

# **Vericiguat Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 5598519-00009
 Date of first issue: 25.03.2020

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Vericiguat Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

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@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

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

- repeated exposure (Oral)

**GHS** label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H372 Causes damage to organs (Cardio-vascular system)

through prolonged or repeated exposure if swallowed.

Precautionary Statements : Prevention:

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.

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

Response:

P314 Get medical advice/ attention if you feel unwell.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

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

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**



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Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 -< 50
Vericiguat	1350653-20-1	>= 1 -< 5
Magnesium stearate	557-04-0	>= 1 -< 5

#### **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.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

Causes damage to organs through prolonged or repeated

exposure if swallowed.

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 when the potential for exposure exists (see section 8).

Notes to physician : 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

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Metal 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



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SO.

Evacuate area.

Special protective equipment:

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective 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**

Static electricity may accumulate and ignite suspended dust Technical measures

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation. Do not breathe dust.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

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

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures If exposure to chemical is likely during typical use, provide eye



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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.

Keep in properly labeled containers. Conditions for safe storage

Store in accordance with the particular national regulations.

Materials to avoid Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

**Explosives** Gases

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

# Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	VLE-PPT	10 mg/m³	NOM-010- STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Vericiguat	1350653-20- 1	TWA	4 μg/m3 (OEB 4)	Internal
		Wipe limit	40 μg/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	VLE-PPT	10 mg/m³	NOM-010- STPS-2014
		TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH

#### **Engineering 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.



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Personal protective equipment

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

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : 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 suite) to evoid expected skip surfaces.

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : tablet

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 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 combustible dust concentrations in air during proce-

ssing, handling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available



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Vapor pressure Not applicable

Relative vapor density Not applicable

Relative density No data available

No data available Density

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

No data available Autoignition temperature

Decomposition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle size No data available

#### **SECTION 10. STABILITY AND REACTIVITY**

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

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

Hazardous decomposition

Oxidizing agents

No hazardous decomposition products are known.

products

### **SECTION 11. TOXICOLOGICAL INFORMATION**

# Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

#### **Acute toxicity**

Not classified based on available information.



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**Components:** 

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

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.



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### Respiratory sensitization

Not classified based on available information.

#### Components:

Magnesium stearate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based 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) Species: Mouse

Application Route: Ingestion

Result: negative

Vericiguat:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Application Route: Intraperitoneal

Result: negative

Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials



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Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

#### Carcinogenicity

Not classified based on available information.

#### Components:

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

#### Reproductive toxicity

Not classified based on available information.

### **Components:**

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Vericiguat:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 50 mg/kg body weight

Result: No effects on fertility.

Effects on fetal development : Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 50 mg/kg body weight Result: Some evidence of adverse effects on development,

based on animal experiments. Remarks: Maternal toxicity observed.

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 2.5 mg/kg body weight

Result: Postimplantation loss.

Remarks: Maternal toxicity observed.

#### Magnesium stearate:



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Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

#### 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

Assessment : Causes damage to organs through prolonged or repeated

exposure.

#### Repeated dose toxicity

#### Components:

#### Cellulose:

Species : Rat

NOAEL : >= 9,000 mg/kg Application Route : Ingestion

Exposure time : 90 Days

#### Vericiguat:

Species : Mouse
NOAEL : 50 mg/kg
Application Route : Oral
Exposure time : 13 Weeks

Remarks : No significant adverse effects were reported

Species : Rat
LOAEL : 15 mg/kg
Application Route : Oral
Exposure time : 4 Weeks

Target Organs : Liver, Prostate, Adrenal gland

Species : Rat
NOAEL : 3 mg/kg
Application Route : Oral



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Exposure time : 13 Weeks
Target Organs : small intestine

Species : Rat
NOAEL : 30 mg/kg
Application Route : Oral
Exposure time : 26 Weeks
Target Organs : Kidney

Species : Dog
NOAEL : 2.5 mg/kg
LOAEL : 7.5 mg/kg
Application Route : Oral
Exposure time : 4 Weeks

Target Organs : Kidney, Gastrointestinal tract

Symptoms : Vomiting

Species : Dog
NOAEL : 2.5 mg/kg
LOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 13 Weeks

Symptoms : No adverse effects.

Species : Dog
NOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 39 Weeks

Symptoms : No adverse effects.

Magnesium stearate:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

Vericiguat:

Ingestion : Target Organs: Cardio-vascular system

Symptoms: hypotension, Headache, Dizziness, Nausea, Diar-

rhea, Vomiting, anemia, acid reflux, constipation



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#### **SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity** 

**Components:** 

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l

Exposure time: 48 h Method: DIN 38412

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 47 h

Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l

Exposure time: 16 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Persistence and degradability

**Components:** 

Cellulose:

Biodegradability : Result: Readily biodegradable.

Magnesium stearate:



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Biodegradability : Result: Not biodegradable

Remarks: Based on data from similar materials

**Bioaccumulative potential** 

**Components:** 

Vericiguat:

Partition coefficient: n-

octanol/water

log Pow: 2.99

Magnesium stearate:

Partition coefficient: n-

octanol/water

log Pow: > 4

Mobility in soil

No data available

Other adverse effects

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**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.

#### **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** 

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable



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#### **SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for

producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined

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

Revision Date : 30.09.2023 Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA, ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average NOM-010-STPS-2014 / VLE- : Time weighted average limit value

PPT

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 Substanc-



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es; (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 Agency, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8