

Boceprevir Formulation

Version 6.0	Revision Date: 06.04.2024		S Number: 691-00023	Date of last issue: 26.09.2023 Date of first issue: 21.10.2014
Section 1:	Identification			
Produ	uct identifier	:	Boceprevir Form	ulation
Reco	mmended use of the ch	em	ical and restriction	ons on use
Recor	mmended use	:	Pharmaceutical	
Restri	ctions on use	:	Not applicable	
Manu	facturer or supplier's d	etai	ils	
Comp	pany	:	MSD	
Addre	PSS	:	50 Tuas West Dr Singapore - Sing	
Telep	hone	:	+1-908-740-4000)
Emer	gency telephone number	:	65 6697 2111 (24	4/7/365)
E-mai	l address	:	EHSDATASTEW	/ARD@msd.com
Section 2:	Hazard identification			
Class	ification of the substan	ce	or mixture	
Repro	oductive toxicity	:	Category 2	

GHS Label elements, including precautionary statements

Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H361f Suspected of damaging fertility.
Precautionary statements :		Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P280 Wear protective gloves/ protective clothing/ eye protec- tion/ face protection/ hearing protection.
		Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention.



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Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. 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)
Boceprevir	394730-60-0	>= 50 -< 70
Starch	9005-25-8	>= 10 -< 20
Cellulose	9004-34-6	>= 10 -< 20
Sodium n-dodecyl sulfate	151-21-3	>= 3 -< 10
Magnesium stearate	557-04-0	>= 1 -< 10

Section 4: First-aid measures

Description of necessary 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.
In case of skin contact	 In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
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. Rinse mouth thoroughly with water.
Most important symptoms an	d effects, both acute and delayed
Risks	 Suspected of damaging fertility. 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).





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	ation of any immediate ment	me :		and special treatment needed atically and supportively.
Section 5	: Fire-fighting measure	S		
Exting	guishing media			
Suita	ble extinguishing media	:	Water spray Alcohol-resista Carbon dioxide Dry chemical	
Unsu media	itable extinguishing a	:	None known.	
Spec	ial hazards arising from	n th	e substance or	mixture
Spec fightir	ific hazards during fire- ng	:	concentrations, potential dust e	ng dust; fine dust dispersed in air in sufficient , and in the presence of an ignition source is a explosion hazard. mbustion products may be a hazard to health.
Haza ucts	rdous combustion prod-	:	Carbon oxides Nitrogen oxides Metal oxides Sulphur oxides	
Spec	ial protective actions fo	or f	ire-fighters	
Spec for fir	ial protective equipment efighters ific extinguishing meth-		In the event of Use personal p Use extinguish cumstances an Use water spra	fire, wear self-contained breathing apparatus. rotective equipment. ing measures that are appropriate to local cir- d the surrounding environment. y to cool unopened containers. naged containers from fire area if it is safe to de
Section 6	: Accidental release me	eas	ures	
	precautions, protective onal precautions	e ec :	Use personal p Follow safe har	mergency procedures protective equipment. Indling advice (see section 7) and personal pro- ent recommendations (see section 8).
	nental precautions onmental precautions	:	Prevent further Retain and disp	o the environment. leakage or spillage if safe to do so. pose of contaminated wash water.

Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.



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		with compresse Dust deposits s es, as these ma leased into the Local or nationa posal of this ma employed in the mine which reg Sections 13 an	of dust in the air (i.e., clearing dust surfaces ed air). should not be allowed to accumulate on surfac- ay form an explosive mixture if they are re- atmosphere in sufficient concentration. al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.

Section 7: Handling and storage

Precautions for safe handling					
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. Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. 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 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, including any incompatibilities					
Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents					



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Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Boceprevir	394730-60-0	TWA	2 mg/m3 (OEB 1)	Internal
Starch	9005-25-8	PEL (long term)	10 mg/m3	SG OEL
		TWA	10 mg/m3	ACGIH
Cellulose	9004-34-6	PEL (long term)	10 mg/m3	SG OEL
		TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	PEL (long term)	10 mg/m3	SG OEL
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH

Appropriate engineering control 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 de- signed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
Individual protection measu	res	, such as personal protective equipment (PPE)
Eye/face protection	:	Wear the following personal protective equipment: Safety goggles
Skin protection	:	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Respiratory protection	:	
Filter type Hand protection	:	Particulates type
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending





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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.

Section 9: Physical and chemical properties

Appearance	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	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)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Density Solubility(ies) Water solubility	:	No data available No data available

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	tion coefficient: n- nol/water	:	Not applicable	
	-ignition temperature	:	No data availat	le
Deco	omposition temperature	:	No data availat	le
Visco			No doto ovoilok	
	iscosity, kinematic	•	No data availat	ne
Expl	osive properties	:	Not explosive	
Oxid	izing properties	:	The substance	or mixture is not classified as oxidizing.
Mole	cular weight	:	No data availat	le
	cle characteristics cle size	:	No data availat	le
ection 1	0: Stability and reactiv	vity		
Cher	ctivity nical stability ibility of hazardous reac	- :	Stable under no May form explo dling or other m	s a reactivity hazard. ormal conditions. sive dust-air mixture during processing, han neans. strong oxidizing agents.
Cond	ditions to avoid	:	Heat, flames ar	
	npatible materials ardous decomposition ucts	:	Avoid dust form Oxidizing agen No hazardous o	
ection 1	1: Toxicological inform	natic	n	
Infor expo	mation on likely routes o sure	f:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity classified based on avail	able	information.	
<u>Proc</u> Acut	luct: e oral toxicity	:	Acute toxicity es Method: Calcula	timate: > 2,000 mg/kg tion method
Com	ponents:			
	eprevir:			
Acut	e oral toxicity	:	LD50 (Rat): > 2,	000 mg/kg
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П				
		LD	50 (Monke	y): > 1,000 mg/kg
Starc	h:			
Acute	oral toxicity	: LD	950 (Rat): >	5,000 mg/kg
Acute	e dermal toxicity	: LD	50 (Rabbit)	: > 2,000 mg/kg
Cellu	lose:			
Acute	oral toxicity	: LD	950 (Rat): >	5,000 mg/kg
Acute	inhalation toxicity	Ex	50 (Rat): > posure time st atmosph	
Acute	e dermal toxicity	: LD	50 (Rabbit)	: > 2,000 mg/kg
Sodiu	um n-dodecyl sulfate	:		
Acute	oral toxicity		950 (Rat): 1 ethod: OEC	,200 mg/kg D Test Guideline 401
Acute	e dermal toxicity	Me	ethod: OEC	2,000 mg/kg D Test Guideline 402 sed on data from similar materials
Magn	esium stearate:			
	oral toxicity	Me As icit	ethod: OEC sessment: y	2,000 mg/kg D Test Guideline 423 The substance or mixture has no acute oral to sed on data from similar materials
Acute	e dermal toxicity			: > 2,000 mg/kg sed on data from similar materials
	corrosion/irritation lassified based on ava	ilable info	rmation.	
<u>Com</u>	oonents:			
Boce	previr:			
Speci Resu			bbit skin irritati	on
Sodiu	um n-dodecyl sulfate	:		
Speci Resu	es It		bbit in irritation	



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Magr Spec Resu Rema	llt	: Rabbit : No skin irritat : Based on dat	on a from similar materials
Not c	ous eye damage/eye classified based on ava ponents:		
Boce Spec Resu		: Rabbit : Mild eye irrita	tion
Stard Spec Resu	ies	: Rabbit : No eye irritati	on
Sodi Spec Resu Meth	llt	: Rabbit	fects on the eye Buideline 405
Magr Spec Resu Rema	llt	: Rabbit : No eye irritati : Based on dat	on a from similar materials
Skin Not c Resp Not c	biratory or skin sensi sensitisation classified based on ava biratory sensitisation classified based on ava ponents:	ilable information.	
	e previr: Type ies	: Maximisation : Guinea pig : negative	Test
Stard Test Expo Spec Resu	Type sure routes ies	: Maximisation : Skin contact : Guinea pig : negative	Test



ersion 0	Revision Date: 06.04.2024		S Number: 91-00023	Date of last issue: 26.09.2023 Date of first issue: 21.10.2014
Test T Expos Specie Result Remai	ure routes es rks esium stearate: ype ure routes es d	e: : : : : : :	Maximisation Skin contact Guinea pig negative Based on data Maximisation Skin contact Guinea pig OECD Test G negative	a from similar materials Test
Rema		:		a from similar materials
Not cla <u>Comp</u> Bocer	cell mutagenicity assified based on ava onents: previr: oxicity in vitro			cterial reverse mutation assay (AMES) ve
Genot	oxicity in vivo	:	Test Type: Ch Result: negati	romosomal aberration ve cronucleus test se bute: Oral
Starch Genot	1: oxicity in vitro	:	Test Type: Ba Result: negati	cterial reverse mutation assay (AMES) ve
Cellul	ose:			
Genot	oxicity in vitro	:	Result: negati	vitro mammalian cell gene mutation test
Genot	oxicity in vivo	:	cytogenetic as Species: Mou	se pute: Ingestion



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Sodiu	um n-dodecyl sulfate):		
Geno	toxicity in vitro	I		eterial reverse mutation assay (AMES) 9 Test Guideline 471 e
			Test Type: In v Result: negativ	itro mammalian cell gene mutation test e
Geno	toxicity in vivo	2	Test Type: Roo Species: Mous Application Ro Result: negativ	ute: Ingestion
Magr	esium stearate:			
	toxicity in vitro	I	Result: negativ	itro mammalian cell gene mutation test e ed on data from similar materials
		I		omosome aberration test in vitro) Test Guideline 473 e
		I	Remarks: Base	ed on data from similar materials
		I	Result: negativ	eterial reverse mutation assay (AMES) e ed on data from similar materials
	nogenicity	nilabla ir	formation.	
	lassified based on ava ponents:			
<u>Comp</u>	oonents:			
Comp Boce Speci Applic	previr: les cation Route sure time	: : (Mouse Dral 72 Weeks 650 mg/kg bod negative	y weight
Comp Boce Speci Applic Expos Dose Resul Speci Applic Expos Dose	previr: es cation Route sure time It es cation Route sure time		Dral 72 Weeks 650 mg/kg bod negative Rat Dral 104 Weeks 125 mg/kg bod	
Comp Boce Speci Applic Expose Resul Speci Applic Expos	previr: es cation Route sure time It es cation Route sure time		Dral 72 Weeks 650 mg/kg bod negative Rat Dral 104 Weeks	
Comp Boce Speci Applic Expos Dose Resul Speci Applic Expos Dose	previr: les cation Route sure time It es cation Route sure time It lose:		Dral 72 Weeks 650 mg/kg bod negative Rat Dral 104 Weeks 125 mg/kg bod	



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Sodium n-dodecyl sulfate:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Method	:	OECD Test Guideline 453
Result	:	negative
Species Application Route Exposure time Method Result Remarks	:	Based on data from similar materials

Reproductive toxicity

Suspected of damaging fertility.

Components:

Boceprevir:

Effects on fertility	 Test Type: Fertility/early embryonic development Species: Rat, male Fertility: LOAEL: 75 mg/kg body weight Symptoms: Effects on fertility Result: positive
	Test Type: Fertility/early embryonic development Species: Rat, female Fertility: LOAEL: 150 mg/kg body weight Symptoms: Effects on fertility Result: positive
Effects on foetal develop- ment	: Test Type: Development Species: Rabbit, male and female Application Route: Oral Developmental Toxicity: NOAEL: 300 mg/kg body weight Result: negative
Reproductive toxicity - As- sessment	: Some evidence of adverse effects on sexual function and fertility, based on animal experiments.
Cellulose:	
Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal develop- ment	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative
Sodium n-dodecyl sulfate:	
Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Rat



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			Application Route Method: OECD T Result: negative	e: Ingestion Test Guideline 416
Effect ment	s on foetal develop-	:	Test Type: Embr Species: Rat Application Route Result: negative	on data from similar materials yo-foetal development e: Ingestion on data from similar materials
Magn	esium stearate:			
	is on fertility	:	reproduction/dev Species: Rat Application Route Method: OECD T Result: negative	oined repeated dose toxicity study with the elopmental toxicity screening test e: Ingestion Test Guideline 422 on data from similar materials
Effect ment	s on foetal develop-	:	Species: Rat Application Rout Result: negative	yo-foetal development e: Ingestion on data from similar materials
STOT	- single exposure			
Not cl	assified based on avail	able	information.	
	- repeated exposure	- h -	information	
	lassified based on avail ated dose toxicity	able	information.	
-	oonents:			
Speci NOAE Applic	EL cation Route sure time	:	Monkey > 200 mg/kg Oral 365 d No significant ad	verse effects were reported
Expos	EL		Rat 75 mg/kg 100 mg/kg Oral 90 d Testis, Prostate	
Speci NOAE	es EL	:	Rat 15 mg/kg	
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LOA			5 mg/kg	
	cation Route sure time		ral 30 d	
	et Organs		estis	
Spec	ies	: N	ouse	
NOA			50 mg/kg	
LOAE	=∟ cation Route		00 mg/kg ral	
Expo	sure time	: 9	b C	
Targe	et Organs	: K	idney	
-	_			
Stard			ot	
Spec NOA			at = 2,000 mg/kg	
Appli	cation Route	: S	kin contact	
Expo Meth	sure time		3 Days ECD Test Guide	line 410
weth	ou	. 0	ECD Test Guide	inne 410
	llose:			
Spec NOA			at	
	⊏∟ cation Route		= 9,000 mg/kg gestion	
	sure time) Days	
Sodi	um n-dodecyl sulfate:	:		
Spec		: R	at	
NOA			38 mg/kg	
Appii Expo	cation Route sure time		gestion) Days	
Rema				m similar materials
Маси	nesium stearate:			
Spec		: R	at	
NOA	EL		100 mg/kg	
Appli	cation Route sure time		gestion) Days	
Rema	arks			m similar materials
-	ration toxicity			
Not c	lassified based on avai	lable inf	ormation.	
Expe	erience with human ex	posure		
<u>Com</u>	ponents:			
Boce	eprevir:			
Inges	stion	: S	ymptoms: Heada	ache, Gastrointestinal disturbance, bitter
			44/00	



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II

Toxicity

taste

Components:		
Boceprevir:		
Toxicity to algae/aquatic plants		EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.5 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 9.5 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic tox- icity)	:	NOEC (Pimephales promelas (fathead minnow)): > 9 mg/l Exposure time: 28 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC (Daphnia magna (Water flea)): 7.2 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	EC50: > 959 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
		NOEC: 959 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Cellulose:		
Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Sodium n-dodecyl sulfate:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 29 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l Exposure time: 72 h



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			NOEC (Desmode Exposure time: 7	esmus subspicatus (green algae)): 30 mg/l 2 h
Toxici icity)	ty to fish (Chronic tox-	:	NOEC (Pimepha mg/l Exposure time: 4	les promelas (fathead minnow)): >= 1.357 2 d
	ty to daphnia and other ic invertebrates (Chron-	:	NOEC (Ceriodap Exposure time: 7	hnia dubia (water flea)): 0.88 mg/l ˈd
	ty to microorganisms	:	EC50: 135 mg/l Exposure time: 3	h
Magn	esium stearate:			
Toxici	ty to fish	:	Exposure time: 4 Method: DIN 384	
	ty to daphnia and other ic invertebrates	:	Exposure time: 4 Test substance: Method: Directive	Water Accommodated Fraction e 67/548/EEC, Annex V, C.2. on data from similar materials
Toxici plants	ty to algae/aquatic	:	mg/l Exposure time: 7 Test substance: Method: OECD 7	Water Accommodated Fraction Fest Guideline 201 on data from similar materials
			mg/l Exposure time: 7 Test substance: Method: OECD 7	kirchneriella subcapitata (green algae)): > 2 h Water Accommodated Fraction Fest Guideline 201 on data from similar materials
Toxici	ty to microorganisms	:	Exposure time: 1 Test substance:	onas putida): > 100 mg/l 6 h Water Accommodated Fraction on data from similar materials

Persistence and degradability

Components:

Boceprevir:



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Bioc	degradability	:	Result: Not readil Biodegradation: (Exposure time: 28	0.6 %	
	l ulose: degradability	:	Result: Readily bi	iodegradable.	
	l ium n-dodecyl sulfate: degradability	:	 Result: Readily biodegradable. Biodegradation: 95 % Exposure time: 28 d Method: OECD Test Guideline 301B 		
	gnesium stearate: degradability	:	Result: Not biode Remarks: Based	gradable on data from similar materials	
Bio	accumulative potential				
Con	nponents:				
Boc	eprevir:				
Bioa	accumulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): 2.6 est Guideline 305	
	ition coefficient: n- nol/water	:	log Pow: 3.18		
Part	lium n-dodecyl sulfate: ition coefficient: n- inol/water	:	log Pow: 0.83		
Part	nesium stearate: ition coefficient: n- nol/water	:	log Pow: > 4		
Mot	oility in soil				
Con	nponents:				
Boc	eprevir:				
	ribution among environ- ntal compartments	:	log Koc: 1.9 Method: OECD T	est Guideline 106	
	er adverse effects data available				



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Section 13: Disposal considerations

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer.
Contaminated packaging	:	Dispose of in accordance with local regulations. 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 UN proper shipping name Transport hazard class(es) Subsidiary risk Packing group Labels	:	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
Environmentally hazardous	:	no
IATA-DGR UN/ID No. UN proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
IMDG-Code UN number UN proper shipping name	:	Not applicable Not applicable

UN 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 IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable



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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 (Hazardous 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 5 DSL not determined IECSC not determined

Section 16: Other information

Revision Date	:	06.04.2024
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 Agen- 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.

Date format	:	dd.mm.yyyy
Full text of other abbreviation	ons	
ACGIH SG OEL	:	USA. ACGIH Threshold Limit Values (TLV) Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.
ACGIH / TWA SG OEL / PEL (long term)	:	8-hour, time-weighted average Permissible Exposure Level (PEL) Long Term

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



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.0	06.04.2024	23691-00023	Date of first issue: 21.10.2014

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.

SG / EN