

according to the Hazardous Products Regulations

# **Orbifloxacin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	801075-00019	Date of first issue: 07/15/2016

#### **SECTION 1. IDENTIFICATION**

Product name	:	Orbifloxacin Solid Formulation
Other means of identification	:	No data available

#### Manufacturer or supplier's details

:	Merck & Co., Inc
:	126 E. Lincoln Avenue
	Rahway, New Jersey U.S.A. 07065
:	908-740-4000
:	1-908-423-6000
:	EHSDATASTEWARD@merck.com
	:

### Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the Hazardous Products Regulati	ons
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Reproductive toxicity	:	Category 2	
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### GI

GHS label elements Hazard pictograms :	
Signal Word :	Warning
Hazard Statements :	H361d Suspected of damaging the unborn child.
Precautionary Statements :	<ul> <li>Prevention:</li> <li>P201 Obtain special instructions before use.</li> <li>P202 Do not handle until all safety precautions have been read and understood.</li> <li>P280 Wear protective gloves, protective clothing, eye protection and face protection.</li> </ul>
	<b>Response:</b> P308 + P313 IF exposed or concerned: Get medical attention.
	<b>Storage:</b> P405 Store locked up.
	Disposal:

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

according to the Hazardous Products Regulations



## **Orbifloxacin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	801075-00019	Date of first issue: 07/15/2016

#### Other hazards

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.

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

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Orbifloxacin	No data availa- ble	113617-63-3	>= 5 - < 10 *
Magnesium stearate	Octadecanoic acid, magnesi- um salt (2:1)	557-04-0	>= 1 - < 5 *

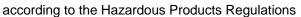
<sup>\*</sup> Actual concentration or concentration range is withheld as a trade secret

#### **SECTION 4. FIRST AID MEASURES**

General advice	:	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Suspected of damaging the unborn child. 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.

### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media	:	
		Alcohol-resistant foam
		Carbon dioxide (CO2)





### **Orbifloxacin Solid Formulation**

Version 3.1	Revision Date: 09/30/2023		OS Number: 1075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016		
	suitable extinguishing	:	Dry chemical None known.			
Spe	media Specific hazards during fire fighting		Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.			
Ha: uct	zardous combustion prod- s	:	Carbon oxides Nitrogen oxides (I Metal oxides	NOx)		
Spo	ecific extinguishing meth-	:	: Use extinguishing measures that are appropriate to loca cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe so.			
	Special protective equipment for fire-fighters		<ul><li>Evacuate area.</li><li>In the event of fire, wear self-contained breathing apparatus.</li><li>Use personal protective equipment.</li></ul>			
SECTIC	N 6. ACCIDENTAL RELE	AS	E MEASURES			
tive	rsonal precautions, protec- e equipment and emer- ncy procedures	:	Follow safe handl	tective equipment. ing advice (see section 7) and personal lent recommendations (see section 8).		
En	vironmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages		
	thods and materials for ntainment and cleaning up	:	Sweep up or vacu container for disp	uum up spillage and collect in suitable osal.		

### SECTION 7. HANDLING AND STORAGE

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.

with compressed air).

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

Sections 13 and 15 of this SDS provide information regarding

determine which regulations are applicable.

certain local or national requirements.

according to the Hazardous Products Regulations



## **Orbifloxacin Solid Formulation**

Version 3.1	Revision Date: 09/30/2023	SDS Number: 801075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016
	al/Total ventilation vice on safe handling	: Do not breath Do not swalld Avoid contact Avoid prolong Handle in acc practice, base assessment Minimize dus Keep contain Keep away fr Take precaut	W.
Cor	nditions for safe storage	Store locked	•
Mat	terials to avoid		rdance with the particular national regulations. with the following product types: ing agents

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

			-	
Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Orbifloxacin	113617-63-3	TWA	0.2 mg/m3 (OEB 2)	Internal
Magnesium stearate	557-04-0	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Inhal- able)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Res- pirable)	3 mg/m <sup>3</sup>	CA BC OEL
		TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

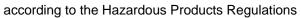
#### Ingredients with workplace control parameters

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 equipment

Respiratory protection

n : If adequate local exhaust ventilation is not available or



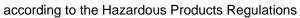


# **Orbifloxacin Solid Formulation**

Version 3.1	Revision Date: 09/30/2023	SDS Number: 801075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016
Hand	er type protection terial		
Eye pr	rotection	If the work envir mists or aeroso Wear a faceshie	sses with side shields or goggles. conment or activity involves dusty conditions, ls, wear the appropriate goggles. eld or other full face protection if there is a ect contact to the face with dusts, mists, or
	nd body protection ne measures	: If exposure to cl eye flushing sys working place. When using do Wash contamin The effective op engineering cor appropriate deg	r laboratory coat. hemical is likely during typical use, provide stems and safety showers close to the not eat, drink or smoke. ated clothing before re-use. beration of a facility should include review of atrols, proper personal protective equipment, owning and decontamination procedures, he monitoring, medical surveillance and the rative controls.

#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
narninability illint		





## **Orbifloxacin Solid Formulation**

Versi 3.1	ion	Revision Date: 09/30/2023		S Number: 075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016
	flamma	bility limit			
	Vapor p	oressure	:	No data available	9
	Relative	e vapor density	:	No data available	9
	Relative	e density	:	No data available	9
	Density	/	:	No data available	9
	Solubili Wat	ity(ies) er solubility	:	No data available	9
		n coefficient: n-	:	No data available	2
	octanol Autoigr	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
		ng properties	:		r mixture is not classified as oxidizing.
		lar weight	:	No data available	
	Particle	9 SIZE	:	No data available	9

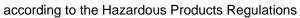
### SECTION 10. STABILITY AND REACTIVITY

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, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials Hazardous decomposition products		Oxidizing agents No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation Skin contact





# **Orbifloxacin Solid Formulation**

Vers 3.1	sion	Revision Date: 09/30/2023		S Number: 1075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016
	Ingestic Eye co				
		<b>toxicity</b> ssified based on availa	ble	information.	
	Produc	ct:			
		oral toxicity	:	Acute toxicity estine Method: Calculation	mate: > 2,000 mg/kg on method
	Compo	onents:			
	Orbiflo	oxacin:			
	Acute o	oral toxicity	:	LD50 (Rat): > 3,00 Remarks: No mor	00 mg/kg tality observed at this dose.
				LD50 (Mouse): > 2 Remarks: No mor	2,000 mg/kg tality observed at this dose.
				LD50 (Dog): > 600 Symptoms: Vomit Remarks: No mor	
	Acute i	nhalation toxicity	:	Remarks: No data	available
	Acute o	dermal toxicity	:	Remarks: No data	available
		oxicity (other routes of stration)	:	LD50 (Rat): > 200 Application Route	
				LD50 (Mouse): 50 Application Route	
				LD50 (Rat): 233 n Application Route	
				LD50 (Mouse): 25 Application Route	
	Magne	sium stearate:			
	-	oral toxicity	:	icity	
	Acute o	dermal toxicity	:	LD50 (Rabbit): > 2 Remarks: Based o	2,000 mg/kg on data from similar materials

### Skin corrosion/irritation

Not classified based on available information.



according to the Hazardous Products Regulations

# **Orbifloxacin Solid Formulation**

Version 3.1	Revision Date: 09/30/2023	SDS Number: 801075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016
<u>Comp</u>	oonents:		
Orbifl	oxacin:		
Speci	es	: Rabbit	
Metho		: Draize Test	
Resul	t	: No skin irritatio	n
Magn	esium stearate:		
Speci	es	: Rabbit	
Resul		: No skin irritatio	
Rema	rks	: Based on data	from similar materials
Serio	us eye damage/eye i	irritation	
Not cl	assified based on ava	ailable information.	
Comp	oonents:		
Orbifl	oxacin:		
Speci	es	: Rabbit	
Resul	-	: Mild eye irritati	ion
Metho	od	: Draize Test	
Magn	esium stearate:		
Speci	es	: Rabbit	
Resul	t	: No eye irritatio	n
Rema	rks	: Based on data	from similar materials
Respi	ratory or skin sensi	tization	
Skin s	sensitization		
Not cl	assified based on ava	ailable information.	

# Respiratory sensitization

Not classified based on available information.

#### **Components:**

#### Orbifloxacin:

Test Type	:	Maximization Test
Routes of exposure	:	Dermal
Species	:	Guinea pig
Result	:	Not a skin sensitizer.

#### Magnesium stearate:

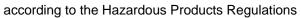
Test Type :	Maximization Test
Routes of exposure :	Skin contact
Species :	Guinea pig
Method :	OECD Test Guideline 406
Result :	negative
Remarks :	Based on data from similar materials

according to the Hazardous Products Regulations



# **Orbifloxacin Solid Formulation**

rsion	Revision Date: 09/30/2023		OS Number: 1075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016
	<b>cell mutagenicity</b> assified based on ava	ilable	information.	
Comp	oonents:			
Orbifl	oxacin:			
Genot	oxicity in vitro	:	Test Type: Bact Result: equivoca	erial reverse mutation assay (AMES) al
			Test Type: Mou Result: positive	se Lymphoma
				mosomal aberration Iman lymphocytes
Genot	oxicity in vivo	:	Test Type: Micro Species: Mouse Cell type: Bone Application Rou Result: negative	marrow te: Intraperitoneal injection
			Test Type: unsc Species: Rat Cell type: Liver of Application Rou Result: negative	te: Oral
	cell mutagenicity - sment	:	Weight of evider cell mutagen.	nce does not support classification as a gerr
Magn	esium stearate:			
-	oxicity in vitro	:	Result: negative	ro mammalian cell gene mutation test d on data from similar materials
			Method: OECD Result: negative	omosome aberration test in vitro Test Guideline 473 d on data from similar materials
			Result: negative	erial reverse mutation assay (AMES) e d on data from similar materials
	n <b>ogenicity</b> assified based on ava	ilable	information.	
Comp	oonents:			
Orbifl	oxacin:			
Specie		:	Rat Oral	

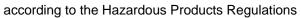




# **Orbifloxacin Solid Formulation**

Versi 3.1	ion	Revision Date: 09/30/2023		9S Number: 1075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016
	Exposu NOAEL Result		:	2 Years 200 mg/kg body v negative	veight
	Species Applica Exposu NOAEL Result	tion Route re time	:	Mouse Oral 2 Years 200 mg/kg body w negative	veight
	-	luctive toxicity ted of damaging the u	nboi	rn child.	
	Compo	onents:			
	Orbiflo	xacin:			
	Effects	on fertility	:	Species: Rat Application Route General Toxicity F	Parent: NOAEL: 50 mg/kg body weight Development: NOAEL: 50 mg/kg body
	Effects	on fetal development	:	Species: Rat Application Route Embryo-fetal toxic Result: No teratog	ity.: LOAEL: 333 mg/kg body weight jenic effects., Embryotoxic effects and in the offspring were detected only at high
				Species: Rabbit Application Route General Toxicity M Embryo-fetal toxic Result: No effects Embryotoxic effect	Aaternal: NOAEL: 20 mg/kg body weight ity.: NOAEL: 60 mg/kg body weight on early embryonic development., ts and adverse effects on the offspring were igh maternally toxic doses, Reduced
	Reprod sessme	uctive toxicity - As- ent	:	Some evidence of animal experimen	adverse effects on development, based on ts.

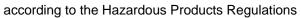
#### Magnesium stearate:





# **Orbifloxacin Solid Formulation**

Version 3.1	Revision Date: 09/30/2023		S Number: 1075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016
Effec	ets on fertility	:	reproduction/c Species: Rat Application Rc Method: OECI Result: negativ	D Test Guideline 422
Effec	ts on fetal development	:	Species: Rat Application Ro Result: negati	
	T-single exposure classified based on availa	able	information.	
STO	T-repeated exposure			
Not c	classified based on availa	able	information.	
Repe	eated dose toxicity			
<u>Com</u>	ponents:			
Orbi	floxacin:			
Expo	EL EL ication Route osure time et Organs	:	Rat 20 mg/kg 80 mg/kg Oral 3 Months Testis, Liver, H Mouse	Kidney, spleen
NOA		÷	80 mg/kg	
LOAI		:	250 mg/kg	
	cation Route	÷	Oral 3 Months	
Spec NOA LOAI Appli Expo Targo	cies EL EL cation Route osure time et Organs otoms		Juvenile dog 50 mg/kg 250 mg/kg Oral 14 Days Heart, Bone Gastrointestin mortality obse	
Spec	ies	:	Juvenile dog	
NOA	EL	:	2 mg/kg	
LOAI		:	3 mg/kg	
	cation Route	:	Oral	
	sure time	÷	90 Days	
Rema	et Organs arks	:	Bone No significant	adverse effects were reported
		·		





## **Orbifloxacin Solid Formulation**

/ersion 8.1	Revision Date: 09/30/2023		S Number: 1075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016
Spec	ies		Dog	
NOA		÷	37.5 mg/kg	
	cation Route sure time	:	Oral 30 Days	
Слро		·	SU Days	
Spec NOA		÷	Cat 7.5 mg/kg	
LOAE		÷	22.5 mg/kg	
	cation Route	:	Oral	
	sure time otoms	:	1 Months Gastrointestina	ldisturbance
Oyin	50113	·	Castronitestine	
Magr	nesium stearate:			
Spec		:	Rat	
NOA Appli	EL cation Route	÷	> 100 mg/kg Ingestion	
	sure time	÷	90 Days	
Rema	Remarks : Based on data from similar materials		from similar materials	
۵sni	ration toxicity			
•	lassified based on availa	ble	information.	
Expe	rience with human exp	osi	ire	
-	ponents:			
	loxacin:			
Inges		÷	Symptoms: cei	ntral nervous system effects, Gastrointestinal
ingee		•	disturbance, liv	er function change, anaphylaxis, Rash cause photosensitization.
CTION	12. ECOLOGICAL INF	OR	IATION	
Ecot	oxicity			
<u>Com</u>	ponents:			
Magr	nesium stearate:			
Toxic	city to fish	:		us idus (Golden orfe)): > 100 mg/l
			Exposure time: Method: DIN 3	
				ed on data from similar materials
Tavia	it to donknip and other		ELEO (Denhaia	
	tity to daphnia and other tic invertebrates	:	EL50 (Daphnia Exposure time:	magna (Water flea)): > 1 mg/l 47 h
			Test substance	e: Water Accommodated Fraction
				ive 67/548/EEC, Annex V, C.2. ed on data from similar materials
				he limit of solubility.
Tari	situ to olgo olgo statis			-
plant	city to algae/aquatic	÷	EL50 (Pseudo) mg/l	<pre>kirchneriella subcapitata (green algae)): &gt; 1</pre>
	-			
			12/14	•

according to the Hazardous Products Regulations



# **Orbifloxacin Solid Formulation**

ersion 1	Revision Date: 09/30/2023	-	DS Number: 01075-00019	Date of last issue: 04/04/2023 Date of first issue: 07/15/2016
			Method: OECD T	Water Accommodated Fraction est Guideline 201 on data from similar materials
			mg/l Exposure time: 7 Test substance: \ Method: OECD T	kirchneriella subcapitata (green algae)): > 1 2 h Water Accommodated Fraction Test Guideline 201 on data from similar materials
Toxic	ity to microorganisms	:	Exposure time: 1 Test substance: \	onas putida): > 100 mg/l 6 h Water Accommodated Fraction on data from similar materials
Persi	stence and degradabi	lity		
<u>Com</u>	oonents:			
-	esium stearate: gradability	:	Result: Not biode Remarks: Based	gradable on data from similar materials
Bioad	ccumulative potential			
Com	oonents:			
Partit	<b>nesium stearate:</b> ion coefficient: n- ol/water	:	log Pow: > 4	
	<b>lity in soil</b> ata available			
Othe	r adverse effects			

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	е
	handling site for recycling or disposal.	
	If not otherwise specified: Dispose of as unused produc	t.

### **SECTION 14. TRANSPORT INFORMATION**

#### **International Regulations**



according to the Hazardous Products Regulations

## Orbifloxacin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	801075-00019	Date of first issue: 07/15/2016

### UNRTDG

Not regulated as a dangerous good

IATA-DGR Not regulated as a dangerous good

**IMDG-Code** Not regulated as a dangerous good

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

Not applicable for product as supplied.

#### **Domestic regulation**

**TDG** Not regulated as a dangerous good

### Special precautions for user

Not applicable

#### SECTION 15. REGULATORY INFORMATION

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

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

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

#### Full text of other abbreviations

ACGIH CA AB OEL	:	USA. ACGIH Threshold Limit Values (TLV) Canada. Alberta, Occupational Health and Safety Code (table
ON AD OLL	•	2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safe- ty, Schedule 1, Part 1: Permissible exposure values for air- borne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWAEV	:	Time-weighted average exposure value

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



## Orbifloxacin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	801075-00019	Date of first issue: 07/15/2016

- 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

Sources of key data used to compile the Material 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/
Revision Date Date format	:	09/30/2023 mm/dd/yyyy

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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