

## Vaniprevir Formulation

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## Section 1: Identification

**Product identifier** : Vaniprevir Formulation

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

**Manufacturer or supplier's details**

Company : MSD  
Address : 50 Tuas West Drive  
Singapore - Singapore 638408  
Telephone : +1-908-740-4000  
Emergency telephone number : 65 6697 2111 (24/7/365)  
E-mail address : EHSDATASTEWARD@msd.com

## Section 2: Hazard identification

**Classification of the substance or mixture**

Specific target organ toxicity - : Category 2 (gallbladder, Liver)  
repeated exposure (Oral)

**GHS Label elements, including precautionary statements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H373 May cause damage to organs (gallbladder, Liver) through prolonged or repeated exposure if swallowed.

Precautionary statements : **Prevention:**  
P260 Do not breathe dust.  
**Response:**  
P314 Get medical advice/ attention if you feel unwell.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

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**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.

**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Vaniprevir	923590-37-8	>= 10 -< 20

**Section 4: First-aid measures****Description of necessary 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**

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

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).

**Indication of any immediate medical attention and special treatment needed**

Treatment : Treat symptomatically and supportively.

**Section 5: Fire-fighting measures****Extinguishing media**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)

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Dry chemical

Unsuitable extinguishing media : None known.

**Special hazards arising from the substance or mixture**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 products : Carbon oxides

**Special protective actions for fire-fighters**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.

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**Section 6: Accidental release measures****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).**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.**Methods and materials 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 deter-

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mine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**Section 7: Handling and storage****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.  
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.
- 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.

**Conditions for safe storage, including any incompatibilities**

- 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

**Section 8: Exposure controls/personal protection****Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Vaniprevir	923590-37-8	TWA	300 µg/m <sup>3</sup>	Internal

- Appropriate engineering** : Ensure adequate ventilation, especially in confined areas.

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**control measures**

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).

**Individual protection measures, such as personal protective equipment (PPE)**

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

**Section 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, han-

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	: dling 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/cm <sup>3</sup>
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 characteristics	
Particle size	: No data available

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**Section 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

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Hazardous decomposition products : No hazardous decomposition products are known.

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**Section 11: Toxicological information**

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

**Acute toxicity**

Not classified based on available information.

**Components:****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:****Vaniprevir:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Vaniprevir:**

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

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

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**Respiratory sensitisation**

Not classified based on available information.

**Components:****Vaniprevir:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****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
	: $\geq 120$ mg/kg body weight
Result	: negative
Species	: Mouse
Application Route	: Oral
Activity duration	: 6 Months
	: $\geq 300$ mg/kg body weight
	: 75 mg/kg body weight
Result	: negative
Target Organs	: gallbladder



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**Reproductive toxicity**

Not classified based on available information.

**Components:****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 (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:****Vaniprevir:**

Species : Rat  
NOAEL : 120 mg/kg  
LOAEL : 360 mg/kg

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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

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**Section 12: Ecological information****Toxicity****Components:****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

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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:****Vaniprevir:**

Biodegradability : Result: not rapidly degradable  
Method: OECD Test Guideline 314

**Bioaccumulative potential****Components:****Vaniprevir:**

Partition coefficient: n-octanol/water : log Pow: 4.12

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**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.

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**Section 14: Transport information****International Regulations**

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**UNRTDG**

UN number	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Environmentally hazardous	: no

**IATA-DGR**

UN/ID No.	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Packing instruction (cargo aircraft)	: Not applicable
Packing instruction (passenger aircraft)	: Not applicable

**IMDG-Code**

UN number	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
EmS Code	: Not applicable
Marine pollutant	: Not applicable

**Transport in bulk according to IMO instruments**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

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**Section 15: Regulatory information****Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations	: Not applicable
Fire Safety (Petroleum and Flammable Materials) Regulations	: Not applicable

**The components of this product are reported in the following inventories:**

AICS	: not determined
DSL	: not determined

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IECSC : not determined

**Section 16: Other information**

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**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 and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

**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 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; 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

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

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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.

SG / EN