

Vaniprevir Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 25793-00022 Date of last issue: 2022/10/01
Date of first issue: 2014/10/27

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Vaniprevir Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use :
Not applicable

2. HAZARDS IDENTIFICATION**GHS classification of chemical product**

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.

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Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

Important symptoms and out- : Dust contact with the eyes can lead to mechanical irritation.
 lines of the emergency as- : Contact with dust can cause mechanical irritation or drying of
 sumed : 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)	ENCS No.
Glycerides, C8-10	85409-09-2	>= 60 - < 70	2-669
Vaniprevir	923590-37-8	>= 10 - < 20	
2,6-Di-tert-butyl-p-cresol	128-37-0	>= 0.025 - < 0.1	3-540, 9-1805

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

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		Alcohol-resistant foam Carbon dioxide (CO ₂) 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
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.

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.

7. HANDLING AND STORAGE

Handling

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding
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- Local/Total ventilation : and bonding, or inert atmospheres.
 Advice on safe handling : Use only with adequate ventilation.
 : 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.
- Avoidance of contact : Oxidizing agents
 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.
- Storage**
- 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
- Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
Vaniprevir	923590-37-8	TWA	300 µg/m ³	Internal
2,6-Di-tert-butyl-p-cresol	128-37-0	TWA (Inhalable fraction and vapor)	2 mg/m ³	ACGIH

- 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-

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sure 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : tan

Odour : odourless

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

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Auto-ignition temperature : No data available

Viscosity
Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Density and / or relative density
Density : 1 g/cm³

Relative vapour density : 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

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.

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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:

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.

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg
 Method: OECD Test Guideline 401

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

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Result : No skin irritation

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

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)

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

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

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2,6-Di-tert-butyl-p-cresol:

Test Type	: Human repeat insult patch test (HRIPT)
Exposure routes	: Skin contact
Species	: Humans
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

2,6-Di-tert-butyl-p-cresol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES)
		Result: negative
		Test Type: In vitro mammalian cell gene mutation test
		Result: negative

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		Test Type: Chromosome aberration test in vitro
		Result: negative
	Genotoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
		Species: Rat
		Application Route: Ingestion
		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

2,6-Di-tert-butyl-p-cresol:

	Species	: Rat
	Application Route	: Ingestion
	Exposure time	: 22 Months
	Result	: negative

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

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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: \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

2,6-Di-tert-butyl-p-cresol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Ingestion
 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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2,6-Di-tert-butyl-p-cresol:

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity**Components:****Glycerides, C8-10:**

Species : Rat
 NOAEL : \geq 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

2,6-Di-tert-butyl-p-cresol:

Species : Rat
 NOAEL : 25 mg/kg
 Application Route : Ingestion
 Exposure time : 22 Months

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

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

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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

2,6-Di-tert-butyl-p-cresol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0.57 mg/l
 Exposure time: 96 h
 Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.48 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l
 Exposure time: 30 d
 Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.316 mg/l
 Exposure time: 21 d

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50: > 10,000 mg/l
 Exposure time: 3 h
 Method: OECD Test Guideline 209

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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

2,6-Di-tert-butyl-p-cresol:

Biodegradability : Result: Not readily biodegradable.
 Biodegradation: 4.5 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301C

Bioaccumulative potential**Components:****Glycerides, C8-10:**

Partition coefficient: n-octanol/water : log Pow: < 4

Vaniprevir:

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

2,6-Di-tert-butyl-p-cresol:

Bioaccumulation : Species: Cyprinus carpio (Carp)
 Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-octanol/water : log Pow: 5.1

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

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.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION**Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
2,6-Di-tert-butyl-4-methylphenol	64

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Industrial Safety and Health Law**Harmful Substances Prohibited from Manufacture**

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**Until March 31st, 2023**

Not applicable

From April 1st, 2023

Not applicable

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High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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**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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIIIC - 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;

Vaniprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
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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; KECl - 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; TECl - 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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