



Version 3.1	Revision Date: 2023/09/30		S Number: 60795-00009	Date of last issue: 2023/04/04 Date of first issue: 2019/08/15		
1. PRODUC	CT AND COMPANY IDE	ENT	IFICATION			
Produc	ct name	:	Fidaxomicin So	id Formulation		
	facturer or supplier's d	etai				
Compa	any	:	MSD			
Addres	SS	:	: 126 E. Lincoln Avenue Rahway, New Jersey U.S.A. 07065			
Teleph	none	:	908-740-4000			
Emerg	gency telephone number	:	: 1-908-423-6000			
E-mail	address	:	EHSDATASTE	VARD@msd.com		
Recon	nmended use of the ch	nem	ical and restrict	ions on use		
	nmended use ctions on use		<ul><li>Pharmaceutical</li><li>Not applicable</li></ul>			
2. HAZARI	DS IDENTIFICATION					
GHS C	Classification					
Acute	toxicity (Oral)	:	Category 4			
GHS la	abel elements					
Hazaro	d pictograms	:				
Signal	word	:	Warning			
Hazaro	d statements	:	H302 Harmful if	swallowed.		
Precau	utionary statements	:		n thoroughly after handling. t, drink or smoke when using this produc		
			Response:			

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

#### Disposal:

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



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#### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture	:	Mixture
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#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Fidaxomicin	873857-62-6	>= 30 -< 60
Cellulose	9004-34-6	>= 10 -< 30
Sodium benzoate	532-32-1	< 10
Citric acid	77-92-9	< 10

#### 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	:	Wash with water and soap.
		Get medical attention if symptoms occur.
In case of eye contact	:	If in eyes, rinse well with water.
		Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting unless directed to do
		so by medical personnel.
		Get medical attention.
		Rinse mouth thoroughly with water.
		Never give anything by mouth to an unconscious person.
Most important symptoms	:	Harmful if swallowed.
and effects, both acute and delayed		Contact with dust can cause mechanical irritation or drying of the skin.
, ,		Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection,
		and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

### **5. FIREFIGHTING MEASURES**

Suitable extinguishing media	:	Water spray
		Alcohol-resistant foam
		Carbon dioxide (CO2)
		Dry chemical
Unsuitable extinguishing	:	None known.





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fightin	fic hazards during fire-	:	Exposure to com Carbon oxides Metal oxides Chlorine compou	bustion products may be a hazard to health.		
Speci ods	fic extinguishing meth-	:	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 do so. Evacuate area.			
	al protective equipment efighters	:		e, wear self-contained breathing apparatus. Detective equipment.		
6. ACCIDE	ENTAL RELEASE MEAS	SUF	RES			
Personal precautions, protec- tive equipment and emer- gency procedures		:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).			
Enviro	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 containment and cleaning up		:	Sweep up or vacuum up spillage and collect in suitable con- tainer 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 surfa- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.			
7. HANDL	ING AND STORAGE					
Techr	nical measures	:	causing an explo Provide adequat	may accumulate and ignite suspended dust osion. e precautions, such as electrical grounding inert atmospheres.		
	/Total ventilation e on safe handling	:	<ul> <li>Use only with adequate ventilation.</li> <li>Do not breathe dust.</li> <li>Do not swallow.</li> <li>Avoid contact with eyes.</li> </ul>			
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	tions for safe storage ials to avoid	Wash skin thoro Handle in accord practice, based of sessment Minimize dust ge Keep container of Keep away from Take precaution Do not eat, drink Take care to pre environment. Keep in properly Store in accorda	or repeated contact with skin. ughly after handling. dance with good industrial hygiene and safety on the results of the workplace exposure as- eneration and accumulation. closed when not in use. heat and sources of ignition. ary measures against static discharges. ary measures against static discharges. ary moke when using this product. went spills, waste and minimize release to the r labelled containers. nce with the particular national regulations. h the following product types: agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Fidaxomicin	873857-62-6	TWA	200 µg/m3 (OEB 2)	Internal
Cellulose	9004-34-6	NAB	10 mg/m3	ID OEL
		TWA	10 mg/m3	ACGIH
Sodium benzoate	532-32-1	TWA (Inhal- able particu- late matter)	2.5 mg/m3	ACGIH

### Components with workplace control parameters

Engineering measures	Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Personal protective equipme	nt
Respiratory protection Filter type	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type
Hand protection	
Material	Chemical-resistant gloves
Eye protection	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or



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Skin and body protection Hygiene measures		<ul> <li>aerosols.</li> <li>Work uniform or laboratory coat.</li> <li>If exposure to chemical is likely during typical use, provid eye flushing systems and safety showers close to the wo ing place.</li> <li>When using do not eat, drink or smoke.</li> <li>Wash contaminated clothing before re-use.</li> <li>The effective operation of a facility should include review engineering controls, proper personal protective equipmer appropriate degowning and decontamination procedures industrial hygiene monitoring, medical surveillance and thruse of administrative controls.</li> </ul>				
9. PHYSIC	CAL AND CHEMICAL P	ROP	ERTIES			
Appe	earance	:	granules			
Colou	ur	:	White to light yellow			
Odou	ır	:	No data available			
Odou	ur Threshold	:	No data available			
pН		:	No data available			
Melti	ng point/freezing point	:	No data available			
Initial range	l boiling point and boiling e	:	No data availab	le		
Flash	n point	:	Not applicable			
Evap	oration rate	:	Not applicable			
Flam	Flammability (solid, gas)		May form explosive dust-air mixture during processing dling or other means.			
Flam	mability (liquids)	:	No data available			
	Upper explosion limit / Upper flammability limit		No data available			

: Not applicable

: Not applicable

:

: No data available

No data available

Lower explosion limit / Lower : No data available

flammability limit

Vapour pressure

Relative density

Density

Relative vapour density



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:	Solubili Wat	ty(ies) er solubility	:	No data available	9
	Partitio	n coefficient: n-	:	Not applicable	
	••••••	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
,	Viscosi Visc	ty osity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	9
	Particle	size	:	No data available	9

### **10. STABILITY AND REACTIVITY**

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

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
Acute toxicity Harmful if swallowed.		
Product: Acute oral toxicity	:	Acute toxicity estimate: 875.04 mg/kg Method: Calculation method



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<u>Comp</u>	oonents:			
Fidax	omicin:			
Acute	oral toxicity	:	LD50 (Rat): > 1,0	00 mg/kg
			LD50 (Dog): > 12	0 mg/kg
Acute	toxicity (other routes of		LD50 (Rat): 200	ma/ka
	istration)	•	Application Route	
Cellu	lose:			
Acute	oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 5.8	
			Exposure time: 4 Test atmosphere	
Aquita	dormal toxicity			
Acute	dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg
Sodiu	ım benzoate:			
Acute	oral toxicity	:	LD50 (Rat): > 2,0	100 mg/kg e substance or mixture has no acute oral t
			icity	
Acute	dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg
			Remarks: Based	on data from similar materials
Citric	acid:			
Acute	oral toxicity	:	LD50 (Mouse): 5	,400 mg/kg
Acute	dermal toxicity	:	LD50 (Rat): > 2,0	100 mg/kg
				est Guideline 402 substance or mixture has no acute derm
			toxicity	
Skin	corrosion/irritation			
Not cl	assified based on availa	ble	information.	
<u>Comp</u>	oonents:			
	ım benzoate:			
Speci Metho		:	Rabbit OECD Test Guid	olino 404
Resul		:	No skin irritation	
Citric	acid:			
Speci		:	Rabbit	
Metho	bd	:	OECD Test Guid	eline 404
Resul	t	:	No skin irritation	





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### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Sodium benzoate:

#### Citric acid:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days
Method	:	OECD Test Guideline 405

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

### Sodium benzoate:

Test Type :	Local lymph node assay (LLNA)
Exposure routes :	Skin contact
Species :	Mouse
Result :	negative
Remarks :	Based on data from similar materials

### Germ cell mutagenicity

Not classified based on available information.

### Components:

### Fidaxomicin:

Genotoxicity in vitro	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Result: positive
Genotoxicity in vivo	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Application Route: Intravenous Result: negative



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		Test Type: cor Species: Rat Result: negativ	
Cellu	Ilose:		
	otoxicity in vitro	: Test Type: Bao Result: negativ	cterial reverse mutation assay (AMES) /e
		Test Type: In v Result: negativ	vitro mammalian cell gene mutation test ve
Genc	otoxicity in vivo	: Test Type: Ma cytogenetic as Species: Mous Application Ro Result: negativ	se function
Sodi	um benzoate:		
Geno	otoxicity in vitro	: Test Type: Bao Result: negativ	cterial reverse mutation assay (AMES) /e
		Test Type: Ch Result: positive	romosome aberration test in vitro e
Geno	otoxicity in vivo		
Citric	c acid:		
Gend	otoxicity in vitro	: Test Type: Bao Result: negativ	cterial reverse mutation assay (AMES) /e
		Test Type: in v Result: positive	vitro micronucleus test e
		Test Type: Bad Result: negativ	cterial reverse mutation assay (AMES) /e
Genc	otoxicity in vivo		

### Carcinogenicity

Not classified based on available information.



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Comp	oonents:		
Cellu	lose:		
Speci	es	: Rat	
	cation Route	: Ingestion	
Expos Resul	sure time t	: 72 weeks : negative	
Sodiu	ım benzoate:		
Speci		: Rat	
	cation Route sure time	: Ingestion	
Resul		: 24 month(s) : negative	
Repro	oductive toxicity		
Not cl	assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
Fidax	omicin:		
Effect	s on fertility	Species: Ra Application I	Fertility/early embryonic development t Route: Intravenous injection AEL: 6.3 mg/kg body weight
Effect ment	s on foetal develop-	Species: Ra Application I	Embryo-foetal development t Route: Intravenous injection ntal Toxicity: NOAEL: 12.6 mg/kg body wei
			o significant adverse effects were reported
			Embryo-foetal development
		Species: Ra Application I	bbit Route: Intravenous injection
		Developmer	ntal Toxicity: NOAEL: 7 mg/kg body weight o significant adverse effects were reported
Cellu	lose:		
Effect	s on fertility		Dne-generation reproduction toxicity study
		Species: Ra Application I Result: nega	Route: Ingestion
Effect	s on foetal develop-	: Test Type: F	Fertility/early embryonic development
	-	Species: Ra Application	t Route: Ingestion
ment		Result: nega	ative
	ım benzoate:		ative





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			ecies: Rat	
			plication Rou sult: negative	
				d on data from similar materials
Effect	s on foetal develop-	: Te	st Type: Emb	ryo-foetal development
ment	·	Sp	ecies: Rat	
			plication Rou	
		Re	sult: negative	
Citric	acid:			
Effect	s on foetal develop-	: Te	st Type: One	-generation reproduction toxicity study
ment	-		ecies: Rat	
			plication Rou	
		Re	sult: negative	2
STOT	- single exposure			
Not cl	assified based on avai	lable info	rmation.	
<u>Com</u>	oonents:			
C:4+:-	acid:			
Citric	uorai			
	ssment	: Ma	ay cause resp	iratory irritation.
Asses	ssment	: Ma	ay cause resp	iratory irritation.
Asses STOT	- repeated exposure			iratory irritation.
Asses STOT Not cl	<ul> <li>repeated exposure</li> <li>assified based on available</li> </ul>			iratory irritation.
Asses STOT Not cl Repe	- repeated exposure assified based on avai ated dose toxicity			iratory irritation.
Asses STOT Not cl Repe	- repeated exposure assified based on avai ated dose toxicity ponents:			iratory irritation.
Asses STOT Not cl Repe Comp Fidax	- repeated exposure assified based on avai ated dose toxicity ponents:	lable info	rmation.	iratory irritation.
Asses STOT Not cl Repe	- repeated exposure assified based on avai ated dose toxicity ponents: comicin: es	lable info : Ra	rmation.	iratory irritation.
Asses STOT Not cl Repe Comp Fidax Speci NOAE	- repeated exposure assified based on avai ated dose toxicity ponents: comicin: es	lable info : Ra	rmation. tt mg/kg	iratory irritation.
Asses STOT Not cl Repe Comp Fidax Speci NOAE Applic Expos	- repeated exposure assified based on avai ated dose toxicity ponents: comicin: es EL cation Route sure time	lable info : Ra : 90 : Or : 28	rmation. t mg/kg al D	
Asses STOT Not cl Reper Comp Fidax Speci NOAE Applic	- repeated exposure assified based on avai ated dose toxicity ponents: comicin: es EL cation Route sure time	lable info : Ra : 90 : Or : 28	rmation. t mg/kg al D	iratory irritation. dverse effects were reported
Asses STOT Not cl Repea Comp Fidax Speci NOAE Applic Expos Rema	- repeated exposure assified based on avai ated dose toxicity ponents: comicin: es EL cation Route sure time trks	lable info : Ra : 90 : Or : 28 : Nc : Ra	rmation. t mg/kg al D significant ad	
Asses STOT Not cl Repea Comp Fidax Speci NOAE Applic Expos Rema Speci NOAE	- repeated exposure assified based on avai ated dose toxicity ponents: comicin: es EL cation Route sure time urks es EL	lable info : Ra : 90 : Or : 28 : No : Ra : 62	rmation. t mg/kg al D significant ac t .5 mg/kg	
Asses STOT Not cl Reper Fidax Speci NOAE Applic Expos Rema Speci NOAE Applic	- repeated exposure assified based on avai ated dose toxicity ponents: comicin: es EL cation Route sure time urks es EL cation Route	lable info : Ra : 90 : Or : 28 : No : Ra : 62 : Int	rmation. t mg/kg al D significant ad t .5 mg/kg ravenous	
Asses STOT Not cl Reper Fidax Speci NOAE Applic Expos Rema Speci NOAE Applic	- repeated exposure assified based on avai ated dose toxicity ponents: comicin: es EL cation Route sure time urks es EL	lable info : Ra : 90 : Or : 28 : No : Ra : 62	rmation. t mg/kg al D significant ad t .5 mg/kg ravenous	
Asses STOT Not cl Reper Comp Fidax Speci NOAE Applic Expos Rema Speci NOAE Applic Expos Speci	- repeated exposure assified based on avail ated dose toxicity ponents: comicin: es EL cation Route sure time trks es EL cation Route sure time es EL cation Route sure time	lable info : Ra : 90 : Or : 28 : Nc : Ra : 62 : Int : 14 : Dc	rmation. t mg/kg al D significant ac t .5 mg/kg ravenous D	
Asses STOT Not cl Reper Comp Fidax Speci NOAE Applic Expos Rema Speci NOAE Applic Expos Speci NOAE	- repeated exposure assified based on avail ated dose toxicity ponents: comicin: es EL cation Route sure time arks es EL cation Route sure time sure time sure time	lable info : Ra : 90 : 0r : 28 : Nc : Ra : 62 : Int : 14 : 0c : 9,6	rmation. t mg/kg al D significant ac t .5 mg/kg ravenous D g 500 mg/kg	
Asses STOT Not cl Reper Comp Fidax Speci NOAE Applic Expos Rema Speci NOAE Applic Expos Speci NOAE Applic Expos	- repeated exposure assified based on avail ated dose toxicity ponents: comicin: es EL cation Route sure time arks es EL cation Route sure time es EL cation Route sure time	lable info : Ra : 90 : 0r : 28 : Nc : Ra : 62 : Int : 14 : 0c : 9,6 : 0r	rmation. t mg/kg al D significant ad t .5 mg/kg ravenous D g 600 mg/kg al	
Asses STOT Not cl Reper Fidax Speci NOAE Applic Expos Speci NOAE Applic Expos Speci NOAE Applic Expos	- repeated exposure assified based on avai ated dose toxicity ponents: comicin: es EL cation Route sure time es EL cation Route sure time es EL cation Route sure time es EL cation Route sure time	lable info : Ra : 90 : Or : 28 : No : Ra : 62 : Int : 14 : Do : 9,6 : Or : 3 N	rmation. t mg/kg al D significant ac t .5 mg/kg ravenous D 9 00 mg/kg al 4	
Asses STOT Not cl Reper Fidax Speci NOAE Applic Expos Speci NOAE Applic Expos Speci NOAE Applic Expos Speci NOAE Applic Expos	- repeated exposure assified based on avail ated dose toxicity ponents: comicin: es EL cation Route sure time time es EL cation Route sure time es EL cation Route sure time toms	lable info : Ra : 90 : Or : 28 : Nc : Ra : 62 : Int : 14 : Dc : 9,6 : Or : 3 N : Vo	rmation. t mg/kg al D significant ac t .5 mg/kg ravenous D 9 000 mg/kg al 4 miting	dverse effects were reported
Asses STOT Not cl Reper Fidax Speci NOAE Applic Expos Speci NOAE Applic Expos Speci NOAE Applic Expos	- repeated exposure assified based on avail ated dose toxicity ponents: comicin: es EL cation Route sure time time es EL cation Route sure time es EL cation Route sure time toms	lable info : Ra : 90 : Or : 28 : Nc : Ra : 62 : Int : 14 : Dc : 9,6 : Or : 3 N : Vo	rmation. t mg/kg al D significant ac t .5 mg/kg ravenous D 9 000 mg/kg al 4 miting	





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NOAE	=1	: 90 mg/kg	
	cation Route	: Oral	
Expos	sure time	: 28 D	<i>"</i>
Rema	arks	: No significant	adverse effects were reported
Speci	ies	: Juvenile rat	
NOAE		: 200 mg/kg	
	cation Route	: Oral : 28 D	
Rema	sure time arks	-	adverse effects were reported
Cellu	lose:		
Speci		: Rat	
NOAE		: >= 9,000 mg/l	kg
	cation Route sure time	: Ingestion : 90 Days	
Sodiu	um benzoate:		
Speci		: Rat	
NOAE		: 1,000 mg/kg	
	cation Route sure time	: Ingestion : 24 Months	
Citric	acid:		
Speci		: Rat	
NOAE LOAE		: 4,000 mg/kg	
-	cation Route	: 8,000 mg/kg : Ingestion	
	sure time	: 10 Days	
<b>A</b> e e ::	etion tovicity		
-	r <b>ation toxicity</b> lassified based on avai	lable information	
	rience with human ex		
-		posule	
	ponents:		
	comicin:		
Inges	tion	: Symptoms: A	bdominal pain, Nausea, Vomiting, constipation
12. ECOL	OGICAL INFORMATIC	ON	
Ecoto	oxicity		
<u>Com</u>	ponents:		
Fidax	comicin:		
	ity to algae/aquatic		ena flos-aquae (cyanobacterium)): > 18.4 mg/l
plants	6	Exposure time	
		wethod: DEC	D Test Guideline 201
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			Remarks: No tox	city at the limit of solubility
			Exposure time: 7 Method: OECD T	a flos-aquae (cyanobacterium)): 5.8 mg/l 2 h rest Guideline 201 ricity at the limit of solubility
Toxicity)	y to fish (Chronic tox-	:	Exposure time: 3 Method: OECD T	les promelas (fathead minnow)): 8.91 mg/l 2 d rest Guideline 210 ricity at the limit of solubility
	y to daphnia and other c invertebrates (Chron- ity)	:	Exposure time: 2	magna (Water flea)): 19.6 mg/l 1 d rest Guideline 211
Toxicit	y to microorganisms	:	EC50: > 50 mg/l Exposure time: 3 Test Type: Respi Method: OECD T	
			NOEC: 5.9 mg/l Exposure time: 3 Test Type: Respi Method: OECD T	
Cellulo	ose:			
Toxicit	y to fish	:	Exposure time: 4	tipes (Japanese medaka)): > 100 mg/l 8 h on data from similar materials
Sodiur	m benzoate:			
Toxicit	y to fish	:	LC50 (Pimephale Exposure time: 9	es promelas (fathead minnow)): 484 mg/l 6 h
	y to daphnia and other c invertebrates	:	EC50 (Daphnia n Exposure time: 9	nagna (Water flea)): > 100 mg/l 6 h
Toxicit <u></u> plants	y to algae/aquatic	:	mg/l Exposure time: 7	chneriella subcapitata (green algae)): > 10 2 h rest Guideline 201
			mg/l Exposure time: 7	rchneriella subcapitata (green algae)): 32 2 h ïest Guideline 201
Citric a	acid:			



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			Exposure time: 9	6 h
	ity to daphnia and othe ic invertebrates	r:	EC50 (Daphnia r Exposure time: 2	nagna (Water flea)): 1,535 mg/l 4 h
Persi	stence and degradab	ility		
Com	oonents:			
Cellu	lose:			
Biode	gradability	:	Result: Readily b	iodegradable.
	um benzoate:		Deputto De sulla 1	ia da ava da bla
BIODE	gradability	:	Result: Readily b Biodegradation: Exposure time: 2	75 %
Citric	acid:			
Biode	gradability	:	Biodegradation: Exposure time: 2	97 %
Bioad	ccumulative potential			
Com	ponents:			
Fidax	omicin:			
	ion coefficient: n- ol/water	:	log Pow: 4.4	
Sodiu	um benzoate:			
	ion coefficient: n- ol/water	:	log Pow: 1.88	
	acid:			
	ion coefficient: n- ol/water	:	log Pow: -1.72	
Mobi	lity in soil			
Com	oonents:			
Fidax	comicin:			
	bution among environ- al compartments	:	log Koc: 0.80	
	r adverse effects ata available			



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### **13. DISPOSAL CONSIDERATIONS**

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### 14. TRANSPORT INFORMATION

#### **International Regulations**

### UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
IATA-DGR		
UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo	:	Not applicable
aircraft)		
Packing instruction (passen-	:	Not applicable
ger aircraft)		
IMDG-Code		
UN number	:	Not applicable

UN number	: Not a	pplicable
Proper shipping name	: Not a	pplicable
Class	: Not a	pplicable
Subsidiary risk		pplicable
Packing group	: Not a	pplicable
Labels	: Not a	pplicable
EmS Code		pplicable
Marine pollutant	: Not a	pplicable

#### 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



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

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances
Hazardous to Health

Hazardous substances that must be registered	:	Not applicable
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#### Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

# Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

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

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

### **16. OTHER INFORMATION**

Revision Date	:	2023/09/30		
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	:	yyyy/mm/dd		
Full text of other abbreviations				



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ACGIH ID OEL	USA. ACGIH Threshold Limit Values (TLV) Indonesia. Occupational Exposure Limits
ACGIH / TWA ID OEL / NAB	8-hour, time-weighted average Long term exposure limit

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.

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