

## **Vaniprevir Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 29.09.2023 25770-00023 5.2 06.04.2024 Date of first issue: 27.10.2014

**SECTION 1: IDENTIFICATION** 

Product name Vaniprevir Formulation

Manufacturer or supplier's details

Company MSD

: Building A - Level 1/26 Talavera Rd Address

Macquarie Park NSW, Australia 2113

Telephone 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use Not applicable

### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

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

repeated exposure (Oral)

**GHS** label elements

Hazard pictograms

Signal word

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 -< 30	

#### **SECTION 4. FIRST AID MEASURES**

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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 eves, 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. May cause damage to organs through prolonged or repeated

Most important symptoms

and effects, both acute and

exposure if swallowed.

delayed

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.

### **SECTION 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 prod: : Carbon oxides





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ucts

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer 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-

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**

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. Use only with adequate ventilation.

Local/Total 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 as-

sessment





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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 : 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**

## 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/m3	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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Particulates type

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



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end of workday.

Eye protection : Wear the following personal protective equipment:

Safety goggles

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

**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-

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



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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

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes : 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 tox-

icity tests.

LD0 (Dog): > 300 mg/kg

Remarks: No adverse effect has been observed in acute tox-

icity tests.

LD50 (Mouse): > 2,000 mg/kg

Remarks: No mortality observed at this dose.



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#### 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.

### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

### Vaniprevir:

Test Type : Local lymph node assay (LLNA)

Species : Mouse Result : negative

## **Chronic toxicity**

## 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



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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 weight75 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: >= 250 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

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



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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 Application Route : Oral Exposure time : 6 Months Target Organs : Liver

Species: DogNOAEL: 15 mg/kgLOAEL: 30 mg/kgApplication Route: OralExposure 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, Stom-

ach

#### **Aspiration toxicity**

Not classified based on available information.



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### **Experience with human exposure**

## **Components:**

Vaniprevir:

Ingestion Symptoms: stomach discomfort, Diarrhoea, Nausea, Head-

ache

#### **SECTION 12. ECOLOGICAL INFORMATION**

### **Ecotoxicity**

#### **Components:**

## Vaniprevir:

aquatic invertebrates

Toxicity to daphnia and other : 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 ma/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

### Persistence and degradability

## **Components:**

Vaniprevir:

Biodegradability Result: not rapidly degradable



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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

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14. TRANSPORT INFORMATION**

### International Regulations

**UNRTDG** 

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

Environmentally hazardous no

IATA-DGR

Not applicable UN/ID No. Not applicable Proper shipping name Not applicable Class Not applicable Subsidiary risk Packing group Not applicable Not applicable Labels Packing instruction (cargo Not applicable

aircraft)

Packing instruction (passen-Not applicable

ger aircraft)

**IMDG-Code** 

**UN** number Not applicable Proper shipping name Not applicable



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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.

## **National Regulations**

**ADG** 

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

Special precautions for user

Not applicable

## **SECTION 15. REGULATORY INFORMATION**

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

Therapeutic Goods (Poisons:

Standard) Instrument

No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or

threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition,

authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regula-

tions

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

AICS : not determined

DSL : not determined

IECSC : not determined

### **SECTION 16: ANY OTHER RELEVANT INFORMATION**

**Further information** 

Revision Date : 06.04.2024

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD



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compile the Safety Data eChem Portal search results and European Chemicals Agen-

Sheet cy, 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 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.

AU / EN