

according to the Hazardous Products Regulations

Halofuginone Formulation

Version 4.3	Revision Date: 12/08/2023		DS Number: 5710-00020	Date of last issue: 09/30/2023 Date of first issue: 08/26/2016
SECTIO	ON 1. IDENTIFICATION			
	oduct name her means of identification		(
Ма	nufacturer or supplier's	deta	ails	
	mpany name of supplier dress	:	126 E. Lincoln Av Rahway, New Jer	enue sey U.S.A. 07065
En	lephone hergency telephone nail address	:	908-740-4000 1-908-423-6000 EHSDATASTEW/	ARD@merck.com
Re	commended use of the c	hen	nical and restriction	ons on use
-	commended use strictions on use	:	Veterinary produc Not applicable	t

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations					
Skin irritation	:	Category 2			
Eye irritation	:	Category 2A			
GHS label elements					
Hazard pictograms	:				
Signal Word	:	Warning			
Hazard Statements	:	H315 Causes skin irritation. H319 Causes serious eye irritation.			
Precautionary Statements	:	Prevention: P264 Wash skin thoroughly after handling. P280 Wear protective gloves, eye protection and face protec- tion.			
		Response: P302 + P352 IF ON SKIN: Wash with plenty of water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332 + P313 If skin irritation occurs: Get medical attention. P337 + P313 If eye irritation persists: Get medical attention. P362 + P364 Take off contaminated clothing and wash it before reuse.			



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Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Lactic acid	Propanoic acid, 2-hydroxy-	50-21-5	>= 1 - < 5 *
Halofuginone	No data availa- ble	82186-71-8	>= 0 - < 0.1 *

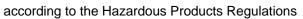
* Actual concentration or concentration range is withheld as a trade secret

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 if symptoms occur.
In case of skin contact	:	
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Causes skin irritation. Causes serious eye 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	:	Water spray
		Alcohol-resistant foam
		Carbon dioxide (CO2)





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Unsui media	table extinguishing	:	Dry chemical None known.	
	fic hazards during fire	:	Exposure to comb	pustion products may be a hazard to health.
	Hazardous combustion prod-		Carbon 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. Evacuate area.	
	al protective equipment e-fighters	:	In the event of fire	e, wear self-contained breathing apparatus. tective equipment.
SECTION	6. ACCIDENTAL RELE	AS	E MEASURES	
tive e	nal precautions, protec- quipment and emer- procedures	:	Follow safe handl	tective equipment. ing advice (see section 7) and personal ient recommendations (see section 8).
Enviro	Environmental precautions		Prevent spreading oil barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g., by containment or se of contaminated wash water. should be advised if significant spillages
	Methods and materials for containment and cleaning up		For large spills, pl containment to ke can be pumped, s container. Clean up remainin absorbent. Local or national d disposal of this m employed in the o determine which n Sections 13 and 1	t absorbent material. rovide diking or other appropriate eep material from spreading. If diked material store recovered material in appropriate ng materials from spill with suitable regulations may apply to releases and aterial, as well as those materials and items leanup of releases. You will need to regulations are applicable. 15 of this SDS provide information regarding tional requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	: See Engineering measures under EXPOSURE
	CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: Use only with adequate ventilation.
Advice on safe handling	: Do not get on skin or clothing.
	Avoid inhalation of vapor or mist.
	Do not swallow.



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		Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and sa practice, based on the results of the workplace exposure assessment Take care to prevent spills, waste and minimize release to environment.		
Cond	itions for safe storage		/ labeled containers. ance with the particular national regulations.	
Mater	rials to avoid	: Do not store with Strong oxidizing Gases	h the following product types: agents	

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
Halofuginone	82186-71-8	TWA	5 µg/m3 (OEB 4)	Internal
	Further information: DSEN, Skin			
		Wipe limit	50 µg/100 cm ²	Internal

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. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.
Personal protective equipment	
Respiratory protection:Filter type:Hand protection	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Organic vapor Type
Material :	Chemical-resistant gloves
Remarks:Eye protection:Skin and body protection:	Consider double gloving. 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 aerosols. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets,



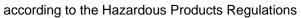
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Hygie	ene measures	Use appropriat contaminated of If exposure to of eye flushing sy working place. When using do Wash contamin The effective of engineering co appropriate des	chemical is likely during typical use, provide stems and safety showers close to the not eat, drink or smoke. nated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	yellow
Odor	:	odorless
Odor Threshold	:	No data available
рН	:	2.1 - 3
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available





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octanc	on coefficient: n- ol/water Inition temperature		o data available o data available	
Decon	nposition temperature	: No	o data available	9
	cosity, kinematic		o data available	9
Explos	sive properties	: No	ot explosive	
Oxidiz	ing properties	: Th	e substance o	r mixture is not classified as oxidizing.
Molec	ular weight	: No	o data available	9
Particl	e size	: No	o 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. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products	:	None known. Oxidizing agents No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

Components:

Lactic acid:



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	Acute	oral toxicity	:	LD50 (Rat): > 2,0 Remarks: Based	00 mg/kg on data from similar materials
	Acute i	nhalation toxicity	:		h dust/mist
	Acute o	dermal toxicity	:	toxicity	2,000 mg/kg substance or mixture has no acute dermal on data from similar materials
	Halofu	ginone:			
		oral toxicity	:	LD50 (Rat): 30 m	g/kg
				LD50 (Mouse): 5	mg/kg
	Acute i	nhalation toxicity	:	LC50 (Rat): 0.053 Test atmosphere:	
	Acute	dermal toxicity	:	LD50 (Rabbit): 16	s mg/kg
		orrosion/irritation s skin irritation.			
	Comp	onents:			
	Lactic	acid:			
	Specie Methoo Result Remar	ł	:		eline 404 to 4 hours of exposure om similar materials
		ginone:			
	Specie Result	S	:	Rabbit Skin irritation	
		s eye damage/eye irr s serious eye irritation.		on	
	Comp	onents:			
	Lactic				
	Specie Remar		:	Chicken eye	om similar materials
		V9	•		
	Result		:	Irreversible effect	s on the eye



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Halo	fuginone:			
Resu	Result		re irritation	
Resp	piratory or skin sensi	tization		
-	sensitization	ailable inform	ation.	
-	iratory sensitization lassified based on ava	ailable inform	ation.	
Com	ponents:			
Test	es of exposure ies It	: Skin : Guine : nega		rom similar materials
Halo	fuginone:			
Route Spec Resu		: Derm : Guine : Sens	ea pig	
	n cell mutagenicity lassified based on ava	ailable inform	ation.	
Com	ponents:			
	c acid:			
Geno	otoxicity in vitro	Meth Resu	od: OECD	
		Rema	arks: Based	d on data from similar materials
		Meth Resu	od: OECD	ro mammalian cell gene mutation test Test Guideline 476 d on data from similar materials
		Meth Resu	od: OECD	
		Rema	aiks. Dase(d on data from similar materials
	fuginone:			
Geno	otoxicity in vitro		Type: Ame It: positive	s test
			Type: Mous lt: negative	se Lymphoma
			8 / 15	



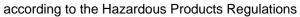
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			nosomal aberration nan lymphoblastoid cells
			damage and repair, unscheduled DNA syn- lian cells (in vitro)
	Genotoxicity in vivo	: Test Type: Micro Species: Mouse Cell type: Bone r Application Route Result: negative	narrow
		Test Type: Cytog Species: Rat Application Route Result: negative	
		Test Type: DNA Species: Mouse Application Route Result: negative	
	Carcinogenicity Not classified based on availal	ble information.	
<u>.</u>	Components:		
	Lactic acid:	. Dot	
	Species Application Route	: Rat : Ingestion	
	Exposure time	: 2 Years	
	Result Remarks	: negative : Based on data fr	om similar materials
l	Halofuginone:		
	Species	: Mouse	
	Application Route	: Oral	
	NOAEL Result	: 0.24 mg/kg body : negative	weight
 	Species Application Route Exposure time NOAEL Result	: Rat : Oral : 63 weeks : 0.36 mg/kg body : negative	weight
, 	Species Application Route Exposure time NOAEL	: Rat : Oral : 26 Months : 0.09 - 0.18 mg/kg	g body weight



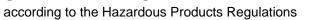
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Res	ult	:	negative	
Not	roductive toxicity classified based on availa nponents:	ble	information.	
	tic acid: cts on fetal development	:	Test Type: Embry Species: Mouse Application Route Result: negative	o-fetal development : Ingestion
Halo	ofuginone:			
Effe	cts on fertility	:	Test Type: Fertility Species: Mouse Application Route Fertility: NOAEL: Result: No effects	: Oral 0.126 mg/kg body weight
			Test Type: Fertility Species: Dog Application Route Fertility: LOAEL: 0 Result: Effects on	: Oral).067 mg/kg body weight
			Species: Mouse Application Route General Toxicity F Symptoms: Reduc	 LOAEL: 0.063 mg/kg body weight ced body weight on fertility and early embryonic
Effe	cts on fetal development	:	Species: Rat Application Route General Toxicity M Embryo-fetal toxic	o-fetal development : Oral /aternal: LOAEL: 0.34 mg/kg body weight city.: NOAEL: 0.67 mg/kg body weight o-fetal toxicity., No teratogenic effects.
			Species: Rabbit Application Route General Toxicity M Embryo-fetal toxic	o-fetal development : Oral /aternal: NOAEL: 0.025 mg/kg body weight city.: NOAEL: 0.076 mg/kg body weight o-fetal toxicity., No teratogenic effects.
	roductive toxicity - As- sment	:		f adverse effects on sexual function and animal experiments.





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		single exposure ssified based on availa	able	information.	
	STOT-	repeated exposure			
		ssified based on availa	able	information.	
	Compo	onents:			
	Halofu	ginone:			
		Organs	:	Blood Causes damage t exposure.	o organs through prolonged or repeated
	Repeat	ted dose toxicity			
	Compo	onents:			
	Lactic	acid:			
		- ation Route ure time	:	Rat > 100 mg/kg Ingestion 13 Weeks Based on data fro	m similar materials
			:	Rat 886 mg/kg Skin contact 13 Weeks	
	Halofu	ginone:			
	Species NOAEL LOAEL Applica Exposu	- S -		Mouse 0.07 mg/kg 0.16 mg/kg Oral 4 Weeks Blood	
	Exposu	_		Rat 0.13 mg/kg 0.88 mg/kg Oral 13 Weeks Liver	
	Exposu	_	:	Dog 0.067 mg/kg 0.134 mg/kg Oral 13 Weeks Blood	
	Specie: NOAEL		:	Dog 0.075 mg/kg	





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Expos	L ation Route sure time t Organs	:	0.16 mg/kg Oral 26 Weeks Blood							
-	ation toxicity assified based on availa	ble	information.							
Exper	Experience with human exposure									
Comp	oonents:									
Gener Inhala Skin c	contact	:	Remarks: May ca May cause sensiti Can be absorbed	use irritation of respiratory tract. use skin irritation and/or dermatitis. zation by skin contact. through skin.						
Eye co	ontact	:	Remarks: May irri	tate eyes.						
SECTION	12. ECOLOGICAL INFO	DRN	IATION							
Ecoto	oxicity									
<u>Comp</u>	oonents:									
Lactio	c acid:									
Toxici	ty to fish	:	Exposure time: 96 Method: OECD Te							
	ty to daphnia and other ic invertebrates	:	Exposure time: 48 Method: OECD Te							
Toxici plants	ty to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD To							
			mg/l Exposure time: 72 Method: OECD To							
Toxici	ty to microorganisms	:	EC50: > 10 - 100 Exposure time: 3 Method: OECD To Remarks: Based o	h						



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ersion .3	Revision Date: 12/08/2023		9S Number: 5710-00020	Date of last issue: 09/30/2023 Date of first issue: 08/26/2016
Halof	uginone:			
	Toxicity to fish		Exposure time: 96	thus mykiss (rainbow trout)): 1.8 mg/l 5 h on data from similar materials
			Exposure time: 72	arpio (Carp)): 0.3 mg/l 2 h on data from similar materials
			Exposure time: 96	acrochirus (Bluegill sunfish)): 0.12 mg/l 5 h on data from similar materials
	ty to daphnia and other ic invertebrates	:	Exposure time: 48	nagna (Water flea)): 0.02 mg/l 3 h on data from similar materials
Toxici plants	ty to algae/aquatic	:	Method: OECD T	oyrenoidosa): 46 mg/l est Guideline 201 on data from similar materials
Persis	stence and degradabili	ity		
<u>Comp</u>	oonents:			
	c acid: gradability	:	Result: Not readil Remarks: Based	y biodegradable. on data from similar materials
	uginone: gradability	:	Result: Not readil	y biodegradable.
Bioac	cumulative potential			
<u>Comp</u>	oonents:			
Partiti	c acid: on coefficient: n- ol/water	:	log Pow: -0.62	
Partiti	uginone: on coefficient: n- ol/water	:	log Pow: 1.18	
Mobil	ity in soil			
<u>Comp</u>	oonents:			
Distrib	uginone: pution among environ- al compartments	:	log Koc: 3.87 Method: FDA 3.08	8

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Other adverse effects

No data available

SECTION 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 handling site for recycling or disposal.
		If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

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

AICS	:	not determined
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DSL	:	not determined
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IECSC

: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

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



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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

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	:	12/08/2023 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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