

according to the Hazardous Products Regulations

# Alvimopan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.1	09/30/2023	643685-00018	Date of first issue: 05/02/2016

### **SECTION 1. IDENTIFICATION**

Product name	:	Alvimopan 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

Not a hazardous substance or mixture.

### **GHS** label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

#### 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.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name		CAS-No.	Concentration (% w/w)
	Name/Synonym		
Alvimopan	No data availa-	170098-38-1	>= 1 - < 5 *
	ble		

Actual concentration or concentration range is withheld as a trade secret

### 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.

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	In case	e of skin contact	:	Wash with water Get medical atter	and soap. ntion if symptoms occur.
	In case	e of eye contact	:	lf in eyes, rinse w	
					ntion if irritation develops and persists.
	If swal	lowed	:		NOT induce vomiting.
					ntion if symptoms occur.
					oughly with water.
		mportant symptoms	:	Contact with dust	t can cause mechanical irritation or drying of
	and ef	fects, both acute and		the skin.	
	delaye	d		Dust contact with	the eyes can lead to mechanical irritation.
	Protec	tion of first-aiders	:		utions are necessary for first aid responders.
	Notes	to physician	:		ically and supportively.
				<b>,</b> , ,	, ,, ,

### 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 potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	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

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		surfaces, as th released into th Local or nation disposal of this employed in th determine whic Sections 13 an	ed air). should not be allowed to accumulate on ese may form an explosive mixture if they are ne atmosphere in sufficient concentration. al regulations may apply to releases and material, as well as those materials and items e cleanup of releases. You will need to ch regulations are applicable. Id 15 of this SDS provide information regarding 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.
		Handle in accordance with good industrial hygiene and safety
		practice, based on the results of the workplace exposure
		assessment
		Minimize dust generation and accumulation.
		Keep container closed when not in use.
		Keep away from heat and sources of ignition.
		Take precautionary measures against static discharges.
		Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labeled containers.
-		Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Alvimopan	170098-38-1	TWA	10 µg/m³	Internal
		Wipe limit	100 µg/100 cm²	Internal

Engineering measures	:	Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
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Pers	sonal protective equipn	nent				
Respiratory protection		:	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside th recommended guidelines, use respiratory protection.			
	ilter type d protection	:	Particulates type	1		
N	laterial	:	Chemical-resistar	it gloves		
R	Remarks	:		repeated contact use protective gloves. re breaks and at the end of workday.		
Eye	protection	:		g personal protective equipment:		
	and body protection ene measures	:	Skin should be wa If exposure to che eye flushing syste working place. When using do no	ashed after contact. emical is likely during typical use, provide ems and safety showers close to the ot eat, drink or smoke. ed clothing before re-use.		

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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	:	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

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	Vapor p	pressure	:	No data available	9
	Relative	e vapor density	:	No data available	)
	Density	,	:	No data available	)
	Solubili Wat	ty(ies) er solubility	:	No data available	
	Partition octanol	n coefficient: n-	:	No data available	
		hition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty cosity, dynamic	:	No data available	
	Visc	osity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
		ng properties	:		r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	)
	Particle	size	:	No data available	2

### 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	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

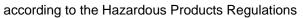
Information on likely routes of exposure Inhalation Skin contact Ingestion Eye contact



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	te toxicity			
Not	classified based on availa	ble	information.	
	<u>luct:</u> e oral toxicity	:	Acute toxicity estin Method: Calculation	mate: > 2,000 mg/kg on method
Acut	e dermal toxicity	:	Acute toxicity estine Method: Calculation	mate: > 2,000 mg/kg on method
<u>Com</u>	iponents:			
Alvi	mopan:			
Acut	e oral toxicity	:	LD50 (Rat): > 500	) mg/kg
			LD50 (Mouse): > -	4,000 mg/kg
Acut	e dermal toxicity	:	LD50 (Mouse): > 2	2,000 mg/kg
	e toxicity (other routes of inistration)	:	Application Route	
-	corrosion/irritation	ble	information.	
<u>Com</u>	ponents:			
Alvi	mopan:			
Spec Resi		:	Rabbit Mild skin irritation	
	ous eye damage/eye irri classified based on availa			
Com	ponents:			
Alvi	mopan:			
Spec Resi		:	Rabbit Mild eye irritation	
Res	piratory or skin sensitiz	atio	n	
	sensitization classified based on availa	ble	information.	
-	piratory sensitization classified based on availa	ble	information.	
Com	<u>iponents:</u>			
	m <b>opan:</b> Type	:	Maximization Tes	t
			6 / 12	



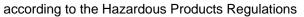


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Vers 2.1	sion	Revision Date: 09/30/2023		9S Number: 3685-00018	Date of last issue: 04/04/2023 Date of first issue: 05/02/2016
	Routes Result	of exposure	:	Dermal negative	
		<b>cell mutagenicity</b> ssified based on availa	ble	information.	
	Compo	onents:			
	Alvimo Genoto	opan: oxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
				-	osome aberration test in vitro
					o mammalian cell gene mutation test se lymphoma cells
	Genoto	oxicity in vivo	:		enicity (in vivo mammalian bone-marrow chromosomal analysis) : Oral
		ogenicity ssified based on availa	ble	information.	
	Compo	onents:			
	Alvimo	opan:			
	Specie Applica	s ation Route ure time	::	Rat Oral 2 Years 500 mg/kg body v negative	veight
	Exposu LOAEL Result	ation Route ure time - Organs			

### **Reproductive toxicity**

Not classified based on available information.





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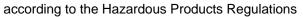
Vers 2.1	sion	Revision Date: 09/30/2023	SDS Number: 643685-00018		Date of last issue: 04/04/2023 Date of first issue: 05/02/2016
	Compo	onents:			
	Alvimo	pan:			
	Effects on fertility :		:	Species: Rat Application Route Fertility: NOAEL: Result: No effects	y/early embryonic development : Intravenous injection 5 mg/kg body weight s on fertility. y/early embryonic development
				Application Route Fertility: NOAEL: Result: No effects	200 mg/kg body weight
				Species: Rabbit Application Route	15 mg/kg body weight
	Effects	on fetal development	:	Species: Rat Application Route	vo-fetal development e: Oral oxicity: NOAEL: 100 mg/kg body weight
				Species: Rat Application Route	oxicity: LOAEL: 200 mg/kg body weight
				Species: Rat Application Route Developmental T	vo-fetal development e: Intravenous injection oxicity: NOAEL: 10 mg/kg body weight cant adverse effects were reported
				Species: Rabbit Application Route Developmental T	vo-fetal development e: Intravenous injection oxicity: NOAEL: 15 mg/kg body weight cant adverse effects were reported

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.





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Repe	ated dose toxicity					
Comp	oonents:					
Alvim	iopan:					
Speci		:	Mouse			
NOAE		:	1000 mg/kg			
	ation Route	:	Oral			
Expos Rema	sure time Irks	:	13 Weeks No significant	adverse effects were reported		
Speci	05		Dog			
NOAE		:	1000 mg/kg			
-	ation Route		Oral			
	sure time	÷	39 Weeks			
Rema		:	: No significant adverse effects were reported			
Speci		:	Rat			
NOAE		:	500 mg/kg			
	ation Route	:	Oral			
	sure time	:	1 y	a la constante de la constante		
Rema	ITKS	:	No significant	adverse effects were reported		
Speci		:	Dog			
NOAE		:	2 mg/kg			
Applic	ation Route	:	Intravenous			
	sure time	:	1 Months No significant	adverse effects were reported		
Expos Rema Aspir Not cl	sure time Irks <b>ation toxicity</b> assified based on availa		No significant	adverse effects were reported		
Expos Rema Aspir Not cl Exper	sure time irks ation toxicity assified based on availa rience with human exp		No significant	adverse effects were reported		
Expos Rema Aspir Not cl Exper	sure time irks ation toxicity assified based on availa rience with human exp ponents:		No significant	adverse effects were reported		
Expos Rema Aspir Not cl Exper Comp Alvim	sure time ation toxicity assified based on availa rience with human exp ponents: hopan:		No significant information.			
Expos Rema Aspir Not cl Exper	sure time ation toxicity assified based on availa rience with human exp ponents: hopan:		No significant information. Ire Symptoms: sto			
Expos Rema Aspir Not cl Exper Comp Alvim Ingest	sure time ation toxicity assified based on availa rience with human exp ponents: hopan:	osı :	No significant information. <b>Ire</b> Symptoms: sto Nausea, Vomi	omach discomfort, Gastrointestinal disturban		
Expos Rema Aspir Not cl Exper Comp Alvim Ingest	sure time irks ation toxicity assified based on availa rience with human exp ponents: iopan: tion	osı :	No significant information. <b>Ire</b> Symptoms: sto Nausea, Vomi	omach discomfort, Gastrointestinal disturband		
Expos Rema Aspir Not cl Exper Comp Alvim Ingest	sure time arks ation toxicity assified based on availa rience with human exp ponents: hopan: tion 12. ECOLOGICAL INFO	osı :	No significant information. <b>Ire</b> Symptoms: sto Nausea, Vomi	omach discomfort, Gastrointestinal disturban		
Expos Rema Aspir Not cl Exper Comp Alvim Ingest CTION Ecoto Comp	sure time arks ation toxicity assified based on availa rience with human exp ponents: tion 12. ECOLOGICAL INFO porients:	osı :	No significant information. <b>Ire</b> Symptoms: sto Nausea, Vomi	omach discomfort, Gastrointestinal disturban		
Expos Rema Aspir Not cl Exper Comp Alvim Ingest CTION Ecoto Comp Alvim	sure time ation toxicity assified based on availa rience with human exp ponents: tion 12. ECOLOGICAL INFO poxicity ponents: aopan:	osı :	No significant information. Ire Symptoms: sto Nausea, Vomi	omach discomfort, Gastrointestinal disturbant		
Expos Rema Aspir Not cl Exper Comp Alvim Ingest CTION Ecoto Comp Alvim	sure time arks ation toxicity assified based on availa rience with human exp ponents: tion 12. ECOLOGICAL INFO porients:	osı :	No significant information. Ire Symptoms: sto Nausea, Vomi IATION	omach discomfort, Gastrointestinal disturban ting, Abdominal pain ales promelas (fathead minnow)): > 17 mg/l		
Expos Rema Aspir Not cl Exper Comp Alvim Ingest CTION Ecoto Comp Alvim	sure time ation toxicity assified based on availa rience with human exp ponents: tion 12. ECOLOGICAL INFO poxicity ponents: aopan:	osı :	No significant information. Ire Symptoms: sto Nausea, Vomi IATION	omach discomfort, Gastrointestinal disturban ting, Abdominal pain ales promelas (fathead minnow)): > 17 mg/l : 96 h		
Expos Rema Aspir Not cl Exper Comp Alvim Ingest CTION Ecoto Comp Alvim	sure time ation toxicity assified based on availa rience with human exp ponents: tion 12. ECOLOGICAL INFO poxicity ponents: aopan:	osı :	No significant information. Ire Symptoms: sto Nausea, Vomi MATION LC50 (Pimeph Exposure time Method: OECI	omach discomfort, Gastrointestinal disturban ting, Abdominal pain ales promelas (fathead minnow)): > 17 mg/l		
Expos Rema Aspir Not cl Exper Comp Alvim Ingest CTION Ecoto Comp Alvim Toxici	sure time ation toxicity assified based on availa rience with human exp ponents: hopan: tion 12. ECOLOGICAL INFO points: hopan: ty to fish	osı : DRM	No significant information. Ire Symptoms: sto Nausea, Vomi MATION LC50 (Pimeph Exposure time Method: OECI Remarks: No t	omach discomfort, Gastrointestinal disturband ting, Abdominal pain ales promelas (fathead minnow)): > 17 mg/l : 96 h D Test Guideline 203 oxicity at the limit of solubility.		
Expos Rema Aspir Not cl Exper Comp Alvim Ingest CTION Ecoto Comp Alvim Toxici	sure time ation toxicity assified based on availa rience with human exp ponents: tion 12. ECOLOGICAL INFO poxicity ponents: aopan:	osı : DRM	No significant information. Ire Symptoms: sto Nausea, Vomi MATION LC50 (Pimeph Exposure time Method: OECI Remarks: No t	omach discomfort, Gastrointestinal disturband ting, Abdominal pain ales promelas (fathead minnow)): > 17 mg/l : 96 h D Test Guideline 203 oxicity at the limit of solubility. a magna (Water flea)): > 17 mg/l		

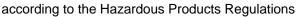


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			Test Guideline 202 oxicity at the limit of solubility.
	E	Exposure time: /lethod: OECD	esmus subspicatus): > 17 mg/l 72 h 9 Test Guideline 201 oxicity at the limit of solubility.
	E	Exposure time: /lethod: OECD	desmus subspicatus): 17 mg/l 72 h 9 Test Guideline 201 oxicity at the limit of solubility.
ty to microorganisms	E T	Exposure time: Test Type: Res	
	E T	Exposure time: Test Type: Res	
stence and degradab	ility		
onents:			
•	E	Biodegradation	
cumulative potential			
onents:			
on coefficient: n-	: 1	og Pow: 0.52	
•			
13. DISPOSAL CONS	IDERA	TIONS	
	09/30/2023 ty to algae/aquatic ty to microorganisms stence and degradab conents: opan: gradability cumulative potential conents: opan: gradability cumulative potential conents: opan: gradability cumulative potential conents: opan: gradability	09/30/2023 6436   ty to algae/aquatic :   ty to algae/aquatic :   ty to microorganisms :   ty to microorganisms :   ty to microorganisms :   stence and degradability   ponents:   opan:   gradability   gradability   opan:   advalability   ity in soil   ta available   adverse effects   ta available   13. DISPOSAL CONSIDERA	09/30/2023643685-00018Method: OECD Remarks: No to Exposure time: Method: OECD Remarks: No toty to algae/aquatic:EC50 (Scened Exposure time: Method: OECD Remarks: No toty to microorganisms:EC50: > 920 mg Exposure time: Test Type: Res Method: OECDNOEC: 920 mg Exposure time: Test Type: Res Method: OECDNOEC: 920 mg Exposure time: Test Type: Res Method: OECDstence and degradability ponents: opan: gradabilityopan: gradability:gradability:cumulative potential ponents: opan: on coefficient: n- bl/wateropan: tty in soil ta available:adverse effects ta available13. DISPOSAL CONSIDERATIONSsal 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.





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		If not otherwise	e specified: Dispose of as unused product.

### **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.

### **Domestic regulation**

**TDG** Not regulated as a dangerous good

# Special precautions for user

Not applicable

### SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:					
AICS	:	not determined			
DSL	:	not determined			
IECSC	:	not determined			

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

### Full text of other abbreviations

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 Con-





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centration 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	:	09/30/2023 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