)				

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			Result: negativ	
				ed on data from similar materials
Carci	nogenicity			
Not cl	lassified based on ava	ilable	information.	
<u>Comp</u>	oonents:			
cimet	tidine:			
Speci	es	:	Rat	
	cation Route	:	Oral	
	sure time	:	2 Years	
Rema	et Organs		Testis Benign tumor(s	<b>)</b>
IVEIIIC		•	Denigh turnor(8	<i>)</i> /
Carcii ment	nogenicity - Assess-	:	No evidence of	carcinogenicity in animal studies.
Cellu	lose:			
Speci		:	Rat	
	cation Route	:	Ingestion	
Expos Resul	sure time	:	72 weeks negative	
itesui	it.	•	negative	
Repro	oductive toxicity			
May o	damage the unborn ch	ild.		
<u>Comp</u>	oonents:			
cimet	tidine:			
Effect	s on fertility	:		tility/early embryonic development
			Species: Rat Application Ro	
				L: 950 mg/kg body weight
				ct on reproduction capacity
Effect	s on foetal develop-	:	Test Type: Dev	velopment
ment			Species: Rat Application Rot	

mentSpecies: Rat<br/>Application Route: Oral<br/>Developmental Toxicity: LOAEL: 17 mg/kg body weight<br/>Symptoms: male reproductive effects<br/>Remarks: Adverse effects were observed in males only.Reproductive toxicity - As-<br/>sessmentMay damage the unborn child.Cellulose:Effects on fertilityTest Type: One-generation reproduction toxicity study<br/>Species: Rat<br/>Application Route: Ingestion<br/>Result: negative

Effects on foetal develop- : Test Type: Fertility/early embryonic development



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ment		Species: Rat Application Rot Result: negativ	•
Magn	esium stearate:		
Effect	ts on fertility	reproduction/de Species: Rat Application Rou Method: OECD Result: negativ	Test Guideline 422
Effect ment	ts on foetal develop-	Species: Rat Application Rou Result: negativ	

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs (Liver, Kidney, Testis) through prolonged or repeated exposure if swallowed.

#### **Components:**

### cimetidine:

Exposure routes :	:	Oral
Target Organs :	:	Liver, Kidney, Testis
Assessment :	:	May cause damage to organs through prolonged or repeated
		exposure.

#### Repeated dose toxicity

### Components:

#### cimetidine:

Species LOAEL Application Route Exposure time Target Organs Remarks	:	Rat 160 mg/kg Oral 2 Months Gastrointestinal tract May cause damage to organs.
Species NOAEL Application Route Exposure time Symptoms Species	:	Rat 200 mg/kg Oral 12 Months No adverse effects Rat

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Expo	cation Route sure time et Organs	: 950 mg/kg : Oral : 2 yr : Liver, Testis, P : May cause dar	rostate nage to organs.
Expo	EL cation Route sure time et Organs	: Dog : 366 mg/kg : Oral : 12 Months : Liver, Kidney, F : May cause dar	Prostate nage to organs.
Expo		: Dog : 144 mg/kg : Oral : 4 yr : No adverse eff	ects
Spec NOA Appli		: Rat : >= 9,000 mg/kg : Ingestion : 90 Days	)
	ies EL cation Route sure time	: Rat : >= 2,000 mg/kg : Skin contact : 28 Days : OECD Test Gu	
Spec NOA Appli	EL cation Route sure time	: Rat : > 100 mg/kg : Ingestion : 90 Days : Based on data	from similar materials
Not c	ration toxicity classified based on ava erience with human e		
	ponents:		
<b>cime</b> Inges	<b>tidine:</b> stion	Dizziness, Nau nervous systen effects	e most common side effects are:, Headache, sea, skin rash, Itching, May cause, central n effects, gynecomastia, impotence, kidney cause harm to breast-fed children.

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### 12. ECOLOGICAL INFORMATION

Ecotoxicity		
Components:		
cimetidine:		
Ecotoxicology Assessment Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded
Cellulose:		
Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Magnesium stearate:		
Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EL50 (Daphnia magna (Water flea)): > 1 mg/l Exposure time: 47 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	:	EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials No toxicity at the limit of solubility
		NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC10 (Pseudomonas putida): > 100 mg/l Exposure time: 16 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials



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	Persis	tence and degradabi	lity		
	Comp	onents:			
	Cellulo	ose:			
	Biodegradability :		Result: Readily b	odegradable.	
	Magne	esium stearate:			
	Biodegradability :		Result: Not biode Remarks: Based	gradable on data from similar materials	
	Bioaco	cumulative potential			
	Comp	onents:			
	cimeti	dine:			
	Partitio octano	n coefficient: n- I/water	:	log Pow: 0.40	
	Magne	esium stearate:			
	Partitio octano	n coefficient: n- I/water	:	log Pow: > 4	
	Mobili	ty in soil			
		a available			
		<b>adverse effects</b> a available			
13. I	DISPOS	SAL CONSIDERATIO	NS		
	Dispos	sal methods			
	-	from residues	:		waste into sewer. ordance with local regulations.

#### 14. TRANSPORT INFORMATION

Contaminated packaging

#### **International Regulations**

UNRTDG

Not regulated as a dangerous good

:

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

dling site for recycling or disposal.

Empty containers should be taken to an approved waste han-

If not otherwise specified: Dispose of as unused product.

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#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

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

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

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

#### **16. OTHER INFORMATION**

Revision Date		30.09.2023		
Further information				
Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/		
Date format	:	dd.mm.yyyy		
Full text of other abbreviations				
ACGIH	:	USA. ACGIH Threshold 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

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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.

IN / EN