

according to the OSHA Hazard Communication Standard

# **Enrofloxacin (10%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.0	09/28/2024	633953-00022	Date of first issue: 04/27/2016

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

Product name	:	Enrofloxacin (10%) Formulation			
Manufacturer or supplier's details					
Company name of supplier	:	Merck & Co., Inc			
Address	:	126 E. Lincoln Avenue			
Telephone		Rahway, New Jersey U.S.A. 07065 908-740-4000			
Emergency telephone	-	1-908-423-6000			
E-mail address	:	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 OSHA Hazard Communication Standard (29 CFR 1910.1200)			
Skin sensitization	:	Category 1	
Reproductive toxicity	:	Category 2	
Specific target organ toxicity - repeated exposure	:	Category 1 (cartilage, Testis)	
GHS label elements Hazard pictograms	:		
Signal Word	:	Danger	
Hazard Statements	:	H317 May cause an allergic skin reaction. H361f Suspected of damaging fertility. H372 Causes damage to organs (cartilage, Testis) through pro- longed or repeated exposure.	
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>P260 Do not breathe mist or vapors.</li> <li>P264 Wash skin thoroughly after handling.</li> <li>P270 Do not eat, drink or smoke when using this product.</li> <li>P272 Contaminated work clothing must not be allowed out of the workplace.</li> <li>P280 Wear protective gloves, protective clothing, eye protection</li> </ul>	

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		P308 + P313 II P333 + P313 If tion.	ction. F ON SKIN: Wash with plenty of soap and water. F exposed or concerned: Get medical attention. f skin irritation or rash occurs: Get medical atten- ntaminated clothing before reuse.
		<b>Storage:</b> P405 Store loc	ked up.
		<b>Disposal:</b> P501 Dispose disposal plant.	of contents and container to an approved waste
	r <b>hazards</b> known.		

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

Substance / Mixture	:	Mixture
---------------------	---	---------

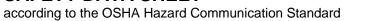
#### Components

••••••		
Chemical name	CAS-No.	Concentration (% w/w)
Enrofloxacin	93106-60-6	>= 10 - < 20
Benzyl alcohol	100-51-6	>= 1 - < 5
A ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) (		

Actual concentration is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

:	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, remove to fresh air. Get medical attention.
:	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.
:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
:	May cause an allergic skin reaction. Suspected of damaging fertility. Causes damage to organs through prolonged or repeated exposure. First Aid responders should pay attention to self-protection,
	::





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Note	es to physician	:	when the potentia	nmended personal protective equipment l for exposure exists (see section 8). cally and supportively.
SECTIO	N 5. FIRE-FIGHTING ME	ASL	IRES	
Suit	able extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
Uns med	uitable extinguishing dia	:	None known.	
Spe figh	cific hazards during fire ting	:	Exposure to comb	pustion products may be a hazard to health.
Haz ucts	ardous combustion prod-	:	Carbon oxides	
Spe ods	cific extinguishing meth-	:	cumstances and t Use water spray to	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	cial protective equipment ire-fighters	:	In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

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).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). 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	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and



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		employed in the determine whe sections 13 a	disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.		
SECTION	7. HANDLING AND ST	ORAGE	-		
Techr	nical measures		ing measures under EXPOSURE PERSONAL PROTECTION section.		
Local	/Total ventilation	: Use only with	adequate ventilation.		
Advice on safe handling		Do not breath Do not swallo Avoid contact Wash skin tho Handle in acc practice, base assessment Do not eat, dr			
Condi	itions for safe storage	Store locked u	rly labeled containers. .p. dance with the particular national regulations.		
Mater	ials to avoid	: Do not store v Strong oxidizi	vith the following product types: ng agents substances and mixtures		

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Enrofloxacin	93106-60-6	TWA	0.2 mg/m3 (OEB 2)	Internal
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL

Engineering measures	:	Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip- less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

#### Personal protective equipment

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Respiratory protection Hand protection		maintain vapo concentration unknown, app Follow OSHA use NIOSH/M by air purifyin hazardous ch supplied resp release, expo circumstance	: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. When concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provide by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.				
	aterial	: Chemical-resistant gloves					
Eye protection Skin and body protection Hygiene measures		If the work en mists or aeros Wear a faces	plasses with side shields or goggles. vironment or activity involves dusty conditions, sols, wear the appropriate goggles. hield or other full face protection if there is a lirect contact to the face with dusts, mists, or				
		: If exposure to eye flushing s working place When using o Contaminated workplace. Wash contam The effective engineering o appropriate d industrial hyg	or laboratory coat. chemical is likely during typical use, provide systems and safety showers close to the do not eat, drink or smoke. do not eat, drink or s				

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
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	:	No data available





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	Evapora	ation rate	:	No data available	
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available	
	Relative	e vapor density	:	No data available	
	Relative	e density	:	No data available	
	Density		:	No data available	
	Solubili Wate	ty(ies) er solubility	:	No data available	
	Partition octanol	n coefficient: n- /water	:	Not applicable	
		ition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosit Visc	ty osity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	mixture is not classified as oxidizing.
	Particle Particle	characteristics size	:	Not applicable	

## SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.
tions		
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.





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#### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

### Acute toxicity

Not classified based on available information.

Product:		
Acute oral toxicity	:	Acute toxicity estimate: 4,724 mg/kg Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Components:		
Enrofloxacin:		
Acute oral toxicity	:	LD50 (Rabbit): 500 - 800 mg/kg
		LD50 (Rat): > 5,000 mg/kg
		LD50 (Mouse): > 5,000 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg
Benzyl alcohol:		
Acute oral toxicity	:	LD50 (Rat): 1,200 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.4 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhala- tion toxicity
Skin corrosion/irritation	able	information.

### Components:

#### Enrofloxacin:

Result	: No skin irritation
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#### Benzyl alcohol:

Species Method	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation





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#### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

#### Enrofloxacin:

Result

: Mild eye irritation

### Benzyl alcohol:

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

#### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### **Respiratory sensitization**

Not classified based on available information.

#### **Components:**

#### Enrofloxacin:

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

#### Benzyl alcohol:

Test Type Routes of exposure Species Result		Human repeat insult patch test (HRIPT) Skin contact Humans positive
Assessment	:	Probability or evidence of low to moderate skin sensitization rate in humans

### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

Enrofloxacin:		
Genotoxicity in vitro	:	Test Type: Chromosomal aberration Result: positive
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Result: negative

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		Test Type: Mammalian bone marrow sister chromatid ex- change Species: Hamster Result: negative Test Type: Chromosomal aberration Species: Rat Result: negative
Benz	yl alcohol:	
	otoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Gend	otoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative
Carc	inogenicity	
Not c	lassified based on av	ailable information.
<u>Com</u>	ponents:	
Enro	floxacin:	
	cation Route sure time	: Rat : Oral : 2 Years : negative
	cation Route sure time	: Mouse : Oral : 2 Years : negative
D		
Spec Appli	cation Route sure time od	<ul> <li>Mouse</li> <li>Ingestion</li> <li>103 weeks</li> <li>OECD Test Guideline 451</li> <li>negative</li> </ul>
IARC		ent of this product present at levels greater than or equal to 0.1% is as probable, possible or confirmed human carcinogen by IARC.
OSH	•	nent of this product present at levels greater than or equal to 0.1% is s list of regulated carcinogens.
NTP		ent of this product present at levels greater than or equal to 0.1% is as a known or anticipated carcinogen by NTP.

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Suspe	oductive toxicity ected of damaging fertilit conents:	y.		
	loxacin: s on fertility	:	Species: Rat Application Rout Fertility: LOAEL:	generation study e: Oral 15 mg/kg body weight n fertility., alteration in sperm morphology
Effect	s on fetal development	:	Result: Reduced	
Repro sessm	oductive toxicity - As- nent	:		of adverse effects on sexual function and animal experiments.
Benz	yl alcohol:			
	s on fertility	:	Species: Rat Application Rout Result: negative	ity/early embryonic development e: Ingestion on data from similar materials
Effect	s on fetal development	:	Test Type: Emb Species: Mouse Application Rout Result: negative	yo-fetal development e: Ingestion
Not cl	-single exposure assified based on availa -repeated exposure			h prolonged or repeated exposure.

Components:

Enrofloxacin:	
<b>—</b> –	

5 5	age, Testis es damage to organs through prolonged or repeated sure.
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Repe	ated dose toxicity		
<u>Com</u>	oonents:		
Enro	floxacin:		
Expos Targe	EL EL cation Route sure time et Organs	: Rat : 36 mg/kg : 150 mg/kg : Oral : 13 Weeks : Testis	
Expo	ΞL	: Dog : 3 mg/kg : 9.6 mg/kg : Oral : 13 Weeks : cartilage	
	EL cation Route sure time	: Cat : 25 mg/kg : Oral : 30 Days : No significant	adverse effects were reported
Benz	yl alcohol:		
	EL cation Route sure time	: Rat : 1.072 mg/l : inhalation (dus : 28 Days : OECD Test Gr	
-	ration toxicity lassified based on ava	ailable information.	
	rience with human e		
Com	oonents:		
Enro	floxacin:		
Inges			astrointestinal disturbance, central nervous sys- ensitivity to light
SECTION	12. ECOLOGICAL IN	IFORMATION	
Ecoto	oxicity		
	oonents:		
-			
	floxacin: ity to fish	: LC50 (Lepomi Exposure time	s macrochirus (Bluegill sunfish)): 79.5 mg/l : 96 h





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ersion D	Revision Date: 09/28/2024		9S Number: 3953-00022	Date of last issue: 09/30/2023 Date of first issue: 04/27/2016
			LC50 (Oncorhync Exposure time: 96	hus mykiss (rainbow trout)): > 196 mg/l ን h
			LC50 (Oryzias lati Exposure time: 96	ipes (Japanese medaka)): > 100 mg/l S h
	ty to daphnia and other c invertebrates	:	EC50 (Hyalella az Exposure time: 96	zteca (Amphipod)): > 206 mg/l S h
			EC50 (Daphnia m Exposure time: 48	agna (Water flea)): 79.9 mg/l 3 h
Toxici plants	ty to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72	chneriella subcapitata (green algae)): 3.1 2 h
			EC50 (Microcystis Exposure time: 5	s aeruginosa (blue-green algae)): 0.049 mg d
	ty to daphnia and other ic invertebrates (Chron-	:	NOEC (Daphnia r Exposure time: 21	nagna (Water flea)): 9.8 mg/l I d
	city)		NOEC (Daphnia r Exposure time: 21	nagna (Water flea)): 5 mg/l I d
			LOEC (Daphnia n Exposure time: 21	nagna (Water flea)): 15 mg/l I d
Benzy	/l alcohol:			
Toxici	ty to fish	:	LC50 (Pimephale: Exposure time: 96	s promelas (fathead minnow)): 460 mg/l 5 h
	ty to daphnia and other c invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
Toxici plants	ty to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD To	
			NOEC (Pseudokin mg/l Exposure time: 72 Method: OECD Te	
	ty to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD To	





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Persi	stence and degradabi	lity		
Com	ponents:			
Benz	yl alcohol:			
Biode	egradability	:	Result: Readily b Biodegradation: Exposure time: 14	92 - 96 %
Bioa	ccumulative potential			
Com	ponents:			
Partit	floxacin: ion coefficient: n- iol/water	:	log Pow: 0.5	
Partit	y <b>l alcohol:</b> ion coefficient: n- iol/water	:	log Pow: 1.05	
Mobi	lity in soil			
<u>Com</u>	ponents:			
Distri	floxacin: bution among environ- al compartments	:	Koc: 5.55	
••	<b>r adverse effects</b> ata available			
SECTION	13. DISPOSAL CONS	DEF	RATIONS	
•	osal methods		Dianaca of in and	ordance with local regulations

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

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

### International Regulations

UNRTDG		
UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ()
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes



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	A-DGR D No.		UN 3082	
	er shipping name	:		y hazardous substance, liquid, n.o.s.
FIOP	er snipping name	•	()	y nazaruous substance, ilquiu, n.o.s.
Class	s		9	
	king group	÷	Ű	
Labe		:	Miscellaneous	
Pack aircra	king instruction (cargo aft)	:	964	
Pack	king instruction (passen-	:	964	
	ronmentally hazardous	:	yes	
IMD	G-Code			
UN r	number	:	UN 3082	
Prop	er shipping name	:	N.O.S.	TALLY HAZARDOUS SUBSTANCE, LIQUID,
Class	c		() 9	
	s king group	:	9 III	
Labe		÷	9	
EmS	Code	:	F-A, S-F	
Marii	ne pollutant	:	yes	
Tran	sport in bulk according	g to	Annex II of MA	RPOL 73/78 and the IBC Code
Not a	applicable for product as	sup	plied.	
Dom	estic regulation			
49 C	FR			
UN/I	D/NA number	:	UN 3082	
Prop	er shipping name	:	Environmentally	y hazardous substance, liquid, n.o.s.
Clas	S	:	9	
	king group	:	III	
Labe		:	CLASS 9	
	Code	:	171	
	ne pollutant	÷	yes()	anly to containers over 110 college of 450
Rem	aiks	÷	liters.	only to containers over 119 gallons or 450
			Shinment by an	ound under DOT is non-regulated: however it

Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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

#### **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.



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#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	:	Respiratory or skin sensitization Reproductive toxicity Specific target organ toxicity (single or repeated exposure)
SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
US State Regulations		
Pennsylvania Right To Kno	ow	

	•		
V	Water		7732-18-5
E	Enrofloxacin		93106-60-6
E	Benzyl alcohol		100-51-6
The ingredients of this product are reported in the following inventories:			
AICS		not determined	

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

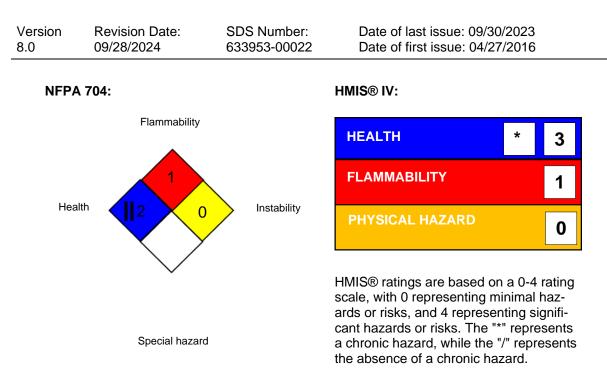
### SECTION 16. OTHER INFORMATION

Further information



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### Full text of other abbreviations

US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA	:	8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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: HMIS - Hazardous Materials Identification System: 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance





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Inventory; 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

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 Agency, http://echa.europa.eu/
Revision Date	:	09/28/2024

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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