

Boceprevir Formulation

Versio 4.1		Revision Date: 26.09.2023		DS Number: 3693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
SECT	ION 1:	Identification of t	the	substance/m	ixture and of the company/undertaking
1.1 Pro	oduct i	dentifier			
Tr	rade na	me	:	Boceprevir Fo	mulation
1 2 Do	lovent	identified upon of th	ha a		ivers and uses advised against
U	se of th tance/M	e Sub-	:	Pharmaceutica	ixture and uses advised against al
	ecomm n use	ended restrictions	:	Not applicable	
1.3 De	tails of	the supplier of the	sat	fety data sheet	
	ompany	••	:	MSD 117 16th Road	l house, Midrand, South Africa
Te	elephon	e	:	+27 11 655 30	00
		ldress of person ble for the SDS	:	EHSDATASTE	EWARD@msd.com
1.4 Em	nergeng	cy telephone numb	er		
	-	23-6000	•		
SECT	ION 2 :	Hazards identific	ati	on	
2.1 Cla	assifica	tion of the substan	ice	or mixture	
		ation (REGULATIO	•	•	08) 61f: Suspected of damaging fertility.
	, bel eler		,		
La	abelling	g (REGULATION (E	C) N	No 1272/2008)	
	-	ictograms	:		
Si	ignal wo	ord	:	Warning	
Ha	azard s	tatements	:	H361f Suspec	ted of damaging fertility.
Pi	recautic	onary statements	:	Prevention: P201 Obtain	special instructions before use

P201 Obtain special instructions before use.P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.



Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	23693-00022	Date of first issue: 21.10.2014
		Response: P308 + P313 attention.	IF exposed or concerned: Get medical advice/

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label: Boceprevir

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Boceprevir	394730-60-0	Repr. 2; H361f	>= 50 - < 70
Sodium n-dodecyl sulfate	151-21-3 205-788-1	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412	>= 3 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
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).
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.



4.1	Revision Date: 26.09.2023		OS Number: 693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
In cas	se of skin contact	:	Remove contami Get medical atter Wash clothing be	
In cas	se of eye contact	:	If in eyes, rinse w Get medical atter	rell with water. ation if irritation develops and persists.
lf swa	llowed	:	Get medical atter	NOT induce vomiting. ntion. oughly with water.
4.2 Most i Risks	mportant symptoms a	nd e :	effects, both acute Suspected of dar	-
			·	the eyes can lead to mechanical irritation.
				,
	•	meo		d special treatment needed
Treat	ment	:	Treat symptomati	ically and supportively.
5.1 Exting	I 5: Firefighting meas uishing media ble extinguishing media	:	Water spray	600m
5.1 Exting	uishing media	:		
5.1 Exting Suital	uishing media ble extinguishing media itable extinguishing	:	Water spray Alcohol-resistant Carbon dioxide (0	
5.1 Exting Suital Unsui media	uishing media ole extinguishing media itable extinguishing	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical None known.	CO2)
5.1 Exting Suital Unsui media 5.2 Specia	uishing media ole extinguishing media itable extinguishing a al hazards arising from fic hazards during fire-	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical None known.	CO2) xture dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a
 5.1 Exting Suital Unsui media 5.2 Specia Specia Specia Specia Specia 	uishing media ole extinguishing media itable extinguishing a al hazards arising from fic hazards during fire-	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical None known.	xture dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health
 5.1 Exting Suital Unsui media 5.2 Specia Speci fightin Hazau ucts 	Juishing media bole extinguishing media itable extinguishing a al hazards arising from fic hazards during fire-	: : :	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical None known. substance or mi Avoid generating concentrations, a potential dust exp Exposure to coml Carbon oxides Nitrogen oxides (Metal oxides	xture dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health
 5.1 Exting Suital Unsui media 5.2 Specia Speci fightir Hazau ucts 5.3 Advice Speci 	uishing media ble extinguishing media itable extinguishing a al hazards arising from fic hazards during fire- ng	: : :	Water spray Alcohol-resistant Carbon dioxide (0 Dry chemical None known. substance or mi Avoid generating concentrations, a potential dust exp Exposure to com Carbon oxides Nitrogen oxides Nitrogen oxides Sulphur oxides	xture dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health NOx)
 5.1 Exting Suital Unsui media 5.2 Specia Speci fightin Hazau ucts 5.3 Advice Speci for fire 	puishing media ble extinguishing media itable extinguishing a al hazards arising from fic hazards during fire- ng rdous combustion prod-	: : :	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical None known. substance or mi Avoid generating concentrations, a potential dust exp Exposure to com Carbon oxides Nitrogen oxides Sulphur oxides Sulphur oxides In the event of fire Use personal pro Use extinguishing cumstances and	xture dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health NOx) e, wear self-contained breathing apparatus.



Version 4.1	Revision Date: 26.09.2023	SDS Number: 23693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014		
		Remove und so. Evacuate are	amaged containers from fire area if it is safe to do ea.		
SECTION	6: Accidental relea	se measures			
6.1 Persor	nal precautions, prote	ctive equipment a	and emergency procedures		
Perso	nal precautions	Follow safe h	I protective equipment. nandling advice (see section 7) and personal pro- ment recommendations (see section 8).		
6.2 Enviro	nmental precautions				
Environmental precautions		Prevent furth Retain and d Local author	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.		
6.3 Metho	ds and material for co	ntainment and cl	eaning up		
Metho	ods for cleaning up	tainer for dis Avoid disper- with compres Dust deposit es, as these leased into th Local or nation posal of this employed in mine which r Sections 13	sal of dust in the air (i.e., clearing dust surfaces		

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 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	:	Use only with adequate ventilation.					
Advice on safe handling	:	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					



Version 4.1	Revision Date: 26.09.2023		DS Number: 693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014	
Hygiene measures		:	 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. 		
7.2 Cond	litions for safe storage,	inc	luding any incom	patibilities	
	uirements for storage s and containers	:		labelled containers. Store locked up. Store in the particular national regulations.	
Adv	ce on common storage	:	Do not store with Strong oxidizing	the following product types: agents	
-	ific end use(s) cific use(s)	:	No data available		

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis		
Boceprevir	394730-60- 0	TWA	2 mg/m3 (OEB 1)	Internal		
Starch	9005-25-8	OEL-RL	10 mg/m3	ZA OEL		
		nation: Occupational hemical Agents	Exposure Limits - Restricted	Limits For		
Cellulose	9004-34-6	OEL-RL	10 mg/m3	ZA OEL		
		Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

	· · ·	0 0	· · ·	
Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Sodium n-dodecyl sulfate	Workers	Inhalation	Long-term systemic effects	285 mg/m3
	Workers	Skin contact	Long-term systemic effects	4060 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	85 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2440 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	24 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:



Version	Revision Date: 26.09.2023	SDS Number:	Date of last issue: 20.03.2023
4.1		23693-00022	Date of first issue: 21.10.2014

Substance name	Environmental Compartment	Value
Sodium n-dodecyl sulfate	Fresh water	0,176 mg/l
	Marine water	0,018 mg/l
	Sewage treatment plant	1,35 mg/l
	Fresh water sediment	6,97 mg/kg dry weight (d.w.)
	Marine sediment	0,697 mg/kg dry weight (d.w.)
	Soil	1,29 mg/kg dry weight (d.w.)

8.2 Exposure controls

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

Eye/face protection	:	Wear the following personal protective equipment: Safety goggles
Hand protection		
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance 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.
Skin and body protection	:	Select appropriate protective clothing based on chemical re- sistance data and an assessment of the local exposure poten- tial. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: powder
Colour	: white
Odour	: No data available
Odour Threshold	: No data available
βΗ	: No data available



Version 4.1	Revision Date: 26.09.2023		S Number: 693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
Meltir	ng point/freezing point	:	No data available	e
	boiling point and boiling	:	No data available	e
range Flash	e point	:	No data available	e
Evap	oration rate	:	No data available	e
Flam	mability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- eans.
	r explosion limit / Upper nability limit	:	No data available	e
	r explosion limit / Lower nability limit	:	No data available	e
Vapo	ur pressure	:	Not applicable	
Relat	ive vapour density	:	Not applicable	
Relat	ive density	:	No data available	e
Dens	ity	:	No data available	e
W	bility(ies) ater solubility blubility in other solvents	:	No data available No data available	
	ion coefficient: n- ol/water	:	Not applicable	
	ignition temperature	:	No data available	e
Deco	mposition temperature	:	No data available	e
Visco Vi	sity scosity, kinematic	:	No data available	e
Explo	osive properties	:	Not explosive	
Oxidi	zing properties	:	The substance o	r mixture is not classified as oxidizing.
9.2 Other	information			
Flam	mability (liquids)	:	Not applicable	
Mole	cular weight	:	No data available	e
Partic	cle size	:	No data available	e



Version 4.1	Revision Date: 26.09.2023	SDS Numbe 23693-00022	
SECTION	10: Stability and re	eactivity	
10.1 Reac	•		
Not c	lassified as a reactivity	hazard.	
	nical stability e under normal conditic	ons.	
10.3 Poss	ibility of hazardous re	eactions	
	rdous reactions	: May forr dling or	n explosive dust-air mixture during processing, han- other means. ct with strong oxidizing agents.
10.4 Cond	litions to avoid		
Cond	itions to avoid		mes and sparks. Ist formation.
10.5 Incoi	npatible materials		
Mate	rials to avoid	: Oxidizin	g agents
	-	-	
	azardous decomposition	n products are l	known.
No ha	azardous decomposition	n products are l	known.
No ha	azardous decomposition I 11: Toxicological i mation on toxicologic nation on likely routes o	n products are l nformation al effects of : Inhalation Skin cont Ingestion	n act
No ha SECTION 11.1 Infor Inforr expos	Azardous decomposition 1 11: Toxicological i mation on toxicologic nation on likely routes of sure	n products are I nformation al effects of : Inhalation Skin cont	n act
No ha SECTION 11.1 Infor Inforr expose Acute	azardous decomposition N 11: Toxicological i mation on toxicologic nation on likely routes of sure e toxicity	n products are l nformation al effects of : Inhalation Skin cont Ingestion Eye cont	n act
No ha SECTION 11.1 Infor Inforr expose Acute Not c	azardous decomposition I 11: Toxicological i mation on toxicologic nation on likely routes of sure e toxicity lassified based on avail	n products are l nformation al effects of : Inhalation Skin cont Ingestion Eye cont	n act
No ha SECTION 11.1 Infor Inforr expose Acute Not c <u>Prod</u>	azardous decomposition I 11: Toxicological i mation on toxicologic nation on likely routes of sure e toxicity lassified based on avail	n products are l nformation al effects of : Inhalation Skin cont Ingestion Eye cont lable informatio : Acute to	n act
No ha SECTION 11.1 Infor Inforr expose Acute Not c Prod Acute	Azardous decomposition A 11: Toxicological i mation on toxicologic nation on likely routes of sure e toxicity lassified based on avail <u>uct:</u>	n products are l nformation al effects of : Inhalation Skin cont Ingestion Eye cont lable informatio : Acute to	n :act n. :icity estimate: > 2.000 mg/kg
No ha SECTION 11.1 Infor Inforr expose Acute Not c Prod Acute	Azardous decomposition A 11: Toxicological i mation on toxicologic nation on likely routes of sure e toxicity lassified based on avail uct: e oral toxicity ponents:	n products are l nformation al effects of : Inhalation Skin cont Ingestion Eye cont lable informatio : Acute to	n :act n. :icity estimate: > 2.000 mg/kg
No ha SECTION 11.1 Infor Inforr expose Acute Not c Prod Acute Comp Boce	Azardous decomposition A 11: Toxicological i mation on toxicologic nation on likely routes of sure e toxicity lassified based on avail uct: e oral toxicity	n products are l nformation al effects of : Inhalation Skin cont Ingestion Eye cont lable informatio : Acute to Method:	n :act n. :icity estimate: > 2.000 mg/kg
No ha SECTION 11.1 Infor Inforr expose Acute Not c Prod Acute Comp Boce	Azardous decomposition A 11: Toxicological i mation on toxicologic nation on likely routes of sure e toxicity lassified based on avail uct: oral toxicity ponents: previr:	n products are l nformation al effects of : Inhalation Skin cont Ingestion Eye cont lable informatio : Acute to Method:	n :act n. :icity estimate: > 2.000 mg/kg Calculation method
No ha	Azardous decomposition A 11: Toxicological i mation on toxicologic nation on likely routes of sure e toxicity lassified based on avail uct: oral toxicity ponents: previr: oral toxicity	n products are l nformation al effects of : Inhalation Skin cont Ingestion Eye cont lable informatio : Acute tox Method: : LD50 (Ra LD50 (Method)	n act n. ticity estimate: > 2.000 mg/kg Calculation method
No ha	Azardous decomposition A 11: Toxicological i mation on toxicologic nation on likely routes of sure e toxicity lassified based on avail uct: oral toxicity ponents: previr:	n products are l nformation al effects of : Inhalation Skin cont Ingestion Eye cont lable informatio : Acute tox Method: : LD50 (Ra LD50 (Ra	n act n. ticity estimate: > 2.000 mg/kg Calculation method



ersion 1	Revision Date: 26.09.2023		Number: 3-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
		R	emarks: Base	d on data from similar materials
-	corrosion/irritation lassified based on av	ailable inf	ormation.	
Com	ponents:			
Boce	previr:			
Speci Resu			abbit lo skin irritatio	n
Sodiu	um n-dodecyl sulfat	e:		
Speci Resu			abbit kin irritation	
	ous eye damage/eye lassified based on av			
	ponents:			
Boce	previr:			
Speci	ies		abbit	
Resu	lt	: N	lild eye irritatio	n
Sodiı	um n-dodecyl sulfat	e:		
Speci			abbit	
Metho Resu			ECD Test Gu reversible effe	ideline 405 ects on the eye
1000				
Resp	iratory or skin sens	itisation		
	sensitisation			
	lassified based on av		ormation.	
-	iratory sensitisatior lassified based on av		ormation.	
<u>Com</u>	ponents:			
	previr:			
Test ⁻ Speci			laximisation T Suinea pig	est
Resu			egative	
Sodiu	um n-dodecyl sulfat	- .		
Test ⁻			laximisation T	est
Expo	sure routes	: S	kin contact	
Speci Resu			luinea pig egative	
	arks			from similar materials



ersion 1	Revision Date: 26.09.2023	SDS Number: 23693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
Germ	cell mutagenicity		
Not cl	lassified based on av	ailable information.	
Comp	oonents:		
Boce	previr:		
	toxicity in vitro	: Test Type: Result: neg	Bacterial reverse mutation assay (AMES) gative
		Test Type: Result: neg	Chromosomal aberration gative
Geno	toxicity in vivo	Species: N	n Route: Oral
Sodiu	ım n-dodecyl sulfat	e:	
	toxicity in vitro	: Test Type:	Bacterial reverse mutation assay (AMES) ECD Test Guideline 471 gative
		Test Type: Result: neg	In vitro mammalian cell gene mutation test gative
Geno	toxicity in vivo	Species: N	n Route: Ingestion
Carci	nogenicity		
	lassified based on av	ailable information.	
<u>Comp</u>	oonents:		
Boce	previr:		
Speci Applic	es cation Route sure time	: Mouse : Oral : 72 Weeks : 650 mg/kg : negative	body weight
	cation Route sure time	: Rat : Oral : 104 Weeks : 125 mg/kg : negative	s body weight
Sodiu	ım n-dodecyl sulfat	e:	
Speci Applic	es cation Route sure time	: Rat : Ingestion : 2 Years	st Guideline 453



Vers 4.1	sion	Revision Date: 26.09.2023		0S Number: 693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
	Result Remar	ks	:	negative Based on data fro	m similar materials
	Repro	ductive toxicity			
	Suspec	cted of damaging fertili	ty.		
	Compo	onents:			
	Восер	revir:			
	Effects	on fertility	:	Species: Rat, mal	75 mg/kg body weight
				Species: Rat, fem	50 mg/kg body weight
	Effects ment	on foetal develop-	:	Test Type: Develor Species: Rabbit, r Application Route Developmental To Result: negative	nale and female
	Reproc sessme	ductive toxicity - As- ent	:		f adverse effects on sexual function and animal experiments.
	Sodiur	n n-dodecyl sulfate:			
		on fertility	:	Species: Rat Application Route Method: OECD To Result: negative	
	Effects ment	on foetal develop-	:	Species: Rat Application Route Result: negative	o-foetal development : Ingestion on data from similar materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.



rsion	Revision Date: 26.09.2023	SDS Number: 23693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
Repe	ated dose toxicity		
<u>Comp</u>	oonents:		
Boce	previr:		
	EL cation Route sure time	: Monkey : > 200 mg/kg : Oral : 365 d : No significan	t adverse effects were reported
Expos	EL	: Rat : 75 mg/kg : 100 mg/kg : Oral : 90 d : Testis, Prosta	ate
Expos	EL	: Rat : 15 mg/kg : 75 mg/kg : Oral : 180 d : Testis	
Expos	EL	: Mouse : 250 mg/kg : 500 mg/kg : Oral : 90 d : Kidney	
Sodiu	um n-dodecyl sulfate		
Speci NOAE Applic	es EL cation Route sure time	: Rat : 488 mg/kg : Ingestion : 90 Days	a from similar materials
•	ration toxicity lassified based on ava	ilable information.	
Expe	rience with human e	xposure	
Comp	oonents:		
Boce Ingest	previr: tion	: Symptoms: H taste	leadache, Gastrointestinal disturbance, bit



Versior 4.1	Revision Date: 26.09.2023		0S Number: 693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
SECTI	ON 12: Ecological infor	ma	tion	
12.1 To	vicity			
	omponents:			
	oceprevir:			
	xicity to algae/aquatic ants	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD Te	
			NOEC (Pseudokir mg/l Exposure time: 72 Method: OECD Te	
То	xicity to microorganisms	:	EC50 : > 959 mg/ Exposure time: 3 Test Type: Respir Method: OECD Te	า ation inhibition
			NOEC : 959 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te	ation inhibition
To icit	xicity to fish (Chronic tox- ty)	:	NOEC: > 9 mg/l Exposure time: 28 Species: Pimepha Method: OECD Te	les promelas (fathead minnow)
aq	xicity to daphnia and other uatic invertebrates (Chron- toxicity)	:	NOEC: 7,2 mg/l Exposure time: 21 Species: Daphnia Method: OECD Te	magna (Water flea)
So	dium n-dodecyl sulfate:			
	xicity to fish	:	LC50 (Pimephales Exposure time: 96	s promelas (fathead minnow)): 29 mg/l h
	xicity to daphnia and other uatic invertebrates	:	EC50 (Ceriodaphi Exposure time: 48	nia dubia (water flea)): 5,55 mg/l h
	xicity to algae/aquatic ants	:	ErC50 (Desmodes Exposure time: 72	smus subspicatus (green algae)): > 120 mg/l h
			NOEC (Desmode: Exposure time: 72	smus subspicatus (green algae)): 30 mg/l h
То	xicity to microorganisms	:	EC50 : 135 mg/l Exposure time: 3 l	ı
То	xicity to fish (Chronic tox-	:	NOEC: >= 1,357 r	ng/l



Versio 4.1	on	Revision Date: 26.09.2023		9S Number: 693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
ic	city)			Exposure time: 42 Species: Pimepha	2 d ales promelas (fathead minnow)
а		to daphnia and other invertebrates (Chron- ty)	:	NOEC: 0,88 mg/l Exposure time: 7 Species: Cerioda	d phnia dubia (water flea)
12.2 P	Persist	ence and degradabil	ity		
<u>C</u>	Compo	onents:			
В	восери	evir:			
В	Biodegi	radability	:	Result: Not readil Biodegradation: (Exposure time: 28	D,6 %
S	Sodiun	n n-dodecyl sulfate:			
В	Biodegi	radability	:	Result: Readily bi Biodegradation: 9 Exposure time: 28 Method: OECD T	95 %
12.3 E	Bioacc	umulative potential			
<u>c</u>	Compo	onents:			
В	Восері	evir:			
	-	umulation	:	Species: Lepomis Bioconcentration Method: OECD T	
	Partition octanol	n coefficient: n- /water	:	log Pow: 3,18	
Р		n n-dodecyl sulfate: n coefficient: n- /water	:	log Pow: 0,83	
12.4 N	Nobilit	y in soil			
<u>C</u>	Compo	onents:			
В	Восері	evir:			
		tion among environ- compartments	:	log Koc: 1,9 Method: OECD T	est Guideline 106
12.5 R	Result	s of PBT and vPvB as	sse	ssment	
Р	Produc	:t:			
	SSESS		:	to be either persis	ixture contains no components considered stent, bioaccumulative and toxic (PBT), or ad very bioaccumulative (vPvB) at levels of

ΙΑΤΑ

14.4 Packing group



Boceprevir Formulation

Version 4.1	Revision Date: 26.09.2023		Number: 93-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014		
12.6 Othe	r adverse effects					
Prod Endo tial	uct: crine disrupting poten-	e F (ered to have end REACH Article 5	nixture does not contain components consid- docrine disrupting properties according to 57(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at r higher.		
SECTION	N 13: Disposal consid	derati	ions			
13.1 Wast	te treatment methods					
Produ Conta	uct aminated packaging	A a V C C C C C C C C C C C C C C C C C C	According to the are not product s Waste codes sh discussion with t Do not dispose of Empty container fling site for rec	cordance with local regulations. European Waste Catalogue, Waste Codes specific, but application specific. ould be assigned by the user, preferably in the waste disposal authorities. of waste into sewer. s should be taken to an approved waste han- ycling or disposal. specified: Dispose of as unused product.		
SECTION	N 14: Transport infor	matio	on			
14.1 UN n	umber					
ADN		: N	Not regulated as	a dangerous good		
ADR		: N	Not regulated as	a dangerous good		
RID		: N	Not regulated as a dangerous good			
IMDG	6	: N	Not regulated as	a dangerous good		
ΙΑΤΑ		: N	Not regulated as	a dangerous good		
14.2 UN p	roper shipping name					
ADN		: N	Not regulated as	a dangerous good		
ADR		: N	Not regulated as	a dangerous good		
RID		: N	Not regulated as	a dangerous good		
IMDG	6	: N	Not regulated as	a dangerous good		
ΙΑΤΑ		: N	Not regulated as	a dangerous good		
14.3 Trans	sport hazard class(es)					
ADN		: N	Not regulated as	a dangerous good		
ADR		: N	Not regulated as	a dangerous good		
RID		: N	Not regulated as	a dangerous good		
IMDG	6	: N	Not regulated as	a dangerous good		

: Not regulated as a dangerous good



Boceprevir Formulation

Version 4.1	Revision Date: 26.09.2023	SDS Number: 23693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
ADN		: Not regulated as	a dangerous good
ADR		: Not regulated as	a dangerous good
RID		: Not regulated as	a dangerous good
IMDG	ì	: Not regulated as	a dangerous good
ΙΑΤΑ	(Cargo)	: Not regulated as	a dangerous good
ΙΑΤΑ	(Passenger)	: Not regulated as	a dangerous good
14.5 Envir	ronmental hazards		
Not re	egulated as a dangero	s good	
14.6 Spec	ial precautions for u	er	
Not a	pplicable		
14.7 Trans	sport in bulk accordi	g to Annex II of Marpo	I and the IBC Code
Rema	arks	: Not applicable for	product as supplied.

SECTION 15: Regulatory information

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

The components of this product are reported in the following inventories:					
AICS	:	not determined			
DSL	:	not determined			
IECSC	:	not determined			

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.		
Full text of H-Statements				
H302 H315 H318 H361f H412	:	Harmful if swallowed. Causes skin irritation. Causes serious eye damage. Suspected of damaging fertility. Harmful to aquatic life with long lasting effects.		
Full text of other abbreviations				
Acute Tox. Aquatic Chronic Eye Dam. Repr. Skin Irrit.	:	Acute toxicity Long-term (chronic) aquatic hazard Serious eye damage Reproductive toxicity Skin irritation		



Version 4.1	Revision Date: 26.09.2023	SDS Number: 23693-00022	Date of last issue: 20.03.2023 Date of first issue: 21.10.2014
ZA C ZA C	DEL DEL / OEL-RL	Agents, Occup : Occupational E	he Regulations for Hazardous Chemical ational Exposure Limits xposure Limit Restricted limit - 8- hour expo- ent (12 hour shifts)
Wate Roa ing o tion of th Euro asso cy S socia bora Tran rying tiona IMD - Inc KEC tion; tiona NO(fect Che of C stan tativ Parli stric Goo SVH Thai - Un	erways; ADR - Agreem d; AIIC - Australian Inve of Materials; bw - Body v (EC) No 1272/2008; CM ine German Institute for S opean Chemicals Agenc ociated with x% response in the sport Association; IBC - g Dangerous Chemicals al Civil Aviation Organize G - International Maritim dustrial Safety and Healt CI - Korea Existing Chem LD50 - Lethal Dose to al Convention for the Pla A)EC - No Observed (A Level; NOELR - No Ol micals; OECD - Organize hemical Safety and Poll ce; PICCS - Philippines e) Structure Activity Rel ament and of the Count tion of Chemicals; RID ds by Rail; SADT - Self- IC - Substance of very I land Existing Chemicals	ent concerning the l ntory of Industrial Ch weight; CLP - Classif IR - Carcinogen, Mut Standardisation; DSL y; EC-Number - Euro e; ELx - Loading rate ng and New Chemica te response; GHS - ternational Agency for International Code for in Bulk; IC50 - Half m ation; IECSC - Inven e Dangerous Goods; th Law (Japan); ISO icals Inventory; LC50 50% of a test popular revention of Pollution dverse) Effect Conce baservable Effect Loa cation for Economic C lution Prevention; PB Inventory of Chemica ationship; REACH - I ncil concerning the F - Regulations concerning high concern; TCSI - Inventory; TSCA - To - United Nations Ref	hational Carriage of Dangerous Goods by Inland International Carriage of Dangerous Goods by emicals; ASTM - American Society for the Test- ication Labelling Packaging Regulation; Regula- tagen or Reproductive Toxicant; DIN - Standard - Domestic Substances List (Canada); ECHA - opean Community number; ECx - Concentration associated with x% response; EmS - Emergen- I Substances (Japan); ErCx - Concentration as- Globally Harmonized System; GLP - Good La- or Research on Cancer; IATA - International Air or the Construction and Equipment of Ships car- naximal inhibitory concentration; ICAO - Interna- tory of Existing Chemical Substances in China; IMO - International Maritime Organization; ISHL - International Organisation for Standardization; - Lethal Concentration to 50 % of a test popula- ation (Median Lethal Dose); MARPOL - Interna- n from Ships; n.o.s Not Otherwise Specified; intration; NO(A)EL - No Observed (Adverse) Ef- ding Rate; NZIoC - New Zealand Inventory of Co-operation and Development; OPPTS - Office T - Persistent, Bioaccumulative and Toxic sub- als and Chemical Substances; (Q)SAR - (Quanti- Regulation (EC) No 1907/2006 of the European Registration, Evaluation, Authorisation and Re- erning the International Carriage of Dangerous position Temperature; SDS - Safety Data Sheet; Taiwan Chemical Substance Inventory; TECI - poxic Substances Control Act (United States); UN commendations on the Transport of Dangerous

Further information

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data		eChem Portal search results and European Chemicals Agen-
Sheet		cy, http://echa.europa.eu/

Classification of the mixture:

Repr. 2

H361f

Goods; vPvB - Very Persistent and Very Bioaccumulative

Classification procedure:

Calculation method

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



Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	23693-00022	Date of first issue: 21.10.2014

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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