



Version 5.1	Revision Date: 30.09.2023		S Number: 2655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
Section 1	: Identification			
Produ	Product name		Grazoprevir F	ormulation
Manu	ifacturer or supplier's d	etai	ls	
Comp	bany	:	MSD	
Addre	Address		33 Whakatiki Upper Hutt - N	Street - Private Bag 908 New Zealand
Telep	hone	:	0800 800 543	
Emer	Emergency telephone number		0800 764 766 CHEMCALL)	(0800 POISON) 0800 243 622 (0800
E-ma	il address	:	EHSDATAST	EWARD@msd.com
Reco	mmended use of the ch	nem	ical and restri	ctions on use
	mmended use ictions on use	:	Pharmaceutic Not applicable	
Section 2	: Hazard identification			
GHS	Classification			
	Specific target organ toxicity - repeated exposure (Oral)		Category 2 (L	iver, Testis)
GHS	label elements			
Haza	rd pictograms	:		
Signa	Signal word		Warning	
Hazard statements		:		use damage to organs (Liver, Testis) through epeated exposure if swallowed.

Precautionary statements : Response:

P314 Get medical advice/ attention if you feel unwell.

Disposal:

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



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	402655-00019	Date of first issue: 07.01.2016

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)
Grazoprevir	1350462-55-3	>= 10 -< 20
Sodium n-dodecyl sulfate	151-21-3	>= 1 -< 2.5
Magnesium stearate	557-04-0	>= 1 -< 10

Section 4: 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.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
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	:	
Most important symptoms and effects, both acute and delayed	:	Headache Gastrointestinal discomfort May cause damage to organs through prolonged or repeated exposure if swallowed.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-	:	Avoid generating dust; fine dust dispersed in air in sufficient



Grazoprevir Formulation

Version 5.1			DS Number: 2655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016	
fightir	ng		potential dust ex	and in the presence of an ignition source is a plosion hazard. nbustion products may be a hazard to health.	
Haza ucts	Hazardous combustion prod- ucts		Carbon oxides Nitrogen oxides Metal oxides Chlorine compo Sulphur oxides		
Speci ods	Specific extinguishing meth- ods		Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to d so.		
	al protective equipment efighters	:	Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.		
Section 6	: Accidental release me	eas	ures		
tive e	onal precautions, protec- quipment and emer- / procedures	:	Follow safe han	otective equipment. dling advice (see section 7) and personal pro- nt recommendations (see section 8).	
Enviro	Environmental precautions		Prevent further Retain and disp	e the environment. eakage or spillage if safe to do so. ose of contaminated wash water. s should be advised if significant spillages ined.	
	Methods and materials for containment and cleaning up		tainer for dispose Avoid dispersal with compresse Dust deposits sl es, as these ma leased into the a Local or national posal of this ma employed in the mine which regu	of dust in the air (i.e., clearing dust surfaces	
Section 7	: Handling and storage				
	Technical measures		causing an expl Provide adequa	may accumulate and ignite suspended dust osion. te precautions, such as electrical grounding inert atmospheres.	

Local/Total ventilation : Use only with adequate ventilation.



Grazoprevir Formulation

Version 5.1	Revision Date: 30.09.2023	SDS Number: 402655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016			
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 s practice, based on the results of the workplace exposure 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 				
Hygie	ne measures	flushing syste place. When using d Wash contam The effective engineering c appropriate de industrial hygi	chemical is likely during typical use, provide eye ms and safety showers close to the working o not eat, drink or smoke. inated clothing before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, egowning and decontamination procedures, ene monitoring, medical surveillance and the strative controls.			
	Conditions for safe storage:Keep in properly labelled containers. Store in accordance with the particular national rMaterials to avoid:Do not store with the following product types: Strong oxidizing agents					

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Grazoprevir	1350462-55- 3	TWA	85 µg/m3 (OEB 3)	Internal
		Wipe limit	850 µg/100 cm ²	Internal
Magnesium stearate	557-04-0	WES-TWA	10 mg/m3	NZ OEL
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH

Engineering measures

: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds





Version 5.1	Revision Date: 30.09.2023		S Number: 2655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016		
Respira	al protective equipm	ent :	the compound to tainment devices) Minimize open ha If adequate local sure assessment ommended guide			
	⁻ type rotection	:	: Particulates type			
Mate	erial	:	Chemical-resistar	nt gloves		
	tection	 Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty condimists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there i potential for direct contact to the face with dusts, mists aerosols. Work uniform or laboratory coat. Additional body garments should be used based upon task being performed (e.g., sleevelets, apron, gauntlet: posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove pote contaminated clothing. 		ses with side shields or goggles. nment or activity involves dusty conditions, , wear the appropriate goggles. d or other full face protection if there is a t contact to the face with dusts, mists, or aboratory coat. arments should be used based upon the med (e.g., sleevelets, apron, gauntlets, dis- avoid exposed skin surfaces. degowning techniques to remove potentially		
Section 9: P	hysical and chemica	l pr	operties			
Appeara	ance	:	powder			
Colour		:	: No data available			
Odour		:	: No data available			
Odour T	hreshold	:	: No data available			
рН		:	: No data available			
Melting	point/freezing point	: No data available				
Initial boiling point and boiling		:	No data available			

range		
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.



Grazoprevir Formulation

Vers 5.1	sion	Revision Date: 30.09.2023		S Number: 2655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
	Flamm	ability (liquids)	:	No data available	9
	Upper explosion limit / Upper flammability limit		:	No data available	9
	Lower explosion limit / Lower flammability limit		:	No data available	9
		pressure	:	Not applicable	
	Relative vapour density		:	Not applicable	
	Relative density		:	No data available	9
	Density		:	No data available	9
	Solubility(ies) Water solubility		:	No data available	9
	Partition coefficient: n- octanol/water Auto-ignition temperature Decomposition temperature		:	Not applicable	
			:	No data available	9
			:	No data available	9
	Viscosity Viscosity, kinematic		:	Not applicable	
	Explosive properties		:	Not explosive	
	Oxidizing properties		:	The substance o	r mixture is not classified as oxidizing.
	Particle	e size	:	No data available	9

Section 10: Stability and reactivity

Reactivity Chemical stability Possibility of hazardous reac- tions		Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	



Version 5.1	Revision Date: 30.09.2023		0S Number: 2655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016					
Section	Section 11: Toxicological information								
Ex	posure routes	:	Inhalation Skin contact Ingestion Eye contact						
	ute toxicity								
	t classified based on availa	ble	information.						
	oduct: ute oral toxicity	:	Acute toxicity esti Method: Calculati	mate: > 2,000 mg/kg on method					
<u>Co</u>	mponents:								
	azoprevir:								
Ac	ute oral toxicity	:	LD50 (Rat): > 2,0	00 mg/kg					
So	dium n-dodecyl sulfate:								
	ute oral toxicity	:	LD50 (Rat): 1,200 Method: OECD T						
Ac	ute dermal toxicity	:	LD50 (Rat): > 2,0 Method: OECD T Remarks: Based						
Ма	ignesium stearate:								
	ute oral toxicity	:	icity						
Ac	ute dermal toxicity	:	LD50 (Rabbit): > Remarks: Based	2,000 mg/kg on data from similar materials					
	in corrosion/irritation t classified based on availa	ble	information.						
<u>Co</u>	mponents:								
Gr	azoprevir:								
	sult	:	No skin irritation						
Sp	dium n-dodecyl sulfate: ecies sult	:	Rabbit Skin irritation						



Grazoprevir Formulation

Magnesium stearate: Species : Rabbit Result : No skin irritation Remarks : Based on data from similar materials Serious eye damage/eye irritation . Not classified based on available information. Components: Grazoprevir: Species : Species : Sodium n-dodecyl sulfate: Species : Species : Magnesium stearate: Species :			
Species:Rabbit .Result:No skin irritation .Remarks:Based on data from similar materialsSerious eye damage/eye irritation .Not classified based on available information.Components:Grazoprevir:Species:Boyine cornea .ResultResult:No eye irritationSodium n-dodecyl sulfate:Species:Result:If Result:If Result:If Result:If Result:Species:Result: <td></td>			
Species:Rabbit No skin irritation RemarksResult:No skin irritation Based on data from similar materialsSerious eye damage/eye irritation Not classified based on available information.Serious eye damage/eye irritation Mot classified based on available information.Components: Grazoprevir: Species:Bovine cornea ResultSpecies:Bovine cornea Result:Species:No eye irritationSodium n-dodecyl sulfate: Result::Species:Rabbit Result:Magnesium stearate: Species::Species:Rabbit Result:Magnesium stearate: Result::Species::Magnesium stearate: Species::Species::Magnesium stearate: Species:Species::Magnesium stearate: Result:Species:Species:Magnesium stearate: Result:Species:Magnesium stearate: ResultSpecies:Species:Species:Species:Result:Result:Result:Magnesium stearate: ResultSpecies:Result:Result:Magnesium stearate: ResultMagnesium stearate: ResultMagnesium stearate: Result <td></td>			
Result:No skin irritationRemarks:Based on data from similar materialsSerious eye damage/eye irritationNot classified based on available information.Not classified based on available information.Components:Grazoprevir:Species:Species:Boyine corneaResult:No eye irritationSodium n-dodecyl sulfate:Species:Result:Itreversible effects on the eyeMethod:OECD Test Guideline 405Magnesium stearate:Species:Result:Result:Result:Result:Result:Result:Result:Result:Result:Result:Magnesium stearate:Species:Result:Result:Magnesium stearate:Species:Result:Result:Result:Result:Result:Result:Result:Result:Result:Result:Result:Result:Result:Result:Result:Result:Result:Result:ResultResult<			
Serious eye damage/eye irritation Not classified based on available information. Components: Grazoprevir: Species : Bovine cornea Result : Species : Species : Species : Species : Species : Magnesium stearate: : Species : Species : Species : Magnesium stearate: : Species : Result : Species : Magnesium stearate: : Result : Result : Result : Species : Result : Result : Result : Result : Magnesium stearate: Result : Result : Result : Result :			
Not classified based on available information. Components: Grazoprevir: Species : Result : Sodium n-dodecyl sulfate: Species : Species : Result : Nethod : Nethod : Magnesium stearate: Species : Species : Result : OECD Test Guideline 405 Magnesium stearate: Species : Result : No eye irritation Result : No eye irritation Result : Result : Species : Result : No eye irritation Remarks : Based on data from similar materials Skin sensitisation Not classified based on available information.			
Components: Grazoprevir: Species : Bovine cornea Result : No eye irritation Sodium n-dodecyl sulfate: : Species Species : Rabbit Result : Irreversible effects on the eye Method : OECD Test Guideline 405 Magnesium stearate: : No eye irritation Result : No eye irritation Respiratory or skin sensitisation . Not classified based on available information. .			
Species Result:Bovine cornea No eye irritationSodium n-dodecyl sulfate:No eye irritationSpecies Method:Rabbit I rreversible effects on the eye OECD Test Guideline 405Magnesium stearate:OECD Test Guideline 405Species Method:No eye irritation E Species MethodMagnesium stearate:Species Method:Species Method:Babbit Mo eye irritation E No eye irritation E Based on data from similar materialsRespiratory or skin sensitisation Not classified based on available information.Species Method			
Result:No eye irritationSodium n-dodecyl sulfate:.Species:RabbitResult:Irreversible effects on the eyeMethod:OECD Test Guideline 405Magnesium stearate:.Species:RabbitResult:No eye irritationResult:No eye irritationRemarks:Based on data from similar materialsSkin sensitisationNot classified based on available information.			
Sodium n-dodecyl sulfate: Species : Rabbit Result : Irreversible effects on the eye Method : OECD Test Guideline 405 Magnesium stearate: Species Species : Rabbit Result : No eye irritation Remarks : Based on data from similar materials Skin sensitisation Not classified based on available information.			
Species : Rabbit Result : Irreversible effects on the eye Method : OECD Test Guideline 405 Magnesium stearate: . Species : Rabbit Result : No eye irritation Remarks : Based on data from similar materials Respiratory or skin sensitisation . Not classified based on available information.			
Result:Irreversible effects on the eyeMethod:OECD Test Guideline 405Magnesium stearate:Species:Species:RabbitResult:No eye irritationRemarks:Based on data from similar materialsRespiratory or skin sensitisationSkin sensitisationNot classified based on available information.			
Method : OECD Test Guideline 405 Magnesium stearate: Species Species : Rabbit Result : No eye irritation Remarks : Based on data from similar materials Respiratory or skin sensitisation Skin sensitisation Not classified based on available information.			
Magnesium stearate: Species : Rabbit Result : No eye irritation Remarks : Based on data from similar materials Respiratory or skin sensitisation Skin sensitisation Not classified based on available information.			
Species : Rabbit Result : No eye irritation Remarks : Based on data from similar materials Respiratory or skin sensitisation Skin sensitisation Not classified based on available information.			
Result : No eye irritation Remarks : Based on data from similar materials Respiratory or skin sensitisation Skin sensitisation Not classified based on available information.			
Remarks : Based on data from similar materials Respiratory or skin sensitisation Skin sensitisation Not classified based on available information.			
Respiratory or skin sensitisation Skin sensitisation Not classified based on available information.			
Skin sensitisation Not classified based on available information.	Based on data from similar materials		
Not classified based on available information.			
Despiratery consideration			
Respiratory sensitisation			
Not classified based on available information.			
Components:			
Grazoprevir:			
Test Type : Local lymph node assay (LLNA)			
Exposure routes : Dermal			
Result : Not a skin sensitizer.			
Sodium n-dodecyl sulfate:			
Test Type : Maximisation Test			
Exposure routes : Skin contact			
Species : Guinea pig Result : negative			
Result : negative Remarks : Based on data from similar materials			

Magnesium stearate:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact



ersion .1	Revision Date: 30.09.2023	SDS Number: 402655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016						
Speci Metho		: Guinea pig : OECD Tes	l st Guideline 406						
Result Remarks		: negative							
Chro	nic toxicity								
	a cell mutagenicity lassified based on ava	ailable information.							
<u>Comp</u>	oonents:								
	oprevir: toxicity in vitro	: Test Type: Result: neg	Bacterial reverse mutation assay (AMES) gative						
		Test Type: Result: neg	Chromosome aberration test in vitro gative						
Geno	toxicity in vivo		In vivo micronucleus test n Route: Oral gative						
	cell mutagenicity - ssment	: Weight of e cell mutage	evidence does not support classification as a ge en.						
Sodiu	um n-dodecyl sulfate	9:							
Geno	toxicity in vitro		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: M	Route: Ingestion						
Magn	esium stearate:								
Geno	toxicity in vitro	Result: neg	In vitro mammalian cell gene mutation test gative Based on data from similar materials						
		Method: O Result: neg	Chromosome aberration test in vitro ECD Test Guideline 473 gative Based on data from similar materials						
		Test Type: Result: neg	Bacterial reverse mutation assay (AMES) gative						





ersion .1	Revision Date: 30.09.2023	SDS Number: 402655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
		Remarks: Bas	ed on data from similar materials
		Romanie. Dao	
	nogenicity lassified based on ava	ailable information.	
Com	oonents:		
Sodiu	um n-dodecyl sulfate	:	
	cation Route sure time od It	: Rat : Ingestion : 2 Years : OECD Test Ge : negative : Based on data	uideline 453 a from similar materials
Kenne		. Dased on date	
-	oductive toxicity lassified based on ava	ailable information.	
	oonents:		
-	oprevir:		
	ts on fertility	: Test Type: Fe Species: Rat Application Ro Fertility: NOAE Result: negativ	oute: Oral EL: 400 mg/kg body weight
		Species: Rat Application Ro Fertility: NOAE	lti-generation study oute: Oral EL: 400 mg/kg body weight ects on fertility, No effects on foetal developmen
Effect ment	ts on foetal develop-	Species: Rat Application Ro Embryo-foetal	nbryo-foetal development oute: Oral toxicity: NOAEL: 200 mg/kg body weight ects on foetal development
		Species: Rabb Application Ro Embryo-foetal	
		Species: Rabb Application Ro Embryo-foetal	nbryo-foetal development bit bute: Intravenous toxicity: NOAEL: 100 mg/kg body weight ects on foetal development



Grazoprevir Formulation

Versio 5.1	on	Revision Date: 30.09.2023	-	9S Number: 2655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016	
5	Sodium	n-dodecyl sulfate:				
Effects on fertility		:	 Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials 			
	Effects on foetal develop- ment		:	 Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials 		
Ν	Magnes	sium stearate:				
Effects on fertility		:	Test Type: Combined repeated dose toxicity study w reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative Remarks: Based on data from similar materials			
	Effects on nent	on foetal develop-	:	Species: Rat Application Route Result: negative	vo-foetal development :: Ingestion on data from similar materials	

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Liver, Testis) through prolonged or repeated exposure if swallowed.

Components:

Grazoprevir:

Target Organs	: Liver. Testis
Talyet Olyans	
Assessment	: May cause damage to organs through prolonged or repeated
	exposure.

Repeated dose toxicity

Components:

Grazoprevir:

Species	:	Rat
NOAEL	:	400 mg/kg
Application Route	:	Oral



Version 5.1	Revision Date: 30.09.2023	SDS Number: 402655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
Expo Rema	sure time arks	: 30 Days : No significant a	adverse effects were reported
	EL cation Route sure time	: Rat : 400 mg/kg : Oral : 180 Days : No significant a	adverse effects were reported
Expo	ΞL	: Dog : 15 mg/kg : 100 mg/kg : Oral : 270 Days : Liver, Blood, B	one marrow, gallbladder, spleen, Testis
Expo	ΞL	: Mouse : 200 mg/kg : 500 mg/kg : Oral : 90 Days : Liver, Kidney,	Blood
Expo	ΞL	: Dog : 20 mg/kg : 600 mg/kg : Oral : 30 Days : Blood, Testis	
Speci NOAI Expos Rema	EL sure time	: Monkey : 10 mg/kg : 8 Days : No significant a	adverse effects were reported
Speci NOAI Applie	EL cation Route sure time	: Rat : 488 mg/kg : Ingestion : 90 Days	from similar materials
Speci NOAI Applie	EL cation Route sure time	: Rat : > 100 mg/kg : Ingestion : 90 Days : Based on data	from similar materials



Version 5.1	Revision Date: 30.09.2023	-	0S Number: 2655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016		
Not c	ration toxicity lassified based on availa					
_	rience with human exp	osı	ire			
<u>Components:</u>						
Graz Inges	oprevir: stion	:	Symptoms: He	adache, Gastrointestinal disturbance		
•	2: Ecological information	on				
Ecot	oxicity					
Com	ponents:					
Graz	oprevir:					
	ity to fish	:	mg/l Exposure time	don variegatus (sheepshead minnow)): > 10 : 96 h oxicity at the limit of solubility		
	ity to daphnia and other tic invertebrates	:	Exposure time Method: OECE	a magna (Water flea)): > 10 mg/l : 48 h) Test Guideline 202 oxicity at the limit of solubility		
			LC50 (America Exposure time	amysis): 8.9 mg/l : 96 h		
Toxic plant	sity to algae/aquatic s	:	mg/l Exposure time Method: OECE	kirchneriella subcapitata (green algae)): > 10 : 72 hrs) Test Guideline 201 oxicity at the limit of solubility		
			mg/l Exposure time Method: OECE	okirchneriella subcapitata (green algae)): 10 : 72 hrs) Test Guideline 201 oxicity at the limit of solubility		
Toxic icity)	to fish (Chronic tox-	:	Exposure time Method: OECE	hales promelas (fathead minnow)): 0.98 mg/l : 32 d) Test Guideline 210 oxicity at the limit of solubility		
	tity to daphnia and other tic invertebrates (Chron- ticity)	:	Exposure time	ia magna (Water flea)): 5 mg/l : 21 d) Test Guideline 211		
Toxic	ity to microorganisms	:	EC50: > 1,000 Exposure time			





/ersion 5.1	Revision Date: 30.09.2023		9S Number: 2655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
			NOEC: 1.3 mg/l Exposure time: 3 Test Type: Resp	Test Guideline 209 3 h
Sodiu	um n-dodecyl sulfate:			
Toxic	ity to fish	:	LC50 (Pimephal Exposure time: 9	es promelas (fathead minnow)): 29 mg/l 96 h
	ity to daphnia and other ic invertebrates	:	EC50 (Ceriodap Exposure time: 4	hnia dubia (water flea)): 5.55 mg/l 48 h
	Toxicity to algae/aquatic plants		ErC50 (Desmod Exposure time: 7	esmus subspicatus (green algae)): > 120 mg/ 72 h
			NOEC (Desmod Exposure time: 7	lesmus subspicatus (green algae)): 30 mg/l 72 h
Toxic icity)	ity to fish (Chronic tox-	:	NOEC (Pimepha mg/l Exposure time: 4	ales promelas (fathead minnow)): >= 1.357 42 d
	ity to daphnia and other ic invertebrates (Chron-	:	NOEC (Cerioda) Exposure time: 7	phnia dubia (water flea)): 0.88 mg/l 7 d
	ity to microorganisms	:	EC50: 135 mg/l Exposure time: 3	3 h
Magn	esium stearate:			
Toxic	ity to fish	:	Exposure time: 4 Method: DIN 384	
	ity to daphnia and other ic invertebrates	:	Exposure time: 4 Test substance: Method: Directiv Remarks: Based	magna (Water flea)): > 1 mg/l 47 h Water Accommodated Fraction re 67/548/EEC, Annex V, C.2. d on data from similar materials e limit of solubility
Toxic plants	ity to algae/aquatic	:	mg/l Exposure time: Test substance: Method: OECD Remarks: Based	rchneriella subcapitata (green algae)): > 1 72 h Water Accommodated Fraction Test Guideline 201 d on data from similar materials e limit of solubility





Version 5.1	Revision Date: 30.09.2023		DS Number: 02655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
Toxic	ity to microorganisms	:	mg/l Exposure time: 7 Test substance: V Method: OECD T Remarks: Based EC10 (Pseudomo Exposure time: 1 Test substance: V	Water Accommodated Fraction est Guideline 201 on data from similar materials onas putida): > 100 mg/l
Persi	stence and degradabi	lity		
Com	ponents:			
	oprevir: egradability	:	Result: Not readi Biodegradation: Exposure time: 2	66 %
	um n-dodecyl sulfate: egradability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD T	95 %
-	esium stearate: egradability	:	Result: Not biode Remarks: Based	gradable on data from similar materials
Bioad	ccumulative potential			
Com	ponents:			
	oprevir: cumulation	:	Species: Lepomis Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): 7.62
	ion coefficient: n- ol/water	:	log Pow: 3.72	
Partiti	um n-dodecyl sulfate: ion coefficient: n- ol/water	:	log Pow: 0.83	
Partiti	nesium stearate: ion coefficient: n- ol/water	:	log Pow: > 4	



/ersion 5.1	Revision Date: 30.09.2023	SDS Number: 402655-00019	Date of last issue: 04.04.2023 Date of first issue: 07.01.2016
Mobi	lity in soil		
Com	ponents:		
Distril	oprevir: bution among environ- al compartments	: log Koc: 4.01	
•	r adverse effects ata available		
ection 1	3: Disposal considera	tions	
Dispo	osal methods		
Waste	e from residues		of waste into sewer. ccordance with local regulations.
Conta	aminated packaging	: Empty contained dling site for re-	ers should be taken to an approved waste han- cycling or disposal. specified: Dispose of as unused product.

International Regulations

UNRTDG	
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UN number Proper shipping name Class Subsidiary risk Packing group Labels	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
IATA-DGR UN/ID No. 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 Proper shipping name Class Subsidiary risk Packing group Labels EmS Code Marine pollutant	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable





Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	402655-00019	Date of first issue: 07.01.2016

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

NZS 5433		
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable
Subsidiary risk Packing group Labels	:	Not applicable Not applicable Not applicable

Special precautions for user

Not applicable

Section 15: Regulatory information

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

HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

HSW Controls

Certified handler certificate not required. Tracking hazardous substance not required. Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:

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

Section 16: Other information

Revision Date	:	30.09.2023	
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/	
Date format	:	dd.mm.yyyy	
Full text of other abbreviations			
ACGIH NZ OEL	:	USA. ACGIH Threshold Limit Values (TLV) New Zealand. Workplace Exposure Standards for Atmospher-	



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ic Contaminants

ACGIH / TWA	:	8-hour, time-weighted average
NZ OEL / WES-TWA	:	Workplace Exposure Standard - Time Weighted average

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their 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.

NZ / EN