

# **Vaniprevir Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 29.09.2023

 7.0
 28.09.2024
 25775-00023
 Date of first issue: 27.10.2014

#### **SECTION 1. IDENTIFICATION**

Product identifier : Vaniprevir Formulation

Manufacturer or supplier's details

Company : MSD

Address : Avenue Comendador Antônio Loureiro Ramos,

nº 1500 - Distrito Industrial

Montes Claros - MG, Brazil 39404-620

Telephone : +55 (38) 3229 7000

Emergency telephone : +55 (38) 3201 5670

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 in accordance with ABNT NBR 14725 Standard

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

repeated exposure (Oral)

Short-term (acute) aquatic

hazard

ic : Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard

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.



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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.	Classification	Concentration (% w/w)
Glycerides, C8-10	85409-09-2	Aquatic Acute, 3	>= 50 -< 70
Vaniprevir	923590-37-8	STOT RE, (Oral)(gallbladder, Liver), 2	>= 10 -< 20

#### **SECTION 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 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.

Most important symptoms and effects, both acute and

Protection of first-aiders

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. 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).

Treat symptomatically and supportively. Notes to physician

## **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.



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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: :

ucts

Carbon oxides

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 fire-fighters

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 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.

#### **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.

Local/Total ventilation

Use only with adequate ventilation.

Advice on safe handling

Do not breathe dust.



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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 : Keep in properly labeled 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**

### Ingredients 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 <sup>3</sup>	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 Hand protection Particulates type

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the



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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.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : powder

Color : tan

Odor : odorless

Odor 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

Vapor pressure : No data available

Relative vapor 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

Autoignition 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,

handling 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**

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



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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.

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

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Vaniprevir:

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

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.



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#### Components:

Glycerides, C8-10:

Test Type : Buehler Test Routes of exposure : 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



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### 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 fetal 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 fetal 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



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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:

Routes of exposure : 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



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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.

Experience with human exposure

**Components:** 

Vaniprevir:

Ingestion : Symptoms: stomach discomfort, Diarrhea, Nausea, Headache

### **SECTION 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



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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-

: log Pow: < 4

octanol/water
Vaniprevir:

Partition coefficient: n-

octanol/water

: log Pow: 4,12



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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.

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.

#### **SECTION 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

**Domestic regulation** 

**ANTT** 

Not regulated as a dangerous good

Special precautions for user

Not applicable

### **SECTION 15. REGULATORY INFORMATION**

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

National List of Carcinogenic Agents for Humans -

Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal

Not applicable

Police

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

AICS : not determined

DSL : not determined

IECSC : not determined



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#### **SECTION 16. OTHER INFORMATION**

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**Further information** 

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, 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.

#### 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



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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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