SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Vaniprevir Formulation

Version: 5.1
Revision Date: 2020/10/16
SDS Number: 25782-00017
Date of last issue: 2020/03/23
Date of first issue: 2014/10/27

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Vaniprevir Formulation

Manufacturer or supplier's details
Company: MSD
Address: 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance: powder
Colour: tan
Odour: odourless

May cause damage to organs through prolonged or repeated exposure. Harmful to aquatic life.

GHS Classification
Specific target organ toxicity - repeated exposure: Category 2
Short-term (acute) aquatic hazard: Category 3

GHS label elements
Hazard pictograms: 

Signal word: Warning

Hazard statements:
H373 May cause damage to organs through prolonged or repeated exposure.
H402 Harmful to aquatic life.

Precautionary statements:
Prevention:
P260 Do not breathe dust.
P273 Avoid release to the environment.
Response:
P314 Get medical advice/ attention if you feel unwell.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.

Health hazards
May cause damage to organs through prolonged or repeated exposure.

Environmental hazards
Harmful to aquatic life.

Other hazards which do not result in classification
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
<td>Glycerides, C8-10</td>
<td>85409-09-2</td>
<td>&gt;= 50 -&lt; 70</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vaniprevir</td>
<td>923590-37-8</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
</tbody>
</table>

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: 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.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment.
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Notes to physician
when the potential for exposure exists (see section 8).
Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media
None known.

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

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.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency 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.
7. HANDLING AND STORAGE

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.
- 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.
Avoidance of contact: Oxidizing agents

Storage
Conditions for safe storage: Keep in properly labelled containers.
- Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types:
- Strong oxidizing agents
Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaniprevir</td>
<td>923590-37-8</td>
<td>TWA</td>
<td>300 µg/m³</td>
<td>Internal</td>
</tr>
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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).

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
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Eye/face protection : Wear the following personal protective equipment: Safety goggles
Skin and body protection : Skin should be washed after contact.
Hand protection

Material : Chemical-resistant gloves
Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder
Colour : tan
Odour : odourless
Odour 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 : No data available
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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Vapour pressure : No data available
Relative vapour density : No data available
Density : 1 g/cm³
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available
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

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
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.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.
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Components:

Glycerides, C8-10:

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
   Method: OECD Test Guideline 401
   Remarks: Based on data from similar materials

Acute inhalation toxicity: LD50 (Rat): > 1.86 mg/l
   Exposure time: 6 h
   Test atmosphere: dust/mist
   Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 402
   Assessment: The substance or mixture has no acute dermal toxicity
   Remarks: Based on data from similar materials

Vaniprevir:

Acute oral toxicity: LD50 (Rat): > 750 mg/kg
   Remarks: No adverse effect has been observed in acute toxicity tests.

LD0 (Dog): > 300 mg/kg
   Remarks: No adverse effect has been observed in acute toxicity tests.

LD50 (Mouse): > 2,000 mg/kg
   Remarks: No mortality observed at this dose.

Skin corrosion/irritation
Not classified based on available information.

Components:

Glycerides, C8-10:

Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Vaniprevir:

Species: Rabbit
Result: No skin irritation

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

Components:

Glycerides, C8-10:

Species: Rabbit
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Result: No eye irritation  
Method: OECD Test Guideline 405  
Remarks: Based on data from similar materials

Vaniprevir:  
Species: Bovine cornea  
Result: Mild eye irritation  
Method: Bovine cornea (BCOP)

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

Respiratory sensitisation  
Not classified based on available information.

Components:  
Glycerides, C8-10:  
Test Type: Buehler Test  
Exposure routes: Skin contact  
Species: Guinea pig  
Method: OECD Test Guideline 406  
Result: negative  
Remarks: Based on data from similar materials

Vaniprevir:  
Test Type: Local lymph node assay (LLNA)  
Species: Mouse  
Result: negative

Germ cell mutagenicity  
Not classified based on available information.

Components:  
Glycerides, C8-10:  
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
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

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials
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**Vaniprevir:**
- **Genotoxicity in vitro:**
  - **Test Type:** Chromosomal aberration
  - **Test system:** Chinese hamster ovary cells
  - **Result:** negative
- **Test Type:** Bacterial reverse mutation assay (AMES)
- **Result:** negative
- **Test Type:** Alkaline elution assay
- **Test system:** rat hepatocytes
- **Result:** negative

**Genotoxicity in vivo:**
- **Test Type:** Micronucleus test
- **Species:** Mouse
- **Application Route:** Oral
- **Result:** negative

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Vaniprevir:**
- **Species**
- **Application Route:** Oral
- **Activity duration:** 104 Weeks
- **Result:** negative

**Specie**
- **Application Route:** Oral
- **Activity duration:** 6 Months
- **Result:** negative
- **Target Organs:** gallbladder

**Reproductive toxicity**
Not classified based on available information.

**Components:**

**Glycerides, C8-10:**
- **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 foetal develop-**
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ment reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Vaniprevir:
Effects on fertility :
Test Type: Fertility/early embryonic development
Species: Rat, male and female
Application Route: Oral
General Toxicity - Parent: NOAEL: \(\geq 250\) mg/kg body weight
Result: No effects on fertility

Effects on foetal development :
Test Type: Development
Species: Rat, female
Application Route: Oral
General Toxicity Maternal: NOAEL: 120 mg/kg body weight
Developmental Toxicity: LOAEC F1: 180 mg/kg body weight
Symptoms: No specific developmental abnormalities
Result: negative

Test Type: Development
Species: Rabbit, female
Application Route: Oral
General Toxicity Maternal: NOAEL: 120 mg/kg body weight
Developmental Toxicity: NOAEL F1: \(\geq 240\) mg/kg body weight
Symptoms: No specific developmental abnormalities
Result: negative

STOT - single exposure
Not classified based on available information.

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

Components:
Vaniprevir:
Exposure routes : Ingestion
Target Organs : gallbladder, Liver
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
Glycerides, C8-10:
Species : Rat
NOAEL : \(\geq 1,000\) mg/kg
Application Route : Ingestion
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| Exposure time | 28 Days |
| Method | OECD Test Guideline 407 |
| Remarks | Based on data from similar materials |

**Vaniprevir:**
- **Species:** Rat
- **NOAEL:** 120 mg/kg
- **LOAEL:** 360 mg/kg
- **Application Route:** Oral
- **Exposure time:** 6 Months
- **Target Organs:** Liver

**Species:** Dog
- **NOAEL:** 15 mg/kg
- **LOAEL:** 30 mg/kg
- **Application Route:** Oral
- **Exposure time:** 9 Months
- **Target Organs:** Liver, gallbladder
- **Symptoms:** Gastrointestinal disturbance

**Species:** Mouse
- **NOAEL:** 150 mg/kg
- **LOAEL:** 300 mg/kg
- **Application Route:** Oral
- **Exposure time:** 90 d
- **Target Organs:** Liver, Kidney, Gastrointestinal tract, Heart, gallbladder, Stomach

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**
- **Vaniprevir:**
  - **Ingestion:** Symptoms: stomach discomfort, Diarrhoea, Nausea, Headache

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Glycerides, C8-10:**
- **Toxicity to fish:** LL50 (Danio rerio (zebra fish)): > 10 - 100 mg/l
  - **Exposure time:** 96 h
  - **Test substance:** Water Accommodated Fraction
  - **Method:** OECD Test Guideline 203
  - **Remarks:** Based on data from similar materials
- **Toxicity to daphnia and other:** EL50 (Daphnia magna (Water flea)): > 100 mg/l
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aquatic invertebrates
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants
NOEC (Desmodesmus subspicatus (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

EL50 (Desmodesmus subspicatus (green algae)): > 10 - 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Vaniprevir:
Toxicity to daphnia and other aquatic invertebrates
EC50 (Daphnia magna (Water flea)): > 4 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

LC50 (Americamysis): > 4 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants
EC50 (Pseudokirchneriella subcapitata (green algae)): > 4 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 4 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms
EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Persistency and degradability

**Components:**

**Glycerides, C8-10:**
- Biodegradability: Result: Readily biodegradable.
- Remarks: Based on data from similar materials

**Vaniprevir:**
- Biodegradability: Result: not rapidly degradable
  - Method: OECD Test Guideline 314

Bioaccumulative potential

**Components:**

**Glycerides, C8-10:**
- Partition coefficient: n-octanol/water: log Pow: < 4

**Vaniprevir:**

Mobility in soil
- No data available

Other adverse effects
- No data available

13. DISPOSAL CONSIDERATIONS

**Disposal methods**

- Waste from residues: 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.

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.

**National Regulations**
GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd

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 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 Develop-
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Disclaimer

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.

CN / EN