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: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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:
P314 Get medical advice/attention 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>Glycerides, C8-10</td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>CAS-No.</td>
</tr>
<tr>
<td></td>
<td>Concentration (%) w/w</td>
</tr>
<tr>
<td>Vaniprevir</td>
<td>923590-37-8</td>
</tr>
<tr>
<td>Polyethylene glycol castor oil</td>
<td>61791-12-6</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)
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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/m³</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 : Combined particulates and organic vapour 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:
Skin and body protection: Safety goggles
Hygiene measures: Skin should be washed after contact.

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:
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 Formulation

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.

Polyethylene glycol castor oil:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

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

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

Polyethylene glycol castor oil:
Species: Rabbit
Method: OECD Test Guideline 404
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

Polyethylene glycol castor oil:
Species: Rabbit
Method: OECD Test Guideline 405
Result: No 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:
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

Polyethylene glycol castor oil:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
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

**Polyethylene glycol castor oil:**

Genotoxicity in vitro:
- Test Type: Chromosome aberration test in vitro  
  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

**Polyethylene glycol castor oil:**

- **Effects on foetal development**
  - Test Type: Embryo-foetal 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
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
- LOAEL: 300 mg/kg
- Application Route: Oral
- Exposure time: 90 d
- Target Organs: Liver, Kidney, Gastrointestinal tract, Heart, gallbladder, Stomach

Polyethylene glycol castor oil:
- Species: Rat
- NOAEL: > 5,000 mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days
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 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
  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
  Method: OECD Test Guideline 209

- NOEC: 1,000 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209

Polyethylene glycol castor oil:
- To fish:
  LC50 (Danio rerio (zebra fish)): > 45 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203

- To daphnia and other aquatic invertebrates:
  LC50 (Mysisidopsis bahia (opossum shrimp)): > 50 mg/l
  Exposure time: 48 h

- To microorganisms:
  EC50: 2.8 mg/l
  Exposure time: 5 min

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

Polyethylene glycol castor oil:
- Biodegradability: Result: rapidly degradable
  Remarks: Based on data from similar materials
Bioaccumulative potential

Components:

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

Vaniprevir:

Polyethylene glycol castor oil:
Partition coefficient: n-octanol/water : log Pow: 1.33

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 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:

AICS - Australian Inventory of Chemical Substances; 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 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; 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.

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