

### **Boceprevir Formulation**

Version 7.1	Revision Date: 26.09.2023	SDS Number: 23655-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014						
SECTION	SECTION 1. IDENTIFICATION								
Prod	uct name	: Boceprevi	r Formulation						
Man	ufacturer or supplier	s details							
Com	pany	: MSD							
Addr	ess		855 Leandro N. Alem St., 8 Floor Buenos Aires, Argentina C1001AFB						
Tele	phone	: 908-740-4	4000						
Eme	rgency telephone	: 1-908-423	3-6000						
E-ma	ail address	: EHSDATA	ASTEWARD@msd.com						
Reco	Recommended use of the chemical and restrictions on use								
	ommended use rictions on use	: Pharmace : Not applic							

#### SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Skin corrosion/irritation	:	Category 3
Reproductive toxicity	:	Category 2
Short-term (acute) aquatic hazard	:	Category 3
GHS label elements Hazard pictograms	:	
Signal Word	:	Warning
Hazard Statements	:	H316 Causes mild skin irritation. H361f Suspected of damaging fertility. H402 Harmful to aquatic life.
Precautionary Statements	:	Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protec-



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		tion/ face pro	tection.						
		attention.	<ul> <li>P308 + P313 IF exposed or concerned: Get medical advice/ attention.</li> <li>P332 + P313 If skin irritation occurs: Get medical advice/ attention</li> </ul>						
		<b>Storage:</b> P405 Store lo	ocked up.						
<b>Disposal:</b> P501 Dispose of contents/ container to an approved waste									
Other	r hazards which do i	•	t.	ainer to an approved waste					
Dust o May f	contact with the eyes orm explosive dust-a	P501 Dispos disposal plan	t. a <b>tion</b> al irritation. essing, handling or						
Dust of May f	contact with the eyes orm explosive dust-ai <b>3. COMPOSITION/IN</b> cance / Mixture	P501 Dispos disposal plan not result in classific can lead to mechanic ir mixture during proce	t. a <b>tion</b> al irritation. essing, handling or						
Dust of May f	contact with the eyes orm explosive dust-ai 3. COMPOSITION/IN	P501 Disposidisposal plan not result in classific can lead to mechanic ir mixture during proce	t. a <b>tion</b> al irritation. essing, handling or	other means.					
Dust of May f	contact with the eyes orm explosive dust-ai <b>3. COMPOSITION/IN</b> cance / Mixture <b>conents</b> nical name	P501 Disposidisposal plan not result in classific can lead to mechanic ir mixture during proce	t. al irritation. essing, handling or GREDIENTS						
Dust of May f CTION Subst Comp	contact with the eyes orm explosive dust-ai 3. COMPOSITION/IN ance / Mixture conents nical name previr	P501 Disposidisposal plan not result in classific can lead to mechanic ir mixture during proce	t. ation al irritation. essing, handling or GREDIENTS CAS-No.	other means.					
Dust of May f CTION Subst Comp Chem Bocep	contact with the eyes orm explosive dust-ai 3. COMPOSITION/IN cance / Mixture conents nical name previr	P501 Disposidisposal plan not result in classific can lead to mechanic ir mixture during proce	t. al irritation. essing, handling or GREDIENTS CAS-No. 394730-60-0	other means. Concentration (% w/w) >= 50 -< 70					
Dust of May f CTION Subst Comp Chem Bocep Starcl Cellul	contact with the eyes orm explosive dust-ai 3. COMPOSITION/IN cance / Mixture conents nical name previr	P501 Disposidisposal plan not result in classific can lead to mechanic ir mixture during proce	t. al irritation. essing, handling or GREDIENTS CAS-No. 394730-60-0 9005-25-8	other means. Concentration (% w/w) >= 50 -< 70 >= 10 -< 20					

General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>
If inhaled	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	<ul> <li>In case of contact, immediately flush skin with plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>
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 and effects, both acute and delayed Protection of first-aiders	<ul> <li>Causes mild skin irritation.</li> <li>Suspected of damaging fertility.</li> <li>Dust contact with the eyes can lead to mechanical irritation.</li> <li>First Aid responders should pay attention to self-protection,</li> </ul>



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No	Notes to physician		:	when the potentia	nmended personal protective equipment I for exposure exists (see section 8). cally and supportively.
SECTI	ON 5. FIRE-FI	IGHTING ME	ASU	IRES	
Su	Suitable extinguishing media		:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
	nsuitable extin edia	guishing	:	None known.	
	Specific hazards during fire fighting		:	concentrations, ar potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. bustion products may be a hazard to health.
	Hazardous combustion prod- ucts		:	Carbon oxides Nitrogen oxides (N Metal oxides Sulfur oxides	NOx)
Sr od	becific extingui	ishing meth-	:	: Use extinguishing measures that are appropriate to I cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is so. Evacuate area.	
	Special protective equipment for fire-fighters				e, wear self-contained breathing apparatus. ective equipment.
SECTI	ON 6. ACCIDI	ENTAL RELE	ASE	EMEASURES	

#### Use personal protective equipment. Personal precautions, protec- : Follow safe handling advice (see section 7) and personal tive equipment and emergency procedures 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 : Sweep up or vacuum up spillage and collect in suitable containment and cleaning up 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



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		certain loca	or national requirements.			
SECTION	N 7. HANDLING AND S	TORAGE				
Tech	Technical measures		icity may accumulate and ignite suspended dust explosion. equate precautions, such as electrical grounding g, or inert atmospheres.			
	al/Total ventilation ce on safe handling	<ul> <li>Use only wi</li> <li>Do not get of</li> <li>Do not brea</li> <li>Do not swal</li> <li>Avoid conta</li> <li>Handle in ad</li> <li>practice, ba</li> <li>assessment</li> <li>Minimize du</li> <li>Keep contai</li> <li>Keep away</li> <li>Take precat</li> <li>Take care to</li> </ul>	th adequate ventilation. on skin or clothing. the dust. low. ct with eyes. ccordance with good industrial hygiene and safety sed on the results of the workplace exposure tst generation and accumulation. ner closed when not in use. from heat and sources of ignition. utionary measures against static discharges. o prevent spills, waste and minimize release to the			
	ditions for safe storage	: Keep in pro Store locked Store in acc	environment. Keep in properly labeled containers. Store locked up. Store in accordance with the particular national regulations.			
wate		: 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 parame- ters / Permissible concentration	Basis
Boceprevir	394730-60-0	TWA	2 mg/m3 (OEB 1)	Internal
Starch	9005-25-8	CMP	10 mg/m <sup>3</sup>	AR OEL
	Further inform	ation: A4 - Not c	lassifiable as a huma	n carcinogen
		TWA	10 mg/m <sup>3</sup>	ACGIH
Cellulose	9004-34-6	CMP	10 mg/m <sup>3</sup>	AR OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Magnesium stearate	557-04-0	CMP	10 mg/m <sup>3</sup>	AR OEL
	Further inform	ation: A4 - Not c	lassifiable as a huma	n carcinogen
		TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH



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Engi	Engineering measures		ure adequate ventilation, especially in confined areas. mize workplace exposure concentrations. ly measures to prevent dust explosions. ure that dust-handling systems (such as exhaust ducts, collectors, vessels, and processing equipment) are gned in a manner to prevent the escape of dust into the c area (i.e., there is no leakage from the equipment).
Pers	onal protective equip	nent	
	viratory protection	expo recor	lequate local exhaust ventilation is not available or osure assessment demonstrates exposures outside the ommended guidelines, use respiratory protection.
	Filter type Hand protection		iculates type
М	aterial	: Cher	mical-resistant gloves
R	Remarks		ose gloves to protect hands against chemicals depending ne concentration specific to place of work. Breakthrough is not determined for the product. Change gloves often! special applications, we recommend clarifying the stance to chemicals of the aforementioned protective es with the glove manufacturer. Wash hands before the and at the end of workday.
Eye	protection	: Wea	ar the following personal protective equipment: ety goggles
Skin	Skin and body protection		ect appropriate protective clothing based on chemical stance data and an assessment of the local exposure ential. I contact must be avoided by using impervious protective hing (gloves, aprons, boots, etc).
Hygi	Hygiene measures :		flushing (gloves, aprons, boots, etc). posure to chemical is likely during typical use, provide flushing systems and safety showers close to the king place. en using do not eat, drink or smoke. sh contaminated clothing before re-use.

#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white
Odor	:	No data available
Odor 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



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Eva	Evaporation rate		No data availa	ble
Flan	Flammability (solid, gas)		May form explo handling or oth	osive dust-air mixture during processing, er means.
Flan	nmability (liquids)	:	Not applicable	
	er explosion limit / Upper mability limit	:	No data availa	ble
	er explosion limit / Lower mability limit	:	No data availa	ble
Vap	or pressure	:	Not applicable	
Rela	ative vapor density	:	Not applicable	
Rela	ative density	:	No data availa	ble
Den	sity	:	No data availa	ble
	ıbility(ies) Vater solubility	:	No data availa	ble
5	Solubility in other solvents	:	No data availa	ble
	ition coefficient: n- nol/water	:	Not applicable	
	bignition temperature	:	No data availa	ble
Dec	omposition temperature	:	No data availa	ble
	Viscosity Viscosity, kinematic		No data availa	ble
Exp	losive properties	:	Not explosive	
Oxic	dizing properties	:	The substance	or mixture is not classified as oxidizing.
Mole	ecular weight	:	No data availa	ble
Part	icle size	:	No data availa	ble

#### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing,
tions		handling or other means.
		Can react with strong oxidizing agents.



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	Conditions to avoid Incompatible materials Hazardous decomposition products		:		
	-	1. TOXICOLOGICAL I ntion on likely routes of re		Inhalation Skin contact Ingestion Eye contact	
		t <b>oxicity</b> ssified based on availa	ble	information.	
	Produc	: <b>t</b> :			
		oral toxicity	:	Acute toxicity estin Method: Calculation	nate: > 5.000 mg/kg on method
	Compo	onents:			
	Восері	revir:			
	Acute o	oral toxicity	:	LD50 (Rat): > 2.00	00 mg/kg
				LD50 (Monkey): >	1.000 mg/kg
	Starch	:			
		oral toxicity	:	LD50 (Rat): > 5.00	)0 mg/kg
	Acute d	lermal toxicity	:	LD50 (Rabbit): > 2	2.000 mg/kg
	Cellulo	se.			
		oral toxicity	:	LD50 (Rat): > 5.00	00 mg/kg
	Acute ir	nhalation toxicity	:	LC50 (Rat): > 5,8 Exposure time: 4 I Test atmosphere:	ר ר
	Acute d	lermal toxicity	:	LD50 (Rabbit): > 2	2.000 mg/kg
	Sodiun	n n-dodecyl sulfate:			
		oral toxicity	:	LD50 (Rat): 1.200 Method: OECD Te	
	Acute d	lermal toxicity	:	LD50 (Rat): > 2.00 Method: OECD Te Remarks: Based o	
	Magne	sium stearate:			
	-	oral toxicity	:	LD50 (Rat): > 2.00 Method: OECD Te	



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			icity	he substance or mixture has no acute oral to
			Remarks: Base	ed on data from similar materials
Acute	dermal toxicity	:	LD50 (Rabbit): Remarks: Base	> 2.000 mg/kg ed on data from similar materials
-	corrosion/irritation es mild skin irritation.			
Comp	oonents:			
Boce	previr:			
Speci		:	Rabbit	
Resul		:	No skin irritatio	n
Sodiu	Im n-dodecyl sulfate	e:		
Speci		:	Rabbit	
Resul	t	:	Skin irritation	
Magn	esium stearate:			
Speci		:	Rabbit	
Resul Rema	t rks	irritati	No skin irritatio Based on data	n from similar materials
Resul Rema Serio Not cl	t		No skin irritatio Based on data on	
Result Rema Serio Not cl <u>Comp</u>	t rks <b>us eye damage/eye</b> assified based on ava		No skin irritatio Based on data on	
Result Rema Serio Not cl <u>Comp</u>	t rks <b>us eye damage/eye</b> assified based on ava ponents: previr:		No skin irritatio Based on data on	
Resul Rema Serio Not cl Comp Boce	t rks us eye damage/eye assified based on ava ponents: previr: es		No skin irritatio Based on data on information.	from similar materials
Resul Rema Serio Not cl Comp Boce Specie	t rks <b>us eye damage/eye</b> assified based on ava <u>ponents:</u> previr: es t		No skin irritatio Based on data on information. Rabbit	from similar materials
Resul Rema Serio Not cl Comp Boce Specie Resul Starc Specie	t rks us eye damage/eye assified based on ava <u>ponents:</u> previr: es t h: es		No skin irritatio Based on data on information. Rabbit Mild eye irritatio Rabbit	from similar materials on
Resul Rema Serio Not cl Comp Boce Specie Resul Starc	t rks us eye damage/eye assified based on ava <u>ponents:</u> previr: es t h: es		No skin irritatio Based on data on information. Rabbit Mild eye irritatio	from similar materials on
Resul Rema Serio Not cl Comp Boce Specia Resul Starc Resul	t rks us eye damage/eye assified based on ava <u>ponents:</u> previr: es t h: es	ailable : : :	No skin irritatio Based on data on information. Rabbit Mild eye irritatio Rabbit	from similar materials on
Resul Rema Serio Not cl Comp Specie Resul Starc Specie Resul Sodiu Specie	t rks us eye damage/eye assified based on ava <u>ponents:</u> previr: es t h: es t m n-dodecyl sulfate es	ailable : : :	No skin irritatio Based on data on information. Rabbit Mild eye irritatio Rabbit No eye irritation Rabbit	from similar materials on
Resul Rema Serio Not cl Comp Specie Resul Starc Specie Resul	t rks us eye damage/eye assified based on ava <u>ponents:</u> previr: es t h: es t m n-dodecyl sulfate es t	ailable : : :	No skin irritatio Based on data on information. Rabbit Mild eye irritatio Rabbit No eye irritation	from similar materials on n
Resul Rema Serio Not cl Comp Boce Specie Resul Starc Specie Resul Sodiu Specie Resul	t rks us eye damage/eye assified based on ava <u>ponents:</u> previr: es t h: es t m n-dodecyl sulfate es t od	ailable : : :	No skin irritatio Based on data on information. Rabbit Mild eye irritatio Rabbit No eye irritation Rabbit Irreversible effe	from similar materials on n
Resul Rema Serio Not cl Comp Boce Specie Resul Specie Resul Specie Resul Specie Resul Metho	t rks us eye damage/eye assified based on ava <u>conents:</u> previr: es t h: es t m n-dodecyl sulfate es t od esium stearate:	ailable : : :	No skin irritatio Based on data on information. Rabbit Mild eye irritation Rabbit No eye irritation Rabbit Irreversible effe OECD Test Gu	from similar materials on n
Resul Rema Serio Not cl Comp Boce Specie Resul Starc Specie Resul Sodiu Specie Resul	t rks us eye damage/eye assified based on ava <u>conents:</u> previr: es t h: es t m n-dodecyl sulfate es t od esium stearate: es	ailable : : :	No skin irritatio Based on data on information. Rabbit Mild eye irritation Rabbit Irreversible effe OECD Test Gu Rabbit No eye irritation	from similar materials on n ects on the eye nideline 405



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Respi	iratory or skin sensi	tizatio	on	
	sensitization assified based on ava	ailable	information.	
-	iratory sensitization assified based on ava		information	
	oonents:			
Boce	previr:			
Test T Speci Resul	es	:	Maximization Te Guinea pig negative	est
Starc	h:			
Test 1 Route Speci Resul	es of exposure	:	Maximization Te Skin contact Guinea pig negative	est
Sodiu	um n-dodecyl sulfate	):		
Test 1 Route Speci Resul Rema	es of exposure es t		Maximization Te Skin contact Guinea pig negative Based on data fi	rom similar materials
Magn	esium stearate:			
Test 1	Гуре es of exposure es od t		Maximization Te Skin contact Guinea pig OECD Test Guid negative Based on data fi	
Germ	cell mutagenicity			
Not cl	assified based on ava	ailable	information.	
Comp	oonents:			
	<b>previr:</b> toxicity in vitro	:	Test Type: Bacte Result: negative	erial reverse mutation assay (AMES)
			Test Type: Chro Result: negative	mosomal aberration
Geno	toxicity in vivo	:	Test Type: Micro Species: Mouse Application Rout Result: negative	e: Oral



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Starc	:h:			
Geno	toxicity in vitro	:	Test Type: Ba Result: negat	cterial reverse mutation assay (AMES) ve
Cellu	lose:			
Geno	toxicity in vitro	:	Test Type: Ba Result: negat	cterial reverse mutation assay (AMES) ve
			Test Type: In Result: negat	vitro mammalian cell gene mutation test ve
Geno	toxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative	
Sodiu	um n-dodecyl sulfate	:		
Geno	toxicity in vitro	:		icterial reverse mutation assay (AMES) D Test Guideline 471 ve
			Test Type: In Result: negat	vitro mammalian cell gene mutation test ve
Geno	toxicity in vivo	:	Species: Mou	oute: Ingestion
Magn	esium stearate:			
Geno	toxicity in vitro	:	Result: negat	vitro mammalian cell gene mutation test ve sed on data from similar materials
			Method: OEC Result: negat	rromosome aberration test in vitro D Test Guideline 473 ve sed on data from similar materials
			Result: negat	ncterial reverse mutation assay (AMES) ve sed on data from similar materials

# Components:

Boce	prev	vir:	
	•		

Species	:	Mouse
Application Route	:	Oral



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	Exposu Dose Result	ire time	:	72 Weeks 650 mg/kg body negative	veight		
		s ition Route ire time	: : : :	Rat Oral 104 Weeks 125 mg/kg body negative	veight		
			:	<ul> <li>Rat</li> <li>Ingestion</li> <li>72 weeks</li> <li>negative</li> </ul>			
	Specie Applica	ition Route ire time I	:	Rat Ingestion 2 Years OECD Test Guid negative Based on data fro	eline 453 om similar materials		
	Suspec	ductive toxicity cted of damaging fertilit	ty.				
	Восер						
		on fertility	:	Species: Rat, ma	75 mg/kg body weight		
				Species: Rat, fen	150 mg/kg body weight		
	Effects	on fetal development	:	Test Type: Devel Species: Rabbit, Application Route Developmental T Result: negative	male and female		
	Reproc sessme	luctive toxicity - As- ent	:		f adverse effects on sexual function and animal experiments.		
	Cellulo	ose:					



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Eff	fects on fertility	:	Test Type: One-g Species: Rat Application Route Result: negative	eneration reproduction toxicity study : Ingestion
Eff	Effects on fetal development		Test Type: Fertilit Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion
Sc	dium n-dodecyl sulfate:			
	fects on fertility	:	Species: Rat Application Route Method: OECD T Result: negative	
Efi	fects on fetal development	:	Species: Rat Application Route Result: negative	ro-fetal development : Ingestion on data from similar materials
Ма	agnesium stearate:			
Eff	fects on fertility	:	reproduction/deve Species: Rat Application Route Method: OECD T Result: negative	
Eff	fects on fetal development	:	Species: Rat Application Route Result: negative	ro-fetal development : Ingestion on data from similar materials
	<b>OT-single exposure</b> ot classified based on availa	able	information.	
	<b>OT-repeated exposure</b> ot classified based on availa	able	information.	
Re	peated dose toxicity			
<u>Cc</u>	omponents:			
Вс	oceprevir:			
	ecies DAEL	:	Monkey > 200 mg/kg	
Ap	plication Route	:	Oral	
Ex	posure time	:	365 d	



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Rema	arks	:	No significant adv	verse effects were reported
Expo	EL		Rat 75 mg/kg 100 mg/kg Oral 90 d Testis, Prostate	
Expo	EL		Rat 15 mg/kg 75 mg/kg Oral 180 d Testis	
Expo	EL		Mouse 250 mg/kg 500 mg/kg Oral 90 d Kidney	
	ies EL cation Route sure time		Rat >= 2.000 mg/kg Skin contact 28 Days OECD Test Guide	eline 410
Spec NOAI Appli			Rat >= 9.000 mg/kg Ingestion 90 Days	
Spec NOAI Appli	EL cation Route sure time			om similar materials
Spec NOAI Appli	EL cation Route sure time		Rat > 100 mg/kg Ingestion 90 Days Based on data fro	om similar materials



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Aspira	ntion toxicity			
Not cla	assified based on availa	ble	information.	
Experi	ience with human exp	osu	ire	
Comp	onents:			
Восер	orevir:			
Ingesti	on	:	Symptoms: Heac taste	ache, Gastrointestinal disturbance, bitter
ECTION 1	2. ECOLOGICAL INFO	ORN	ATION	
Ecoto	xicity			
<u>Comp</u>	onents:			
Восер	previr:			
Toxicit plants	y to algae/aquatic	:	mg/l Exposure time: 7	chneriella subcapitata (green algae)): > 9,5 2 h est Guideline 201
			mg/l Exposure time: 7	rchneriella subcapitata (green algae)): 9,5 2 h est Guideline 201
Toxicit icity)	y to fish (Chronic tox-	:	Exposure time: 2	les promelas (fathead minnow)): > 9 mg/l 8 d est Guideline 210
	y to daphnia and other c invertebrates (Chron- ity)	:	Exposure time: 2	magna (Water flea)): 7,2 mg/l 1 d est Guideline 211
Toxicit	y to microorganisms	:	EC50: > 959 mg/ Exposure time: 3 Test Type: Respi Method: OECD T	h
			NOEC: 959 mg/l Exposure time: 3 Test Type: Respi Method: OECD T	
Cellul	ose:			
	y to fish	:	Exposure time: 4	tipes (Japanese medaka)): > 100 mg/l 8 h on data from similar materials
Sodiu	m n-dodecyl sulfate:			
	y to fish	:	LC50 (Pimephale Exposure time: 9	es promelas (fathead minnow)): 29 mg/l 6 h



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		to daphnia and other invertebrates	:	EC50 (Ceriodaphi Exposure time: 48	nia dubia (water flea)): 5,55 mg/l 3 h
	Toxicity plants	to algae/aquatic	:	ErC50 (Desmodes Exposure time: 72	smus subspicatus (green algae)): > 120 mg/l 2 h
				NOEC (Desmode: Exposure time: 72	smus subspicatus (green algae)): 30 mg/l 2 h
	Toxicity icity)	to fish (Chronic tox-	:	NOEC (Pimephale mg/l Exposure time: 42	es promelas (fathead minnow)): >= 1,357 2 d
	aquatic	to daphnia and other invertebrates (Chron-	:	NOEC (Ceriodaph Exposure time: 7	nnia dubia (water flea)): 0,88 mg/l d
	ic toxici Toxicity	to microorganisms	:	EC50: 135 mg/l Exposure time: 3	h
	Magne: Toxicity	<b>sium stearate:</b> to fish	:	Exposure time: 48 Method: DIN 3841	
		to daphnia and other invertebrates	:	Exposure time: 47 Test substance: V Method: Directive	Vater Accommodated Fraction 67/548/EEC, Annex V, C.2. on data from similar materials
	Toxicity plants	to algae/aquatic	:	mg/l Exposure time: 72 Test substance: V Method: OECD Te Remarks: Based o No toxicity at the l	Vater Accommodated Fraction est Guideline 201 on data from similar materials
				Exposure time: 72 Test substance: V Method: OECD Te	Vater Accommodated Fraction
	Toxicity	to microorganisms	:	Exposure time: 16 Test substance: V	nas putida): > 100 mg/l 5 h Vater Accommodated Fraction on data from similar materials



rsion	Revision Date: 26.09.2023		DS Number: 655-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
Persi	stence and degradabi	lity		
<u>Comp</u>	oonents:			
Boce	previr:			
Biode	gradability	:	Result: Not readil Biodegradation: ( Exposure time: 28	0,6 %
Cellu	lose:			
Biode	gradability	:	Result: Readily bi	iodegradable.
Codiu	un a de de eul eulfete.			
	<b>Im n-dodecyl sulfate:</b> gradability	:	Result: Readily bi	iodegradable
2.000	9	-	Biodegradation:	95 %
			Exposure time: 28 Method: OECD T	8 d est Guideline 301B
-	esium stearate:			
Biode	gradability	:	Result: Not biode Remarks: Based	gradable on data from similar materials
Bioac	cumulative potential			
Comp	oonents:			
Boce	previr:			
Bioac	cumulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): 2,6 est Guideline 305
	on coefficient: n- ol/water	:	log Pow: 3,18	
Sodiu	Im n-dodecyl sulfate:			
	on coefficient: n- ol/water	:	log Pow: 0,83	
-	esium stearate:			
	on coefficient: n- ol/water	:	log Pow: > 4	
	ity in soil			
<u>Com</u> p	oonents:			
Boce	previr:			
Distrik	oution among environ- al compartments	:		est Guideline 106
Other	adverse effects			
	ita available			



### **Boceprevir Formulation**

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#### 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	:	

#### **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.

#### Special precautions for user

Not applicable

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

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

Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable
Control of precursors and essential chemicals for the preparation of drugs.	:	Not applicable

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

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

Revision Date	:	26.09.2023
Date format	:	dd.mm.yyyy

#### **Further information**



Version 7.1	Revision Date: 26.09.2023		DS Number: 655-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014	
cor	urces of key data used to npile the Material Safety ta Sheet	:		data, data from raw material SDSs, OECD arch results and European Chemicals Agen- ropa.eu/	
Ful	Il text of other abbreviation	ons			
	GIH OEL	:		eshold Limit Values (TLV) ational Exposure Limits	
	GIH / TWA OEL / CMP	:	8-hour, time-weig TLV (Threshold L		
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					

tem; 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.

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