

according to the Hazardous Products Regulations

Aprepitant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/26/2023
6.2	01/24/2024	20590-00026	Date of first issue: 10/09/2014

SECTION 1. IDENTIFICATION

Product name	:	Aprepitant Formulation
Other means of identification	:	No data available

Manufacturer or supplier's details

Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use	: Pharmaceutical
Restrictions on use	: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Specific target organ toxicity	:	Category 2 (Prostate, Testis)
 repeated exposure (Oral) 		

GHS label elements

Hazard pictograms



Signal Word	:	Warning

Hazard Statements : H373 May cause damage to organs (Prostate, Testis) through prolonged or repeated exposure if swallowed.

Precautionary Statements

Prevention: P260 Do not breathe dust.

Response:

P314 Get medical attention if you feel unwell.

Disposal:

:

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

Other hazards

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.



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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

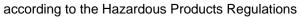
Components			
Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Aprepitant	No data availa- ble	170729-80-3	37.1
Sucrose	.alphaD- Glucopyra- noside, .beta D- fructofuranosyl	57-50-1	37.1
Cellulose	No data availa- ble	9004-34-6	17

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.
In case of eye contact		Get medical attention if symptoms occur. If in eyes, rinse well with water.
in case of eye contact	•	Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting.
		Get medical attention if symptoms occur.
Most important symptoms		Rinse mouth thoroughly with water. May cause damage to organs through prolonged or repeated
and effects, both acute and	•	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
Notes to physician	:	when the potential for exposure exists (see section 8). Treat symptomatically and supportively.
		· · · · · · · · · · · · · · · · · · ·

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a





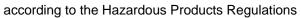
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			potential dust exp Exposure to com	plosion hazard. Soustion products may be a hazard to health.
Haza ucts	ardous combustion prod-	:	Carbon oxides Fluorine compour Nitrogen oxides (l	
Spec ods	Specific extinguishing meth- ods		cumstances and t Use water spray t	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do
•	cial protective equipment re-fighters	:		e, wear self-contained breathing apparatus. tective equipment.

Personal precaution tive equipment and gency procedures		Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental prec	autions :	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 mater containment and cl		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 with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe dust.
		Do not swallow.
		Avoid contact with eyes.
		Avoid prolonged or repeated contact with skin.





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		practice, based assessment Minimize dust y Keep contained Keep away from Take precautio Take care to pre environment.	ardance with good industrial hygiene and safety d on the results of the workplace exposure generation and accumulation. r closed when not in use. m heat and sources of ignition. nary measures against static discharges. revent spills, waste and minimize release to the
Con	ditions for safe storage		ly labeled containers. lance with the particular national regulations.
Mate	erials to avoid		ith the following product types:

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Aprepitant	170729-80-3	TWA	0.2 mg/m3 (OEB 2)	Internal
Sucrose	57-50-1	TWA	10 mg/m ³	CA AB OEL
		TWA (Total dust)	10 mg/m ³	CA BC OEL
		TWA (respir- able dust fraction)	3 mg/m³	CA BC OEL
		TWAEV	10 mg/m ³	CA QC OEL
		TWA	10 mg/m ³	ACGIH
Cellulose	9004-34-6	TWA	10 mg/m ³	CA AB OEL
		TWA (Total dust)	10 mg/m ³	CA BC OEL
		TWA (respir- able dust fraction)	3 mg/m ³	CA BC OEL
		TWAEV (to- tal dust)	10 mg/m ³	CA QC OEL
		TWA	10 mg/m ³	ACGIH

Ingredients with workplace control parameters

Engineering measures	:	Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Personal protective equipme	nt	
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Particulates type

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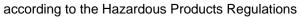


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	protection aterial	: Chemical-resis	tant gloves
Eye p	rotection	If the work env mists or aeroso Wear a facesh	asses with side shields or goggles. ironment or activity involves dusty conditions, ols, wear the appropriate goggles. ield or other full face protection if there is a rect contact to the face with dusts, mists, or
	and body protection ne measures	: If exposure to e eye flushing sy working place. When using do Wash contamin The effective o engineering co appropriate de industrial hygie	or laboratory coat. chemical is likely during typical use, provide restems and safety showers close to the o not eat, drink or smoke. hated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the trative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	colored
Odor	:	odorless
Odor 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	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available





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R	elative vapor density	:	No data available	e
R	elative density	:	No data available	e
D	ensity	:	No data available	e
S	olubility(ies) Water solubility	:	No data available	e
	artition coefficient: n- ctanol/water	:	No data available	e
	utoignition temperature	:	No data available	e
D	ecomposition temperature	:	No data available	e
Vi	iscosity Viscosity, kinematic	:	No data available	e
E	xplosive properties	:	Not explosive	
0	xidizing properties	:	The substance o	r mixture is not classified as oxidizing.
М	olecular weight	:	No data available	e
М	inimum ignition energy	:	< 3 mJ	
Pa	article size	:	No data available	e

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.
Incompatible materials Hazardous decomposition products		Oxidizing agents No hazardous decomposition products are known.
•		

SECTION 11. TOXICOLOGICAL INFORMATION

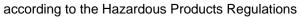
Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact



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	e toxicity			
Not c	lassified based on availa	ble	information.	
Com	ponents:			
Apre	pitant:			
Acute	e oral toxicity	:	LD50 (Rat): > 2,00	00 mg/kg
			LD50 (Mouse): > 2	2,000 mg/kg
	e toxicity (other routes of nistration)	:	LD50 (Rat): 800 - Application Route	
			LD50 (Mouse): > 2 Application Route	
Sucro	ose:			
Acute	e oral toxicity	:	LD50 (Rat): 29,70	10 mg/kg
Cellu	lose:			
Acute	e oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere:	h
Acute	e dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
Not c	corrosion/irritation lassified based on availa ponents:	ble	information.	
	pitant:			
Speci			Rabbit	
Metho		÷	Draize Test	
Resu	lt	:	No skin irritation	
	ous eye damage/eye irri lassified based on availa			
	ponents:	-	·	
Apre	pitant:			
Speci	ies	:	Rabbit	
Resu		:	No eye irritation	
Metho	DO	:	Draize Test	





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Resp	iratory or skin sens	sitizatior	n	
_	sensitization lassified based on av	/ailable i	nformation.	
-	iratory sensitization		nformation.	
Com	oonents:			
Apre Rema	pitant: arks	:	No data availa	able
	cell mutagenicity lassified based on av	/ailable i	nformation.	
Com	oonents:			
Apre	pitant:			
Geno	toxicity in vitro		Test Type: Ar Result: negati	
				nromosomal aberration Chinese hamster ovary cells ive
				kaline elution assay rat hepatocytes ive
			Test Type: in Test system: Result: negati	human lymphoblastoid cells
Geno	toxicity in vivo	:	Test Type: Mi Species: Mou Application Ro Result: negati	oute: Oral
Sucro				
	toxicity in vitro	:	Test Type: In Result: negati	vitro mammalian cell gene mutation test ive
Cellu	lose.			
	toxicity in vitro		Test Type: Ba Result: negati	acterial reverse mutation assay (AMES)
			Test Type: In Result: negati	vitro mammalian cell gene mutation test ive
Geno	toxicity in vivo		Test Type: Ma cytogenetic as Species: Mou	
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sion	Revision Date: 01/24/2024		98 Number: 590-00026	Date of last issue: 09/26/2023 Date of first issue: 10/09/2014
			Application Route Result: negative	e: Ingestion
			-	
Carci	nogenicity			
Not cl	assified based on avail	able	information.	
Comp	oonents:			
Apre	pitant:			
Speci	es	:	Mouse, male	
	cation Route	:	Oral	
	sure time	:	106 weeks	
Dose		:	>=1000 mg/kg b	ody weight
Resul		:	positive	or mode of action is not relevant in humans
Rema	IIKS	·	The mechanism	or mode of action is not relevant in numari
Speci		:	Mouse, female	
	ation Route	:	Oral	
	sure time	:	106 weeks	4
Dose Resul	4	:	>= 500 mg/kg bo positive	ay weight
Rema		÷		or mode of action is not relevant in humans
Snaai	20		Mouse	
Speci	cation Route	:	Oral	
	sure time	:	105 weeks	
Dose		÷	2000 mg/kg body	[,] weight
Resul	t	:	positive	
Rema	irks	:	The mechanism	or mode of action is not relevant in humans
Cellu	lose:			
Speci			Rat	
	cation Route	÷	Ingestion	
	sure time	:	72 weeks	
Resul	t	:	negative	
Repro	oductive toxicity			
-	assified based on avail	able	information.	
Comp	oonents:			
Aprei	pitant:			
	s on fertility	;	Test Type: Fertili	tv
	- ···· /		Species: Rat, ma	le and female
			Fertility: NOAEL:	2,000 mg/kg body weight
			Result: No effect	
Effort	s on fotal dovelopment		Test Tupo: Doug	onmont
Enect	s on fetal development	:	Test Type: Deve Species: Rat	opment
			Application Rout	e: Oral
				oxicity: NOAEL: 2,000 mg/kg body weight
				s on fetal development.



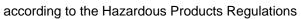
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rsion	Revision Date: 01/24/2024		9S Number: 590-00026	Date of last issue: 09/26/2023 Date of first issue: 10/09/2014
				it
Cellu	lose:			
Effect	s on fertility	:	Test Type: On Species: Rat Application Ro Result: negativ	
Effect	s on fetal development	:	Test Type: Fer Species: Rat Application Ro Result: negativ	
STOT	-single exposure			
Not c	lassified based on availa	able	information.	
	-repeated exposure			
May o lowed		s (Pr	ostate, Testis) t	hrough prolonged or repeated exposure if swa
<u>Com</u>	oonents:			
Apre	pitant:			
	et Organs ssment	:	Prostate, Testi May cause dar exposure.	s mage to organs through prolonged or repeated
Repe	ated dose toxicity			
	oonents:			
Aprei	pitant:			
Speci LOAE Applic Expos	es	: : : : : : : : : : : : : : : : : : : :	Dog >= 50 mg/kg Oral 39 Weeks Prostate, Testi	s
		:	Rat 125 mg/kg Oral 27 Weeks	



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Expos			Rat, female 125 mg/kg Oral 106 Weeks Kidney	
Cellu	lose:			
Speci NOAE Applic	es	:	Rat >= 9,000 mg/kg Ingestion 90 Days	
-	ation toxicity assified based on availa	blo	information	
	rience with human exp			
-	ponents:			
	pitant:			
Inges		:		lache, Fatigue, hiccups, constipation, anores change, Rash, Nausea, Diarrhea, hypoten-
ECTION	12. ECOLOGICAL INFO	ORI	MATION	
Ecoto	oxicity			
<u>Com</u>	oonents:			
Apre	pitant:			
Toxici	ity to fish	:	Exposure time: 9 Method: OECD T	es promelas (fathead minnow)): > 0.462 mg/ 6 h est Guideline 203 icity at the limit of solubility.
	ity to daphnia and other ic invertebrates	:	Exposure time: 4 Method: OECD T	nagna (Water flea)): > 0.345 mg/l 8 h est Guideline 202 icity at the limit of solubility.
Toxici plants	ity to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD T	rchneriella subcapitata (green algae)): 0.184 2 h est Guideline 201 icity at the limit of solubility.
			0.184 mg/l Exposure time: 7: Method: OECD T	chneriella subcapitata (green algae)): > 2 h est Guideline 201 icity at the limit of solubility.





ersion 2	Revision Date: 01/24/2024		0S Number: 590-00026	Date of last issue: 09/26/2023 Date of first issue: 10/09/2014	
Toxicity to fish (Chronic tox- icity)		:	NOEC (Pimephales promelas (fathead minnow)): 0.195 Exposure time: 32 d Method: OECD Test Guideline 210		
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)		:	NOEC (Daphnia r Exposure time: 2 ⁻ Method: OECD T		
Toxicity to microorganisms		:	EC50: > 100 mg/l Exposure time: 3 Test Type: Respin Method: OECD T Remarks: No toxi	h ration inhibition	
Cellulo	ose:				
	y to fish	:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials	
Persis	tence and degradabili	ity			
<u>Compo</u>	onents:				
Aprepi	itant:				
Biodeg	radability	:	Result: not rapidly Biodegradation: 9 Exposure time: 66 Method: OECD T	50 % 6 Days	
Cellulo	ose:				
Biodeg	radability	:	Result: Readily bi	odegradable.	
Bioacc	cumulative potential				
<u>Compo</u>	onents:				
Aprepi	itant:				
	umulation	•		s macrochirus (Bluegill sunfish) factor (BCF): 50.1 est Guideline 305	
Partitio octanol	n coefficient: n- I/water	:	log Pow: 4.75		
Sucros	se:				
Partitio	n coefficient: n- I/water	:	Pow: < 1		





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Mobi	lity in soil			
Com	ponents:			
Distri	pitant: bution among environ- al compartments	:	log Koc: 3.10	
	r adverse effects ata available			
SECTION	13. DISPOSAL CONS	SIDER	TIONS	
Disp	osal methods			
Wast	e from residues			e of waste into sewer. accordance with local regulations.
Conta	aminated packaging	:	Empty contain	ers should be taken to an approved waste or recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

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



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EmS Marin	Code e pollutant	: F-A, S-F : yes	
	sport in bulk accord	-	MARPOL 73/78 and the IBC Code
Dome	estic regulation		
TDG			
	umber er shipping name	: UN 3077 : ENVIRON N.O.S. (Aprepitan	MENTALLY HAZARDOUS SUBSTANCE, SOLID,
Class		: 9	
Packi Label	ng group	: III : 9	
ERG		: 9 : 171 : yes(Aprepi	tant)

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

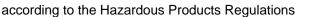
The ingredients of this prod	uct	are reported in the following inventories:
AICS	:	not determined

DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations				
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)		
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)		
CA BC OEL	:	Canada. British Columbia OEL		
CA QC OEL	:	Québec. Regulation respecting occupational health and safe- ty, Schedule 1, Part 1: Permissible exposure values for air- borne contaminants		
ACGIH / TWA	:	8-hour, time-weighted average		
CA AB OEL / TWA	:	8-hour Occupational exposure limit		
CA BC OEL / TWA	:	8-hour time weighted average		
CA QC OEL / TWAEV	:	Time-weighted average exposure value		

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





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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

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 Agen- cy, http://echa.europa.eu/
Revision Date Date format	:	01/24/2024 mm/dd/yyyy

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.

CA / Z8