

# Vaniprevir Formulation

Version 3.2	Revision Date: 06.04.2024		S Number: 803-00023	Date of last issue: 29.09.2023 Date of first issue: 27.10.2014	
Section 1	: Identification				
Prod	luct identifier	:	Vaniprevir Form	ulation	
Reco	ommended use of the ch	nem	ical and restriction	ons on use	
	ommended use rictions on use	:	Pharmaceutical Not applicable		
Man	ufacturer or supplier's d	letai	ls		
Com	pany	:	MSD		
Addr	ess	:	50 Tuas West D Singapore - Sin		
Telep	phone	:	+1-908-740-400	0	
Eme	rgency telephone number	·:	65 6697 2111 (2	4/7/365)	
E-ma	ail address	:	EHSDATASTEV	/ARD@msd.com	
Section 2	2: Hazard identification				
	sification of the substar				
	ific target organ toxicity - ated exposure (Oral)	:	Category 2 (gall	bladder, Liver)	
GHS	Label elements, includi	ing	precautionary st	atements	
Haza	ard pictograms	:			
Signa	al word	:	Warning		
Haza	ard statements	:	: H373 May cause damage to organs (gallbladder, Liver) through prolonged or repeated exposure if swallowed.		
Prec	autionary 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
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Components

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

#### Section 4: First-aid measures

Description of necessary	first-aid measures
General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical a vice immediately.</li> <li>When symptoms persist or in all cases of doubt seek med advice.</li> </ul>
If inhaled	<ul> <li>If inhaled, remove to fresh air.</li> <li>Get medical attention if symptoms occur.</li> </ul>
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 symptom	s and effects, both acute and delayed
Risks	<ul> <li>May cause damage to organs through prolonged or repear exposure if swallowed.</li> <li>Contact with dust can cause mechanical irritation or drying the skin.</li> </ul>
Protection of first-aiders	<ul> <li>Dust contact with the eyes can lead to mechanical irritation</li> <li>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).</li> </ul>
Indication of any immedia	ate medical attention and special treatment needed
Treatment	: Treat symptomatically and supportively.

#### Extinguishing media

Suitable extinguishing media	:	Water spray
		Alcohol-resistant foam
		Carbon dioxide (CO2)



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Unsu media	itable extinguishing	:	Dry chemical None known.	
Spec	ial hazards arising from	n th	e substance or	mixture
-	fic hazards during fire-	:	Avoid generating concentrations, potential dust ex	g dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a plosion hazard. nbustion products may be a hazard to health
Haza ucts	rdous combustion prod-	:	Carbon oxides	
Spec	ial protective actions for	or fi	re-fighters	
for fire	al protective equipment efighters fic extinguishing meth-	:	Use personal pr Use extinguishir cumstances and Use water spray	ire, wear self-contained breathing apparatus rotective equipment. Ing measures that are appropriate to local cir- d the surrounding environment. / to cool unopened containers. aged containers from fire area if it is safe to
Section 6	: Accidental release me	eas	ures	
Dorconol	processions protective		uinmont and am	
	precautions, protective onal precautions	;	Use personal pr Follow safe han	otective equipment. dling advice (see section 7) and personal pro nt recommendations (see section 8).
	ental precautions onmental precautions	:	Prevent further Retain and disp	leakage or spillage if safe to do so. ose of contaminated wash water. s should be advised if significant spillages
	and materials for conta ods for cleaning up	iinn :	Sweep up or va tainer for dispos Avoid dispersal with compresse Dust deposits sl es, as these ma leased into the a Local or nationa posal of this ma employed in the mine which regu	cuum up spillage and collect in suitable con- al. of dust in the air (i.e., clearing dust surfaces



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## Section 7: Handling and storage

Precautions for safe handling	
Technical measures :	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation : 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 as- sessment 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
Hygiene measures :	environment. 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, in	cluding any incompatibilities
Conditions for safe storage : Materials to avoid :	Keep in properly labelled containers. Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents

## Section 8: Exposure controls/personal protection

## **Control parameters**

### Occupational Exposure Limits

Components	CAS-No.		Control parame- ters / Permissible concentration	Basis
Vaniprevir	923590-37-8	TWA	300 µg/m3	Internal

Appropriate engineering	:	Ensure adequate ventilation, especially in confined areas.
control measures		Minimize workplace exposure concentrations.
		Apply measures to prevent dust explosions.
		Ensure that dust-handling systems (such as exhaust ducts,
		dust collectors, vessels, and processing equipment) are de-



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			manner to prevent the escape of dust into the .e., there is no leakage from the equipment).				
Indivi	idual protection mea	asures, such as pe	rsonal protective equipment (PPE)				
	ace protection	Safety gogg					
	protection iratory protection	: If adequate sure assess	<ul> <li>Skin should be washed after contact.</li> <li>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</li> </ul>				
	ter type protection	: Particulates					
Ma	aterial	: Chemical-re	sistant gloves				
Re	emarks	on the conce stance and s determined applications chemicals o	ves to protect hands against chemicals dependin entration and quantity of the hazardous sub- specific to place of work. Breakthrough time is no for the product. Change gloves often! For specia , we recommend clarifying the resistance to f the aforementioned protective gloves with the facturer. Wash hands before breaks and at the day.				
Section 9	: Physical and chem	ical properties					
Appea	arance	: powder					
Colou	ır	: tan					
Odou	r	: odourless					

Odour Infestion I no data available	Odour Threshold	: No data available
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рΗ

Melting point/freezing point : No data available	Melting point/freezing point	:	No data available	
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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.

: No data available

Flammability (liquids)	:	No data available
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	r explosion limit / Upper nability limit	:	No data available	9
	r explosion limit / Lower nability limit	:	No data available	9
Vapo	ur pressure	:	No data available	9
Relat	ive vapour density	:	No data available	9
Dens	ity	:	1 g/cm <sup>3</sup>	
	bility(ies) ater solubility	:	No data available	9
	ion coefficient: n- ol/water	:	No data available	9
	ignition temperature	:	No data available	9
Deco	mposition temperature	:	No data available	9
Visco Vi	sity scosity, dynamic	:	No data available	9
Vi	scosity, kinematic	:	No data available	9
Explo	sive properties	:	Not explosive	
Oxidi	zing properties	:	The substance o	r mixture is not classified as oxidizing.
Moleo	cular weight	:	No data available	9
	cle characteristics cle size	:	No data available	9

## Section 10: Stability and reactivity

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials	:	Heat, flames and sparks. Avoid dust formation. Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

## Section 11: Toxicological information



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Inforr expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity lassified based on availa	able	information.	
Com	ponents:			
-	orevir: e oral toxicity	:		50 mg/kg lverse effect has been observed in acute to
			LD0 (Dog): > 30 Remarks: No ac icity tests.	0 mg/kg Iverse effect has been observed in acute to
			LD50 (Mouse): : Remarks: No mo	> 2,000 mg/kg ortality observed at this dose.
Not c	<b>corrosion/irritation</b> lassified based on availa <b>ponents:</b>	able		
Not c <u>Com</u>	lassified based on availa ponents: previr: ies	able :		
Not c <u>Com</u> Vanij Spec Resu Seric	lassified based on availa ponents: previr: ies	itati	information. Rabbit No skin irritation	
Not c Com Vanij Spec Resu Seric Not c	lassified based on availa ponents: previr: ies It bus eye damage/eye irr	itati	information. Rabbit No skin irritation	
Not c Com Vanij Spec Resu Seric Not c Com	lassified based on availa ponents: previr: ies It bus eye damage/eye irr lassified based on availa ponents: previr: ies It	itati	information. Rabbit No skin irritation	n
Not c Com Vanij Spec Resu Seric Not c Com Vanij Spec Resu Meth	lassified based on availa ponents: previr: ies It bus eye damage/eye irr lassified based on availa ponents: previr: ies It	: itati able	information. Rabbit No skin irritation on information. Bovine cornea Mild eye irritatio Bovine cornea (	n
Not c Com Spec Resu Seric Not c Com Vaniț Spec Resu Metho Resp Skin	lassified based on availa ponents: previr: ies It pus eye damage/eye irr lassified based on availa ponents: previr: ies It od	itati able	information. Rabbit No skin irritation on information. Bovine cornea Mild eye irritatio Bovine cornea (	n
Not c Com Spec Resu Seric Not c Com Vanij Spec Resu Metho Resp Skin Not c Resp	lassified based on availa ponents: previr: ies It bus eye damage/eye irr lassified based on availa ponents: ponents: previr: ies It od biratory or skin sensitis sensitisation	itati able	information. Rabbit No skin irritation on information. Bovine cornea Mild eye irritatio Bovine cornea ( on information.	n
Not c Com Spec Resu Seric Not c Com Vanij Spec Resu Metho Resp Skin Not c Resp Not c	lassified based on availa ponents: previr: ies It bus eye damage/eye irr lassified based on availa ponents: previr: ies It od biratory or skin sensitis sensitisation lassified based on availa biratory sensitisation	itati able	information. Rabbit No skin irritation on information. Bovine cornea Mild eye irritatio Bovine cornea ( on information.	n
Not c Com Vanij Spec Resu Serio Not c Com Vanij Spec Resu Metho Resp Skin Not c Resp Not c Com	lassified based on availa ponents: previr: ies It pus eye damage/eye irr lassified based on availa ponents: previr: ies It od pratory or skin sensitistics sensitisation lassified based on availa piratory sensitisation lassified based on availa ponents: previr:	itati able	information. Rabbit No skin irritation on information. Bovine cornea Mild eye irritatio Bovine cornea ( on information.	n



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sion	Revision Date: 06.04.2024	SDS Number: 25803-00023	Date of last issue: 29.09.2023 Date of first issue: 27.10.2014
Speci Resul		: Mouse : negative	
	cell mutagenicity assified based on ava	ailable information.	
Comp	oonents:		
Vanip	previr:		
	toxicity in vitro		Chromosomal aberration m: Chinese hamster ovary cells gative
		Test Type: Result: neg	Bacterial reverse mutation assay (AMES) gative
			Alkaline elution assay m: rat hepatocytes gative
Geno	toxicity in vivo	Species: N	Route: Oral
Carci	nogenicity		
Not cl	assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
Vanip	previr:		
	es cation Route ty duration	: Oral : 104 Weeks	and female s /kg body weight
Resul	t	: negative	rig body weight
Activit Resul	cation Route ty duration		/kg body weight body weight
-	oductive toxicity		

## Components:

Vaniprevir:



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Effect	ts on fertility	Species: Rat, Application Ro	ity - Parent: NOAEL: >= 250 mg/kg body weight
Effect ment	ts on foetal develop-	Developmenta	female oute: Oral ity Maternal: NOAEL: 120 mg/kg body weight al Toxicity: LOAEC F1: 180 mg/kg body weight o specific developmental abnormalities
		Developmenta weight	bit, female bute: Oral ity Maternal: NOAEL: 120 mg/kg body weight al Toxicity: NOAEL F1: >= 240 mg/kg body o specific developmental abnormalities

## 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	:	Dog
NOAEL	:	15 mg/kg
		5 0



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Expos Targe Symp Specie NOAE LOAE Applic Expos	cation Route sure time t Organs toms es EL		30 mg/kg Oral 9 Months Liver, gallbladd Gastrointestina Mouse 150 mg/kg 300 mg/kg Oral 90 d Liver, Kidney, f ach	
-	ation toxicity assified based on av	ailable	information.	
Exper	rience with human e	exposi	ıre	
<u>Comp</u>	oonents:			
Vanip	orevir:			
Ingest	tion	:	Symptoms: sto ache	mach discomfort, Diarrhoea, Nausea, Head-
ction 12	2: Ecological inform	: nation	• •	mach discomfort, Diarrhoea, Nausea, Head-
ction 12 Toxic	2: Ecological inform ity	ation	• •	mach discomfort, Diarrhoea, Nausea, Head-
tion 12 Toxic <u>Comp</u>	2: Ecological inform ity <u>ponents:</u>	: nation	• •	mach discomfort, Diarrhoea, Nausea, Head-
tion 12 Toxic <u>Comp</u> Vanip Toxici	2: Ecological inform ity <u>ponents:</u>		EC50 (Daphnia Exposure time Method: OECE	a magna (Water flea)): > 4 mg/l
tion 12 Toxic <u>Comp</u> Vanip Toxici	2: Ecological inform ity ponents: previr: ty to daphnia and oth		ache EC50 (Daphnia Exposure time Method: OECE Remarks: No t LC50 (America Exposure time Method: US-El	a magna (Water flea)): > 4 mg/l : 48 h 0 Test Guideline 202 oxicity at the limit of solubility amysis): > 4 mg/l
tion 12 Toxic <u>Comp</u> Vanip Toxici aquati	2: Ecological inform ity ponents: previr: ty to daphnia and oth ic invertebrates ty to algae/aquatic		ache EC50 (Daphnia Exposure time Method: OECE Remarks: No t LC50 (America Exposure time Method: US-El Remarks: No t EC50 (Pseudo mg/l Exposure time Method: OECE	a magna (Water flea)): > 4 mg/l : 48 h D Test Guideline 202 oxicity at the limit of solubility amysis): > 4 mg/l : 96 h PA OPPTS 850.1035 oxicity at the limit of solubility kirchneriella subcapitata (green algae)): > 4



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Toxic	city to microorganisms		
		NOEC: 1,0 Exposure ti Test Type: Method: Ol	
Pers	istence and degradat	ility	
<u>Com</u>	ponents:		
	previr:		
Biode	egradability	: Result: not Method: Ol	rapidly degradable ECD Test Guideline 314
Bioa	ccumulative potentia		
<u>Com</u>	ponents:		
Parti	<b>previr:</b> tion coefficient: n- nol/water	: log Pow: 4.	12
	<b>ility in soil</b> ata available		
Othe	er adverse effects		
No d	ata available		
Section 1	3: Disposal consider	ations	
Disp	osal methods		
-	te from residues		ose of waste into sewer.

Waste ITOITITESIQUES	•	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 han-
		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
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	Not applicable
Subsidiary risk	:	Not applicable



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Labels	onmentally hazardous		pplicable pplicable	
UN/ID UN pro Class Subsid Packir Labels Packir aircraf	No. oper shipping name diary risk ng group s ng instruction (cargo ft) ng instruction (passen-	: Not a : Not a : Not a : Not a : Not a : Not a	pplicable pplicable pplicable pplicable pplicable pplicable pplicable	
Class Subsic Packir Labels EmS ( Marine	imber oper shipping name diary risk ng group s Code e pollutant	Not a Not a Not a Not a Not a Not a Not a	pplicable pplicable pplicable pplicable pplicable pplicable pplicable pplicable	
	port in bulk according	-	struments	5
Speci	al precautions for use	r		

Not applicable

### Section 15: Regulatory information

#### Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.
Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazard-ous Substances) Regulations
Fire Safety (Petroleum and Flammable Materials) : Not applicable
Regulations
The components 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 Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Date format	:	dd.mm.yyyy

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China: IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only 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





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intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN