

/ersion 3.1	Revision Date: 30.09.2023		S Number: 329-00025	Date of last issue: 04.04.2023 Date of first issue: 16.02.2015
SECTION	1. IDENTIFICATION			
Produ	lct name	:	Letermovir S	olid Formulation
Manu	facturer or supplier	's detai	ls	
Comp	bany	:	MSD	
Addre	ess	:		N. Alem St., 8 Floor s, Argentina C1001AFB
Telep	hone	:	908-740-400	0
Emer	gency telephone	:	1-908-423-60	000
E-mai	il address	:	EHSDATAST	reward@msd.com
Reco	mmended use of the	e chem	ical and restr	ictions on use
	mmended use ictions on use	:	Pharmaceuti Not applicabl	

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification		
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Liver, spleen, Blood)
Short-term (acute) aquatic hazard	:	Category 3
GHS label elements Hazard pictograms	:	
Signal Word	:	Warning
Hazard Statements	:	H361d Suspected of damaging the unborn child. H373 May cause damage to organs (Liver, spleen, Blood) through prolonged or repeated exposure if swallowed. H402 Harmful to aquatic life.
Precautionary Statements	:	Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood.

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		P273 Avoid r P280 Wear p	P260 Do not breathe dust. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protec- tion/ face protection.						
		Response: P308 + P313 attention.	IF exposed or cond	cerned: Get medical advice/					
		Storage: P405 Store lo	ocked up.						
		Disposal: P501 Dispos disposal plan		iner to an approved waste					
Conta May	act with dust can caus form explosive dust-a	can lead to mechanic se mechanical irritation ir mixture during proce	n or drying of the sk essing, handling or o						
Subs	tance / Mixture	: Mixture							
Com	ponents		-						
	nical name		CAS-No.	Concentration (% w/w)					
Cellu			9004-34-6	>= 30 -< 50					
	movir		917389-32-3	>= 30 -< 50					
Iviagr	nesium stearate		557-04-0	>= 1 -< 5					
ECTION	4. FIRST AID MEAS	URES							
Gene	eral advice	advice immed	iately.	eel unwell, seek medical cases of doubt seek medical					
If inh	aled	: If inhaled, rem Get medical a	nove to fresh air. ttention.						
In ca	se of skin contact	: In case of con of water. Remove conta Get medical a Wash clothing	tact, immediately flu						
	se of eye contact	: If in eyes, rins Get medical a	e well with water. ttention if irritation c	levelops and persists.					
lf swa	allowed		 If swallowed, DO NOT induce vomiting. Get medical attention. 						

Rinse mouth thoroughly with water.Most important symptoms
and effects, both acute and
delayed:Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated
exposure if swallowed.



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	ction of first-aiders to physician	:	the skin. Dust contact wit First Aid respon and use the reco when the potent	st can cause mechanical irritation or drying of h the eyes can lead to mechanical irritation. ders should pay attention to self-protection, ommended personal protective equipment ial for exposure exists (see section 8). tically and supportively.
SECTION	5. FIRE-FIGHTING ME	٩SL	JRES	
Suitab	Suitable extinguishing media		Water spray Alcohol-resistan Carbon dioxide Dry chemical	
Unsui [.] media	Unsuitable extinguishing media		None known.	
Specil fightin	fic hazards during fire g	:	concentrations, potential dust ex	g dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a plosion hazard. nbustion products may be a hazard to health.
Hazar ucts	Hazardous combustion prod- ucts		Carbon oxides Metal oxides Nitrogen oxides	(NOx)
Specil ods	Specific extinguishing meth- ods		cumstances and Use water spray	ng measures that are appropriate to local cir- I the surrounding environment. I to cool unopened containers. aged containers from fire area if it is safe to do
Specia	al protective equipment	:	In the event of fi	re, wear self-contained breathing apparatus. otective equipment.

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces 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



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		determine w Sections 13	the cleanup of releases. You will need to hich regulations are applicable. and 15 of this SDS provide information regarding or national requirements.			
SECTION	7. HANDLING AND ST	TORAGE				
Tech	nical measures	causing an Provide ade	icity may accumulate and ignite suspended dust explosion. quate precautions, such as electrical grounding g, or inert atmospheres.			
Local/Total ventilation Advice on safe handling		 Use only with Do not breat Do not swalt Avoid contation Avoid protore Handle in action practice, base assessment Minimize dut Keep contait Keep away Take precation 	th adequate ventilation. the dust. low. ct with eyes. nged or repeated contact with skin. ccordance with good industrial hygiene and safety sed on the results of the workplace exposure st generation and accumulation. ner closed when not in use. from heat and sources of ignition. utionary measures against static discharges. o prevent spills, waste and minimize release to the			
	litions for safe storage rials to avoid	 environment. Keep in properly labeled containers. Store locked up. Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents 				

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Cellulose	9004-34-6	CMP	10 mg/m ³	AR OEL
		TWA	10 mg/m ³	ACGIH
Letermovir	917389-32-3	TWA	0.4 mg/m3 (OEB 2)	Internal
Magnesium stearate	557-04-0	CMP	10 mg/m ³	AR OEL
	Further informa	lassifiable as a huma	n carcinogen	
		TWA	10 mg/m ³	ACGIH
		(Inhalable	-	
		particulate		
		matter)		
		TWA	3 mg/m ³	ACGIH
		(Respirable		
		particulate		
		matter)		

Ingredients with workplace control parameters



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Engii	neering measures	compou All engin design a	ible engineering controls to minimize exposure to nd. eering controls should be implemented by facility nd operated in accordance with GMP principles to roducts, workers, and the environment.				
Perso	onal protective equip	ment					
Fil	Respiratory protection		ate local exhaust ventilation is not available or assessment demonstrates exposures outside the ended guidelines, use respiratory protection. tes type				
	protection aterial	: Chemica	: Chemical-resistant gloves				
Eye p	protection	If the wo mists or Wear a f	fety glasses with side shields or goggles. rk environment or activity involves dusty conditions aerosols, wear the appropriate goggles. aceshield or other full face protection if there is a for direct contact to the face with dusts, mists, or				
	Skin and body protection Hygiene measures		form or laboratory coat. Ire to chemical is likely during typical use, provide ing systems and safety showers close to the place. ing do not eat, drink or smoke. ntaminated clothing before re-use. ctive operation of a facility should include review of ing controls, proper personal protective equipment ate degowning and decontamination procedures, I hygiene monitoring, medical surveillance and the dministrative controls.				

Appearance	:	powder
Color	:	No data available
Odor	:	No data available
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	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.

SAFETY DATA SHEET



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	Flamma	ability (liquids)	:	No data available	
	Upper explosion limit / Upper flammability limit		:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	Not applicable	
	Relative	e vapor density	:	Not applicable	
	Relative	e density	:	No data available	
	Density	,	:	No data available	
	Solubili Wat	ty(ies) er solubility	:	No data available	
		n coefficient: n-	:	Not applicable	
	octanol Autoign	/water iition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty osity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidizir Particle	ng properties	:	The substance or No data available	mixture is not classified as oxidizing.
			•		

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.
producto		

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation



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exposure		Skin contac Ingestion Eye contact			
	e toxicity assified based on ava	ilable information			
Produ					
	oral toxicity		ty estimate: > 5.000 mg/kg lculation method		
Comp	onents:				
Cellul	ose:				
Acute	oral toxicity	: LD50 (Rat):	> 5.000 mg/kg		
Acute	inhalation toxicity	Exposure ti	LC50 (Rat): > 5,8 mg/l Exposure time: 4 h Test atmosphere: dust/mist		
Acute	dermal toxicity	: LD50 (Rabb	bit): > 2.000 mg/kg		
Leteri	novir:				
Acute	oral toxicity	: LD50 (Rat):	> 2.000 mg/kg		
		LD50 (Mou	se): > 2.000 mg/kg		
Magn	esium stearate:				
Acute	oral toxicity	Method: OE Assessmen icity	> 2.000 mg/kg CD Test Guideline 423 t: The substance or mixture has no acute oral tox ased on data from similar materials		
Acute	dermal toxicity		bit): > 2.000 mg/kg ased on data from similar materials		
-	corrosion/irritation	ilable information			
	onents:				
Leteri					
Rema		: No data ava	ailable		
Magn	esium stearate:				
Specie		: Rabbit			
Result Rema		: No skin irrit	ation ata from similar materials		
кеша	112	. Daseu un u			

Serious eye damage/eye irritation

Not classified based on available information.



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	<u>Comp</u>	onents:			
	Letern	novir:			
	Remar	ks	:	No data available	
	Magne	esium stearate:			
	Specie		:	Rabbit	
	Result		:	No eye irritation	
	Remar	ks	:	Based on data fro	om similar materials
	Respir	atory or skin sensiti	zatio	on	
	Skin s	ensitization			
	Not cla	ssified based on avail	able	information.	
	Respir	atory sensitization			
	Not cla	ssified based on avail	able	information.	
	<u>Comp</u>	onents:			
	Letern	novir:			
	Remar	ks	:	No data available	
	Magne	esium stearate:			
	Test T		:	Maximization Tes	t
		s of exposure	:	Skin contact	
	Specie Methor		:	Guinea pig OECD Test Guide	alina 406
	Result		÷	negative	
	Remar	ks	:		om similar materials
	Germ	cell mutagenicity			
	Not cla	ssified based on avail	able	information.	
	<u>Comp</u>	onents:			
	Cellul	ose:			
	Genote	oxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
				Test Type: In vitro Result: negative	o mammalian cell gene mutation test
	Genote	oxicity in vivo	:	Test Type: Mamn cytogenetic assay Species: Mouse Application Route Result: negative	
	Letern	novir:			
		oxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)



rsion	Revision Date: 30.09.2023		S Number: 329-00025	Date of last issue: 04.04.2023 Date of first issue: 16.02.2015
			Test Type: Ch Result: negativ	romosome aberration test in vitro /e
Geno	toxicity in vivo	:	cytogenetic as Species: Mous	se ute: Intraperitoneal injection
	cell mutagenicity -	:	Weight of evid cell mutagen.	ence does not support classification as a gerr
Magn	esium stearate:			
-	toxicity in vitro	:	Result: negativ	vitro mammalian cell gene mutation test ve ed on data from similar materials
			Method: OECI Result: negativ	romosome aberration test in vitro D Test Guideline 473 /e ed on data from similar materials
			Result: negativ	cterial reverse mutation assay (AMES) /e ed on data from similar materials
	nogenicity lassified based on avai	lable	information.	
<u>Com</u>	oonents:			
Cellu	lose:			
Speci Applie	es cation Route	:	Rat Ingestion 72 weeks	
	sure time	:	negative	
Expo Resu Repr e	sure time	: : unbo	negative	
Expos Resu Repr o Suspo	sure time It oductive toxicity	: : unbo	negative	
Expos Resu Repr o Suspo	sure time It oductive toxicity ected of damaging the ponents:	: : unboi	negative	
Expos Resu Repro Suspo <u>Com</u>	sure time It oductive toxicity ected of damaging the ponents:	: unbo :	negative rn child.	



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	ermovir:			
Effe	Effects on fertility		Species: Rat, fem Application Route	: Oral 240 mg/kg body weight
			Species: Rat, mal Application Route Fertility: LOAEL: 1 Result: No effects	: Oral 180 mg/kg body weight
			Species: Monkey, Application Route	: Oral 240 mg/kg body weight
Effeo	cts on fetal development	:	Species: Rat Developmental To Result: Embryo-fe	ro-fetal development oxicity: LOAEL: 250 mg/kg body weight etal toxicity. al toxicity observed.
			Species: Rabbit Developmental To Result: Embryo-fe Abortion	ro-fetal development oxicity: LOAEL: 225 mg/kg body weight etal toxicity., Malformations were observed., al toxicity observed.
•	roductive toxicity - As- ment	:	Some evidence of animal experimen	f adverse effects on development, based on ts.
Mag	nesium stearate:			
Effe	cts on fertility	:	reproduction/deve Species: Rat Application Route Method: OECD To Result: negative	
Effe	cts on fetal development	:	Species: Rat Application Route Result: negative	ro-fetal development : Ingestion on data from similar materials



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STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

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

Components:

Letermovir:

Routes of exposure Target Organs	:	Ingestion Liver, spleen, Blood
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cellulose:

Species:NOAEL:Application Route:Exposure time:	Rat >= 9.000 mg/kg Ingestion 90 Days
Letermovir:	
Species:NOAEL:LOAEL:Application Route:Exposure time:Target Organs:	Mouse 40 mg/kg 100 mg/kg Oral 13 Weeks Liver, spleen
Species:NOAEL:Application Route:Exposure time:Remarks:	Rat 150 mg/kg Oral 26 Weeks No significant adverse effects were reported
Species:NOAEL:LOAEL:Application Route:Exposure time:Target Organs:	Monkey 100 mg/kg 200 - 250 mg/kg Oral 39 Weeks Kidney
Species:NOAEL:LOAEL:Exposure time:Target Organs:	Rat 60 mg/kg 180 mg/kg 13 Weeks Testis, Blood, Liver, spleen, Immune system
Species : NOAEL :	Monkey 30 mg/kg



Exposu Target Magnes Species	tion Route re time	:	100 mg/kg Oral	
Species		:	4 Weeks Blood	
Species	sium stearate:			
NOAEL Applica Exposu Remark	s - tion Route ire time	:	Rat > 100 mg/kg Ingestion 90 Days Based on data	from similar materials
Not clas	tion toxicity ssified based on availa			
<u>Compo</u>	ence with human exp onents:	osu	ire	
Leterm Ingestic	ovir:	:		arrhea, Nausea, Vomiting, Headache, Dizzi- Back pain, Edema, Rash, muscle pain
Ecotox <u>Compo</u> Cellulo Toxicity	onents: se:	:	Exposure time	
			Remarks: Base	ed on data from similar materials
Leterm Toxicity		:	Exposure time	i beryllina (Silverside)): > 100 mg/l : 96 h D Test Guideline 203
	v to daphnia and other invertebrates	:	EC50 (America Exposure time	
			Exposure time	a magna (Water flea)): > 100 mg/l : 48 h) Test Guideline 202
Toxicity plants	v to algae/aquatic	:	mg/l Exposure time Method: OECE	kirchneriella subcapitata (green algae)): > 8,8 : 72 h D Test Guideline 201 oxicity at the limit of solubility.



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				2 h est Guideline 201 city at the limit of solubility.
Toxic icity)	ity to fish (Chronic tox-	:	Exposure time: 32 Method: OECD T	es promelas (fathead minnow)): 1 mg/l 2 d est Guideline 210 city at the limit of solubility.
	ity to daphnia and other tic invertebrates (Chron- icity)	:	Exposure time: 2	magna (Water flea)): 1,2 mg/l 1 d est Guideline 211
Toxic	ity to microorganisms	:	EC50: > 972 mg/ Exposure time: 3 Test Type: Respi Method: OECD T	h
			NOEC: 29,6 mg/l Exposure time: 3 Test Type: Respi Method: OECD T	
Magn	esium stearate:			
Toxic	ity to fish	:	Exposure time: 4 Method: DIN 384	
	ity to daphnia and other tic invertebrates	:	Exposure time: 4 Test substance: 1 Method: Directive	Water Accommodated Fraction e 67/548/EEC, Annex V, C.2. on data from similar materials
Toxic plants	ity to algae/aquatic	:	mg/l Exposure time: 77 Test substance: \ Method: OECD T	Nater Accommodated Fraction est Guideline 201 on data from similar materials
			mg/l Exposure time: 77 Test substance: \ Method: OECD T	kirchneriella subcapitata (green algae)): > 1 2 h Nater Accommodated Fraction est Guideline 201 on data from similar materials
Toxic	ity to microorganisms	:	EC10 (Pseudomo Exposure time: 1	onas putida): > 100 mg/l 6 h



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				e: Water Accommodated Fraction ed on data from similar materials
Persi	stence and degradabi	lity		
<u>Com</u>	ponents:			
Cellu	lose:			
Biode	egradability	:	Result: Readily	/ biodegradable.
Leter	movir:			
Biode	egradability	:	Result: rapidly Biodegradatior Exposure time	n: 50 %
Magr	nesium stearate:			
Biode	egradability	:	Result: Not bio Remarks: Base	degradable ed on data from similar materials
Bioa	ccumulative potential			
Com	ponents:			
Leter	movir:			
	ion coefficient: n- ol/water	:	log Pow: 2,29	
Magr	nesium stearate:			
	ion coefficient: n- ol/water	:	log Pow: > 4	
Mobi	lity in soil			
Com	ponents:			
Leter	movir:			
	bution among environ- al compartments	:	log Koc: 3,46	
Othe	r adverse effects			
No da	ata available			

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.





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SECTION 14. TRANSPORT INFORMATION

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

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

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable
Control of precursors and essential chemicals for the preparation of drugs.	:	Not applicable

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

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

SECTION 16. OTHER INFORMATION

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Further information Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/		
Full text of other abbreviations				
ACGIH AR OEL	:	USA. ACGIH Threshold Limit Values (TLV) Argentina. Occupational Exposure Limits		
ACGIH / TWA	:	8-hour, time-weighted average		



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AR OEL / CMP

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided 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.

AR / Z8