

Vaniprevir Formulation

Version 4.0 Revision Date: 2023/04/04 SDS Number: 25787-00021 Date of last issue: 2022/10/01
Date of first issue: 2014/10/27

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Vaniprevir Formulation

Manufacturer or supplier's details

Company : MSD

Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia

Telephone : 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

Restrictions on use :
Not applicable

2. HAZARDS IDENTIFICATION**GHS Classification**

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

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.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Vaniprevir	923590-37-8	>= 10 -< 30

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 : 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).

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.

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

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- 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.
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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.
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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.
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- Conditions for safe storage : Take care to prevent spills, waste and minimize release to the environment.
 : 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

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

- 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

SAFETY DATA SHEET



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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/cm ³
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.

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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:**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.

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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.

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
: >= 120 mg/kg body weight
Result : negative

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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

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.

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Repeated dose toxicity**Components:****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:****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

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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:****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

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
 Do not dispose of waste into sewer.

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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14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable

IATA-DGR

UN/ID No.	: Not applicable
Proper shipping name	: Not applicable
Class	: 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
Proper shipping name	: Not applicable
Class	: 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

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Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

AICC - 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 Con-

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centration 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 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.

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