

according to the Hazardous Products Regulations

Vericiguat Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.1	09/30/2023	5598512-00009	Date of first issue: 03/25/2020

SECTION 1. IDENTIFICATION

Product name	:	Vericiguat 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	: Pharma	ceutical
Restrictions on use	: Not app	licable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Specific target organ toxicity	:	Category 1 (Cardio-vascular system)
 repeated exposure (Oral) 		

GHS label elements

Hazard pictograms



Signal Word	:	Danger
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Hazard Statements

Precautionary Statements

Prevention: P260 Do not breathe dust. P264 Wash skin thoroughly after handling.

H372 Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

P270 Do not eat, drink or smoke when using this product.

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.



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May form combustible dust concentrations in air during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Cellulose	No data availa- ble	9004-34-6	>= 30 - < 60 *
Vericiguat	No data availa- ble	1350653-20-1	>= 1 - < 5 *
Magnesium stearate	Octadecanoic acid, magnesi- um salt (2:1)	557-04-0	>= 1 - < 5 *

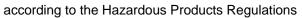
Actual concentration or concentration range is withheld as a trade secret

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.
In case of skin contact	:	Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact	:	If in eyes, rinse well with water.
If swallowed	:	Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur.
Most important symptoms and effects, both acute and	:	Rinse mouth thoroughly with water. Causes damage to organs through prolonged or repeated exposure if swallowed.
delayed		Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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	:	
Specific hazards during fire	:	Avoid generating dust; fine dust dispersed in air in sufficient





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fighting			potential dust exp	nd in the presence of an ignition source is a losion hazard. oustion products may be a hazard to health.	
	Hazard ucts	ous combustion prod-	:	Carbon oxides Metal oxides	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t Remove undamag so.	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special for fire-	protective equipment fighters	:		e, wear self-contained breathing apparatus. ective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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 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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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type	Control parame-	Basis
Componenta	0/10/110.	(Form of	ters / Permissible	Dasis
		·	concentration	
Cellulose	9004-34-6	exposure) TWA		CA AB OEL
Cellulose	9004-34-0		10 mg/m ³	
		TWA (Total	10 mg/m³	CA BC OEL
		dust)		
		TWA (respir-	3 mg/m ³	CA BC OEL
		able dust		
		fraction)		
		TWAEV (to-	10 mg/m ³	CA QC OEL
		tal dust)		
		TWA	10 mg/m ³	ACGIH
Vericiguat	1350653-20-	TWA	4 µg/m3 (OEB 4)	Internal
0	1			
		Wipe limit	40 µg/100 cm ²	Internal
Magnesium stearate	557-04-0	TWA	10 mg/m ³	CA AB OEL
		TWAEV	10 mg/m ³	CA QC OEL
		TWA (Inhal-	10 mg/m ³	CA BC OEL
		able)		
		TWA (Res-	3 mg/m ³	CA BC OEL
		pirable)	Ū	
		TWA	10 mg/m ³	ACGIH
		(Inhalable	Ĭ	
		particulate		
		, matter)		
		TWA	3 mg/m ³	ACGIH
		(Respirable	Ĭ	
		particulate		

Ingredients with workplace control parameters



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			matter)
Engi	neering measures	:	Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.
	onal protective equip	nent	
Fi	iratory protection Iter type protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type
M	aterial	:	Chemical-resistant gloves
	emarks protection	:	Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin	and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Hygie	ene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	tablet
Color	:	No data available
Odor	:	No data available





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	Odor T	hreshold	:	No data available	
	рН		:	No data available	
	Melting	point/freezing point	:	No data available	
	Initial b range	ooiling point and boiling	:	No data available	
	Flash p	point	:	Not applicable	
	Evapor	ration rate	:	Not applicable	
	Flamm	ability (solid, gas)	:	May form combus ssing, handling o	stible dust concentrations in air during proce- r other means.
	Flamm	ability (liquids)	:	Not applicable	
		explosion limit / Upper ability limit	:	No data available	
		explosion limit / Lower ability limit	:	No data available	
	Vapor	pressure	:	Not applicable	
	Relativ	e vapor density	:	Not applicable	
	Relativ	e density	:	No data available	
	Density	ý	:	No data available	
	Solubil Wat	ity(ies) ter solubility	:	No data available	
		n coefficient: n-	:	Not applicable	
	octano Autoigr	nition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosi Visc	ity cosity, kinematic	:	Not applicable	
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance or	mixture is not classified as oxidizing.
	Molecu	ılar weight	:	No data available	
	Particle	e size	:	No data available	•



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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 combustible dust concentrations in air 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					

Acute toxicity

Not classified based on available information.

Components:

Cellulose:

Cellulose.		
Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg
Vericiguat:		
Acute oral toxicity	:	LD50 (Rat): > 60 mg/kg Remarks: No mortality observed at this dose.
		LD50 (Dog): > 30 mg/kg Remarks: No mortality observed at this dose.
Magnesium stearate:		
Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 Assessment: The substance or mixture has no acute oral tox- icity Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Remarks: Based on data from similar materials

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Skin corrosion/irritation

Not classified based on available information.

Components:

Magnesium stearate:

Species	:	Rabbit
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Magnesium stearate:

Species	:	Rabbit
Result	:	No eye irritation
Remarks	:	Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Magnesium stearate:

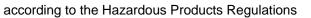
laximization Test
kin contact
Buinea pig
ECD Test Guideline 406
egative
ased on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:		
Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)





		55	0S Number: 98512-00009	Date of last issue: 04/04/2023 Date of first issue: 03/25/2020
			Species: Mouse Application Route Result: negative	e: Ingestion
Verici	quat:			
	oxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
			Test Type: Mouse Result: negative	e Lymphoma
Genot	oxicity in vivo	:	Test Type: Micror Species: Mouse Application Route Result: negative	
Magn	esium stearate:			
-	oxicity in vitro	:	Result: negative	o mammalian cell gene mutation test on data from similar materials
				nosome aberration test in vitro est Guideline 473
				on data from similar materials
			Result: negative	rial reverse mutation assay (AMES) on data from similar materials
Carcir	nogenicity			
	assified based on av	ailable	information.	
Comp	onents:			
Cellul	ose:			
Specie	es	:	Rat	
	ation Route	:	Ingestion	
Expos Result	sure time t	:	72 weeks negative	
•	oductive toxicity			
	assified based on av	allable	information.	
-	oonents:			
Cellul			-	
Effects	s on fertility	:	Test Type: One-g Species: Rat Application Route Result: negative	generation reproduction toxicity study



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	Effects	on fetal development	:	Test Type: Fertilit Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion
	Vericig	juat:			
	Effects	on fertility	:	Test Type: Fertility Species: Rat Application Route Fertility: NOAEL: Result: No effects	: Oral 50 mg/kg body weight
	Effects	on fetal development	:	Result: Some evic based on animal e	: Oral oxicity: LOAEL: 50 mg/kg body weight dence of adverse effects on development,
				Result: Postimpla	oxicity: LOAEL: 2.5 mg/kg body weight
	Magne	sium stearate:			
	Effects	on fertility	:	reproduction/deve Species: Rat Application Route Method: OECD To Result: negative	
	Effects	on fetal development	:	Species: Rat Application Route Result: negative	o-fetal development : Ingestion on data from similar materials
	STOT	single exposure			

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

Components:

Vericiguat:

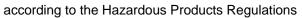
Target Organs

: Cardio-vascular system





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	Assess	sment	:	Causes damage t exposure.	o organs through prolonged or repeated
	Repea	ted dose toxicity			
	Compo	onents:			
	Cellulo	ose:			
			:	Rat >= 9,000 mg/kg Ingestion 90 Days	
	Vericio	guat:			
		L ation Route ure time	:	Mouse 50 mg/kg Oral 13 Weeks No significant adv	erse effects were reported
	Exposi			Rat 15 mg/kg Oral 4 Weeks Liver, Prostate, A	drenal gland
	Exposi			Rat 3 mg/kg Oral 13 Weeks small intestine	
	Exposi			Rat 30 mg/kg Oral 26 Weeks Kidney	
	Exposi	- ation Route ure time Organs		Dog 2.5 mg/kg 7.5 mg/kg Oral 4 Weeks Kidney, Gastroint Vomiting	estinal tract
		ation Route ure time		Dog 2.5 mg/kg 5 mg/kg Oral 13 Weeks No adverse effect	S.





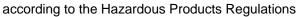
ersion 1	Revision Date: 09/30/2023		OS Number: 98512-00009	Date of last issue: 04/04/2023 Date of first issue: 03/25/2020
	EL cation Route sure time		Dog 5 mg/kg Oral 39 Weeks No adverse effec	ts.
Magn	esium stearate:			
	EL cation Route sure time	: : :	Rat > 100 mg/kg Ingestion 90 Days Based on data fro	om similar materials
-	ation toxicity			
Not c	lassified based on availa	ble	information.	
Expe	rience with human exp	osi	ire	
Com	oonents:			
Veric	iguat:			
Inges	tion	:	Symptoms: hypot	ardio-vascular system tension, Headache, Dizziness, Nausea, Dia nemia, acid reflux, constipation
ECTION	12. ECOLOGICAL INFO	OR	ATION	
Ecoto	oxicity			
Com	oonents:			
Cellu				
	ity to fish	:	Exposure time: 4	iipes (Japanese medaka)): > 100 mg/l 8 h on data from similar materials
Magn	esium stearate:			
Toxic	ity to fish	:	Exposure time: 4 Method: DIN 384	
	ity to daphnia and other ic 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	:	EL50 (Pseudokiro mg/l Exposure time: 7	chneriella subcapitata (green algae)): > 1 2 h





ersion 1	Revision Date: 09/30/2023		DS Number: 98512-00009	Date of last issue: 04/04/2023 Date of first issue: 03/25/2020
			Method: OECD Remarks: Base	Water Accommodated Fraction Test Guideline 201 d on data from similar materials e limit of solubility.
			mg/l Exposure time: Test substance Method: OECD	okirchneriella subcapitata (green algae)): > 7 72 h Water Accommodated Fraction Test Guideline 201 d on data from similar materials
Toxic	ity to microorganisms	:	Exposure time: Test substance	nonas putida): > 100 mg/l 16 h Water Accommodated Fraction d on data from similar materials
Persi	stence and degradabi	lity		
<u>Com</u>	ponents:			
Cellu Biode	lose: egradability	:	Result: Readily	biodegradable.
-	nesium stearate: egradability	:	Result: Not bioc Remarks: Base	legradable d on data from similar materials
Bioad	ccumulative potential			
<u>Com</u>	ponents:			
Partit	iguat: ion coefficient: n- ol/water	:	log Pow: 2.99	
Partit	nesium stearate: ion coefficient: n- ol/water	:	log Pow: > 4	
	lity in soil ata available			
	r adverse effects 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.





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If not otherwise 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				
ACGIH CA AB OEL	:	USA. ACGIH Threshold Limit Values (TLV) 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	:	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