SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Vericiguat Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Vericiguat Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
              Kilsheelan
              Clonmel Tipperary, IE
   Telephone : 353-51-601000
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   +1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Warning
   Hazard statements : H373 May cause damage to organs through prolonged or repeated exposure.
   Precautionary statements :
   Prevention: P260 Do not breathe dust.
   Response: P314 Get medical advice/attention if you feel unwell.
Hazardous components which must be listed on the label:
Vericiguat

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Index-No.</td>
<td>Registration number</td>
</tr>
<tr>
<td>Vericiguat</td>
<td>1350653-20-1</td>
<td></td>
</tr>
</tbody>
</table>

Classification: STOT RE 1; H372 (Cardio-vascular system)
Concentration (% w/w): >= 1 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May cause damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : 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 products : Carbon oxides
Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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. 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 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Explosives
  - Gases

7.3 Specific end use(s)

Specific use(s):
- No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>Vericiguat</td>
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<td></td>
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</tbody>
</table>

8.2 Exposure controls

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.

Personal protective equipment
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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 faceshell or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

Respiratory protection

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : tablet

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form combustible dust concentrations in air during processing, 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

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available
### SECTION 10: Stability and reactivity

#### 10.1 Reactivity
Not classified as a reactivity hazard.

#### 10.2 Chemical stability
Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions
Hazardous reactions: May form combustible dust concentrations in air during processing, handling or other means. Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

#### 10.5 Incompatible materials
Materials to avoid: Oxidizing agents
10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure: Inhalation, Skin contact, Ingestion, Eye contact

Acute toxicity
Not classified based on available information.

Components:
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.

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:
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
Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

Components:

Verigiguat:
- 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 foetal 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.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Verigiguat:
- Target Organs: Cardio-vascular system
- Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Verigiguat:
- 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
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

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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Experience with human exposure

Components:

Vericiguat:
Ingestion: Target Organs: Cardio-vascular system
Symptoms: hypotension, Headache, Dizziness, Nausea, Diarrhoea, Vomiting, anemia, acid reflux, constipation

SECTION 12: Ecological information

12.1 Toxicity
No data available

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

Components:

Vericiguat:
Partition coefficient: n-octanol/water: log Pow: 2.99

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:
Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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

14.1 UN number or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Other regulations:
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.
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The components of this product are reported in the following inventories:

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-statements

**H372**: Causes damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations

- **STOT RE**: Specific target organ toxicity - repeated exposure
- **ADN**: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; **ADR**: European Agreement concerning the International Carriage of Dangerous Goods by Road; **AIIC**: Australian Inventory of Industrial Chemicals; **ASTM**: American Society for the Testing of Materials; **bw**: Body weight; **CLP**: Classification Labelling Packaging Regulation; **EC** Number - European Community number; **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; **GHS**: Globally Harmonized System; **GLP**: Good Laboratory Practice; **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; **ISO**: International Organisation for Standardization; **KECIL**: 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; **NO(A)EC**: No Observed (Adverse) Effect Concentration; **NO(A)EL**: No Observed (Adverse) Effect Level; **NOELR**: No Observable Effect Loading Rate; **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; **RID**: Regulations concerning the International Carriage of Dangerous Goods by Rail; **SADT**: Self-Accelerating Decomposition Temperature; **SDS**: Safety Data Sheet; **SVHC**: Substance of very high concern; **TCSI**: Taiwan Chemical Substance 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 Bio-accumulative

**Further information**

Sources of key data used to compile the Safety Data Sheet:
- Internal technical data
- Data from raw material SDSs
- OECD eChem Portal search results

**Classification of the mixture:**
- STOT RE 2
- H373

**Classification procedure:**
- Calculation method

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.

NO / EN