1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Vaniprevir Formulation

Manufacturer or supplier’s details

Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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

GHS label elements
Hazard pictograms: 
Signal word: Warning
Hazard statements: H373 May cause damage to organs (gallbladder, Liver) through prolonged or repeated exposure if swallowed. H402 Harmful to aquatic life.
Precautionary statements: Prevention:
P260 Do not breathe dust.
P273 Avoid release to the environment.
Response:
P319 Get medical help if you feel unwell.

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

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>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

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

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.
3. SAFETY DATA SHEET

Vaniprevir Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>16.10.2020</td>
<td>25790-00017</td>
<td>23.03.2020</td>
<td>27.10.2014</td>
</tr>
</tbody>
</table>

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

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.

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

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/m^3</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

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.

Eye protection:
Wear the following personal protective equipment:
Safety goggles

Skin and body protection:
Skin should be washed after contact.

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
- **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
SAFETY DATA SHEET

Vaniprevir Formulation

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

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

Acute toxicity
Not classified based on available information.

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

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

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

Respiratory sensitisation
Not classified based on available information.

Components:
Glycerides, C8-10:
SAFETY DATA SHEET
Vaniprevir Formulation

Version: 5.1
Revision Date: 16.10.2020
SDS Number: 25790-00017
Date of last issue: 23.03.2020
Date of first issue: 27.10.2014

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

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: Rat, male and female
Application Route: Oral
Activity duration: 104 Weeks
>= 120 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Oral
Activity duration: 6 Months
>= 300 mg/kg body weight
75 mg/kg body weight
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 development: 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

Vaniprevir:

Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, male and female
Application Route: Oral
General Toxicity - Parent: NOAEL: >= 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: >= 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 (gallbladder, Liver) through prolonged or repeated exposure if swallowed.

**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: >= 1,000 mg/kg  
Application Route: Ingestion  
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
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 aquatic invertebrates:
- EL50 (Daphnia magna (Water flea)): > 100 mg/l
- 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

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

Persistence 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:
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 IMO instruments: Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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: dd.mm.yyyy

Full text of other abbreviations
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.

IN / EN