

## Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/08
10.0	2024/09/28	845719-00022	Date of first issue: 2016/08/26

### **1. PRODUCT AND COMPANY IDENTIFICATION**

Chemical product name	:	Halofuginone Formulation
Other means of identification	:	HALOCUR (A009802) HALOCUR ORAL SOLUTION FOR TREATMENT OF CALVES (57163)

#### Supplier's company name, address and phone number

Company name of supplier	:	MSD
Address	:	Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone	:	048-588-8411
E-mail address	:	EHSDATASTEWARD@msd.com
Emergency telephone number	:	+1-908-423-6000

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

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

### 2. HAZARDS IDENTIFICATION

GHS classification of chemic Skin corrosion/irritation	al   :	product Category 2
Serious eye damage/eye irri- tation	:	Category 2
Short-term (acute) aquatic hazard	:	Category 3
Long-term (chronic) aquatic hazard	:	Category 3
GHS label elements		
Hazard pictograms	:	
Signal word	:	Warning



## Halofuginone Formulation

Version 10.0	Revision Date: 2024/09/28	SDS Number: 845719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26		
Haza	rd statements		skin irritation. serious eye irritation. to aquatic life with long lasting effects.		
Precautionary statements		<ul> <li>Prevention:</li> <li>P264 Wash skin thoroughly after handling.</li> <li>P273 Avoid release to the environment.</li> <li>P280 Wear protective gloves/ eye protection/ face protection.</li> </ul>			
		P305 + P351 - for several mir easy to do. Co P332 + P313   tion. P337 + P313   tention.	F ON SKIN: Wash with plenty of water. + P338 IF IN EYES: Rinse cautiously with water hutes. Remove contact lenses, if present and ontinue rinsing. f skin irritation occurs: Get medical advice/ atten- f eye irritation persists: Get medical advice/ at- Take off contaminated clothing and wash it before		
		<b>Disposal:</b> P501 Dispose disposal plant.	of contents/ container to an approved waste		

# Other hazards which do not result in classification None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	: Mixture	

### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Lactic acid	50-21-5	>= 1 - < 10	2-1369
Benzoic acid	65-85-0	>= 0.1 - < 1	3-1397
Halofuginone	82186-71-8	>= 0.025 - < 0.1	-

### 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air.
		Get medical attention if symptoms occur.
In case of skin contact	:	In case of contact, immediately flush skin with plenty of water
		for at least 15 minutes while removing contaminated clothing



Version 10.0	Revision Date: 2024/09/28		OS Number: 5719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26
In cas	se of eye contact	:	In case of cont for at least 15	before reuse. an shoes before reuse. act, immediately flush eyes with plenty of wate minutes. emove contact lens, if worn.
lf swa	allowed	:	<ul> <li>If swallowed, DO NOT induce vomiting.</li> <li>Get medical attention if symptoms occur.</li> <li>Rinse mouth thoroughly with water.</li> </ul>	
and e delay		:	Causes skin irr Causes seriou	
Prote	ction of first-aiders	:	and use the re	nders should pay attention to self-protection, commended personal protective equipment ntial for exposure exists (see section 8).
	s to physician	•		atically and supportively.
	GHTING MEASURES			
Suita	ble extinguishing media	:	Water spray Alcohol-resista Carbon dioxide Dry chemical	
Unsu media	itable extinguishing a	:	None known.	
Spec fightir	ific hazards during fire- ng	:	Exposure to co	mbustion products may be a hazard to health
Haza ucts	rdous combustion prod-	:	Carbon oxides	
Speci ods	ific extinguishing meth-	:	cumstances ar Use water spra	ing measures that are appropriate to local cir- nd the surrounding environment. ay to cool unopened containers. naged containers from fire area if it is safe to
	ial protective equipment efighters	:		fire, wear self-contained breathing apparatus protective equipment.
. ACCIDI	ENTAL RELEASE MEAS	SUF	RES	
	onal precautions, protec- quipment and emer-	:		protective equipment. ndling advice (see section 7) and personal pro

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment.





Version 10.0	Revision Date: 2024/09/28	SDS Number: 845719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26
		Prevent spread barriers). Retain and disp	leakage or spillage if safe to do so. ing over a wide area (e.g. by containment or oil oose of contaminated wash water. s should be advised if significant spillages ained.
Methods and materials for containment and cleaning up		For large spills, ment to keep m be pumped, sto Clean up remai bent. Local or nationa posal of this ma employed in the mine which reg Sections 13 and	ert absorbent material. provide dyking or other appropriate contain- aterial from spreading. If dyked material can re recovered material in appropriate container. ning materials from spill with suitable absor- al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.

### 7. HANDLING AND STORAGE

Handling		
Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation Advice on safe handling	:	Use only with adequate ventilation.
Avoidance of contact Hygiene measures	:	Oxidizing agents If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
Storage		
Conditions for safe storage	:	Keep in properly labelled containers.



Version	Revision Date: 2024/09/28	SDS Number:	Date of last issue: 2023/12/08
10.0		845719-00022	Date of first issue: 2016/08/26
Mater	rials to avoid		ance with the particular national regulations. h the following product types: agents

Packaging material

: Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Concentra- tion standard / Permissible con- centration	Basis	
Benzoic acid	65-85-0	TWA (Inhal- able fraction and vapor)	0.5 mg/m3	ACGIH	
Halofuginone	82186-71-8	TWA	5 µg/m3 (OEB 4)	Internal	
	Further information: DSEN, Skin				
		Wipe limit	50 µg/100 cm <sup>2</sup>	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 poten- tial exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.
Personal protective equipmen	t
Respiratory protection :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type : Hand protection	Organic vapour type
Material :	Chemical-resistant gloves
Remarks :	Consider double gloving. Impermeable protective gloves
Eye protection :	Wear safety glasses with side shields or goggles.

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 aerosols.
Skin and body protection	:	Work uniform or laboratory coat.



Version 10.0	Revision Date: 2024/09/28		9S Number: 5719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26	
			task being perform posable suits) to Use appropriate of	arments should be used based upon the med (e.g., sleevelets, apron, gauntlets, dis- avoid exposed skin surfaces. degowning techniques to remove potentially	
9 PHYSI	CAL AND CHEMICAL P	ROF	contaminated clo	tning.	
	ical state	:	liquid		
Colo		:	yellow		
Odou	ır	:	odourless		
Odou	ur Threshold	:	No data availabl	e	
Melti	ng point/freezing point	:	No data availabl	e	
	ng point, initial boiling and boiling range	:	No data availabl	e	
Flam	mability (solid, gas)	:	Not applicable		
Flam	mability (liquids)	:	No data availabl	e	
U	er explosion limit and upp pper explosion limit / Up er flammability limit				
	Lower explosion limit / Lower flammability limit		: No data available		
Flash	n point	:	No data availabl	e	
Deco	omposition temperature	:	No data availabl	e	
pН		:	2.1 - 3		
Evap	oration rate	:	No data availabl	e	
Auto	-ignition temperature	:	No data availabl	e	
Visco Vi	osity iscosity, kinematic	:	No data availabl	e	
	bility(ies) /ater solubility	:	No data availabl	e	
	tion coefficient: n- nol/water	:	No data availabl	e	
Vapo	our pressure	:	No data availabl	e	



## Halofuginone Formulation

Version 10.0	Revision Date: 2024/09/28	SDS Numb 845719-00		e of last issue: 2023/12/08 e of first issue: 2016/08/26		
	sity and / or relative den ensity		a available			
Relat	tive vapour density	: No dat	a available			
Explo	osive properties	: Not ex	olosive			
Oxidi	zing properties	ties : The substance or mixture is not classified as o				
Mole	cular weight	: No dat	a available			
	Particle characteristics Particle size		: No data available			
10. STAB		۲				
Chen	Reactivity Chemical stability Possibility of hazardous reac- tions		ssified as a rea under normal c act with strong (			
Incor	litions to avoid npatible materials irdous decomposition ucts	: Oxidizi	<ul> <li>None known.</li> <li>Oxidizing agents</li> <li>No hazardous decomposition products are known.</li> </ul>			
11. TOXIC						
	Information on likely routes of exposure		on ntact n ntact			
	<b>e toxicity</b> classified based on avai	lable informat	00			
	ponents:		011.			
	ic acid:					
	e oral toxicity		Rat): > 2,000 mg s: Based on da	g/kg ta from similar materials		
Acute	e inhalation toxicity	: LC50 (Rat): > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403				

Assessment: Corrosive to the respiratory tract. Remarks: Based on data from similar materials



ersion ).0	Revision Date: 2024/09/28	SDS Number:Date of last issue: 2023/12/08845719-00022Date of first issue: 2016/08/26	
		Assessment: The substance or mixture has no acute toxicity Remarks: Based on data from similar materials	derma
II Benz	oic acid:		
	e oral toxicity	: LD50 (Rat): 2,250 mg/kg Method: OECD Test Guideline 401	
Acute	inhalation toxicity	: LC50 (Rat): > 12.2 mg/l Exposure time: 4 h Test atmosphere: dust/mist	
Acute	e dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute toxicity	derma
Halof	uginone:		
Acute	e oral toxicity	: LD50 (Rat): 30 mg/kg	
		LD50 (Mouse): 5 mg/kg	
Acute	inhalation toxicity	: LC50 (Rat): 0.053 mg/l Test atmosphere: dust/mist	
Acute	e dermal toxicity	: LD50 (Rabbit): 16 mg/kg	
	corrosion/irritation es skin irritation.		
<u>Com</u>	ponents:		
Lacti	c acid:		
Speci Metho Resu Rema	od It	<ul> <li>Rabbit</li> <li>OECD Test Guideline 404</li> <li>Corrosive after 1 to 4 hours of exposure</li> <li>Based on data from similar materials</li> </ul>	
Benz	oic acid:		
Speci Resu		: Guinea pig : Skin irritation	
Halof	uginone:		
Speci Resu	ies	: Rabbit : Skin irritation	

## Serious eye damage/eye irritation

Causes serious eye irritation.



ersion 0.0	Revision Date: 2024/09/28		DS Number: 5719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26
<u>Com</u>	ponents:			
Lacti	c acid:			
Speci Rema	ies arks	:	Chicken eye Based on data	from similar materials
Resu	lt	:	Irreversible effe	ects on the eye
	oic acid:			
Speci Resu		:	Rabbit Irreversible effe	ects on the eye
Halof	uginone:			
Resu	lt	:	Severe irritation	ו
Resp	iratory or skin sens	sitisatio	on	
Not c	sensitisation lassified based on av iratory sensitisatio		information.	
-	lassified based on av		information.	
Com	ponents:			
Lacti	c acid:			
Test		:	Buehler Test	
	sure routes	:	Skin contact	
Speci Resu		:	Guinea pig negative	
Rema		:		from similar materials
	oic acid:			
Test	Type sure routes	:	Local lymph no Skin contact	de assay (LLNA)
Speci		:	Mouse	
Resu		:	negative	
	uginone:			
	sure routes	:	Dermal	
			Guinea pig Sensitiser	
Speci		:	Guinea pig Sensitiser	
	n <b>cell mutagenicity</b> lassified based on av	vailable	information.	



ersion 0.0	Revision Date: 2024/09/28	SDS Number: 845719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26
Geno	otoxicity in vitro	Method: OECE Result: negativ	cterial reverse mutation assay (AMES) D Test Guideline 471 re ed on data from similar materials
		Method: OECE Result: negativ	vitro mammalian cell gene mutation test D Test Guideline 476 ve ed on data from similar materials
		Method: OECE Result: negativ	romosome aberration test in vitro D Test Guideline 473 re ed on data from similar materials
II Benz	oic acid:		
	otoxicity in vitro	: Test Type: Chr Result: equivor	romosome aberration test in vitro cal
		Test Type: in v Result: negativ	ritro micronucleus test re
Geno	otoxicity in vivo	: Test Type: Roo Species: Rat Application Ro Result: negativ	
Halof	fuginone:		
	otoxicity in vitro	: Test Type: Am Result: positive	
		Test Type: Mo Result: negativ	use Lymphoma /e
			romosomal aberration uman lymphoblastoid cells /e
			A damage and repair, unscheduled DNA syn- nalian cells (in vitro) re
Geno	otoxicity in vivo	: Test Type: Mic Species: Mous Cell type: Bone Application Ro Result: negativ	e e marrow ute: Oral
		-	ogenetic assay



	Te	esult: negativ	
	Te	esult: negativ	_
	Te		e
	A	est Type: DN/ pecies: Mouse oplication Rou esult: negative	e ute: Oral
genicity			
sified based on ava	ailable info	ormation.	
ents:			
cid:			
on Route e time	: In : 2 : ne	gestion Years egative	from similar materials
none:			
on Route	: O : 0.	ral 24 mg/kg boc	dy weight
on Route e time	: O : 63 : 0.	ral 3 weeks 36 mg/kg boc	dy weight
on Route e time	: O : 26 : 0.	ral 6 Months 09 - 0.18 mg/	′kg body weight
ictive toxicity			
	ailable info	ormation.	
c <b>id:</b> n foetal develop-	SI Al	pecies: Mouse oplication Rou	ute: Ingestion
acid:			
n fertility	: Te	est Type: Fou	r-generation reproduction toxicity study
	sified based on avaients: cid: on Route a time on Route on Route a time on Route a time on Route a time on Route a time con Route a time	sified based on available info ents: cid: cid: con Route : In a time : 2 in ne con Route : O con Route	sified based on available information. <b>rents:</b> <b>cid:</b> (a) Route : Ingestion (a) time : 2 Years (b) negative : Based on data <b>fnone:</b> (c) Route : Oral (c) 0.24 mg/kg bood (c) negative (c) Rat (c) 0.24 mg/kg bood (c) negative (c) Rat (c) 0.36 mg/kg bood (c) negative (c) Rat (c) 0.36 mg/kg bood (c) negative (c) 0.36 mg/kg bood (c) 0



ersion 0.0	Revision Date: 2024/09/28	SDS Number: 845719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26
		Species: Rat Application Ro Result: negati	oute: Ingestion ive
Halo	fuginone:		
	ts on fertility		se
		Test Type: Fe Species: Dog Application Ro Fertility: LOAE Result: Effects	oute: Oral EL: 0.067 mg/kg body weight
		Species: Mou Application Ro General Toxic Symptoms: Ro	oute: Oral city F1: LOAEL: 0.063 mg/kg body weight educed body weight fects on fertility and early embryonic develop-
Effec ment	ts on foetal develop-	Species: Rat Application Ro General Toxic Embryo-foeta	nbryo-foetal development oute: Oral city Maternal: LOAEL: 0.34 mg/kg body weight I toxicity: NOAEL: 0.67 mg/kg body weight nbryo-foetal toxicity, No teratogenic effects
		Species: Rabl Application Ro General Toxic Embryo-foetal	
Repro sessr	oductive toxicity - As- ment		ce of adverse effects on sexual function and I on animal experiments.
	<b>F - single exposure</b> lassified based on avai	able information.	
STO	<b>Γ - repeated exposure</b> lassified based on avai		
<u>Com</u>	ponents:		
	oic acid:		at/miat/fuma)

Exposure routes

: inhalation (dust/mist/fume)



Image: Argent Organs	Version 10.0	Revision Date: 2024/09/28	SDS Number:Date of last issue: 2023/12/08845719-00022Date of first issue: 2016/08/26	
Assessment       :       Shown to produce significant health effects in animals at concentrations of 0.02 mg//6h/d or less.         Halofuginone:       Target Organs       :       Blood         Assessment       :       Causes damage to organs through prolonged or repeated exposure.         Repeated dose toxicity       Components:       Lactic acid:         Species       :       Rat         NOAEL       :       > 100 mg/kg         Application Route       :       Ingestion         it is to be a set of a data from similar materials       Species         Species       :       Rat         LOAEL       :       > 13 Weeks         Remarks       :       Based on data from similar materials         Species       :       Rat         LOAEL       :       386 mg/kg         Application Route       :       Shin contact         Exposure time       :       13 Weeks         Benzoic acid:       Species       :         Species       :       Note         LOAEL       :       :         LOAEL       :       :         LOAEL       :       :         Species       :       Mouse         NOAEL <td< td=""><td>11</td><td></td><td></td><td></td></td<>	11			
Target Organs       :       Blood         Assessment       :       Causes damage to organs through prolonged or repeated exposure.         Repeated dose toxicity         Components:         Lactic acid:         Species       :       Rat         NOAEL       :       > 100 mg/kg         Application Route       :       Ingestion         Exposure time       :       13 Weeks         Remarks       :       Based on data from similar materials         Species       :       Rat         LOAEL       :       986 mg/kg         Application Route       :       Shin contact         Exposure time       :       13 Weeks         Benzoic acid:       :       Species         Species       :       Rat         LOAEL       :       :         Species       :       Rat         LOAEL       :       :         NOAEL       :       :         Mapplication Route       :       :         Species       :       Mouse         NOAEL       :       :         LOAEL       :       :         Target Organs			: Shown to produce significant health effects in animals at o	con-
Assessment       :       Causes damage to organs through prolonged or repeated exposure.         Repeated dose toxicity       Components:         Lactic acid:       Species       :         Species       :       Rat         NOAEL       :       > 100 mg/kg         Application Route       :       Ingestion         Exposure time       :       13 Weeks         Remarks       :       Based on data from similar materials         Species       :       Rat         LOAEL       :       866 mg/kg         Application Route       :       Skin contact         Exposure time       :       13 Weeks         Benzoic acid:       :       Species         Species       :       Rat         LOAEL       :       < 0.025 mg/l	Halof	uginone:		
Species       :         Ret       NOAEL       :         NOAEL       :       > 100 mg/kg         Application Route       :       Ingestion         Exposure time       :       13 Weeks         Remarks       :       Based on data from similar materials         Species       :       Rat         LOAEL       :       886 mg/kg         Application Route       :       Skin contact         Exposure time       :       13 Weeks         Benzoic acid:       :       Species         Species       :       Rat         LOAEL       :       < 0.025 mg/l			: Causes damage to organs through prolonged or repeated	I
Lactic acid:         Species       :       Rat         NOAEL       :       > 100 mg/kg         Application Route       :       Ingestion         Exposure time       ::       13 Weeks         Remarks       :       Based on data from similar materials         Species       ::       Rat         LOAEL       ::       886 mg/kg         Application Route       ::       Skin contact         Exposure time       ::       13 Weeks         Benzoic acid:       :       Species         Species       ::       Rat         LOAEL       ::       < 0.025 mg/l	Repe	ated dose toxicity		
Species       :       Rat         NOAEL       :       > 100 mg/kg         Application Route       :       Ingestion         Exposure time       :       13 Weeks         Remarks       :       Based on data from similar materials         Species       :       Rat         LOAEL       :       886 mg/kg         Application Route       :       Skin contact         Exposure time       :       13 Weeks         Benzoic acid:       :       Species         Species       :       Rat         LOAEL       :       < 0.025 mg/l	Com	oonents:		
NOAEL       : > 100 mg/kg         Application Route       : Ingestion         Exposure time       : 13 Weeks         Remarks       : Based on data from similar materials         Species       : Rat         LOAEL       : 886 mg/kg         Application Route       : Skin contact         Exposure time       : 13 Weeks         Benzoic acid:       :         Species       : Rat         LOAEL       : 0.02 mg/l         Application Route       : inhalation (dust/mist/fume)         Exposure time       : 28 Days         Halofuginone:       :         Species       : Mouse         NOAEL       : 0.07 mg/kg         LOAEL       : 0.16 mg/kg         Application Route       : Oral         Exposure time       : 4 Weeks         Target Organs       : Blood         Species       : Rat         NOAEL       : 0.13 mg/kg         LOAEL       : 0.88 mg/kg         Application Route       : Oral         Species       : Rat         NOAEL       : 0.38 mg/kg         Application Route       : Oral         Species       : Rat         NOAEL	Lacti	c acid:		
Application Route       :       Ingestion         Exposure time       :       13 Weeks         Remarks       :       Based on data from similar materials         Species       :       Rat         LOAEL       :       886 mg/kg         Application Route       :       Skin contact         Exposure time       :       13 Weeks         Benzoic acid:       :       Species         Species       :       Rat         LOAEL       :       < 0.025 mg/l				
Remarks       :       Based on data from similar materials         Species       :       Rat         LOAEL       :       886 mg/kg         Application Route       :       Skin contact         Exposure time       :       13 Weeks         Benzoic acid:				
Species       : Rat         LOAEL       : 886 mg/kg         Application Route       : Skin contact         Exposure time       : 13 Weeks         Benzoic acid:				
LÓAEL : 886 mg/kg Application Route : Skin contact Exposure time : 13 Weeks Benzoic acid: Species : Rat LOAEL : <0.025 mg/l Application Route : inhalation (dust/mist/fume) Exposure time : 28 Days Halofuginone: Species : Mouse NOAEL : 0.07 mg/kg LOAEL : 0.07 mg/kg LOAEL : 0.16 mg/kg Application Route : Oral Exposure time : 4 Weeks Target Organs : Blood Species : Rat NOAEL : 0.13 mg/kg LOAEL : 0.88 mg/kg Application Route : Oral Exposure time : 13 Weeks Target Organs : Liver Species : Lore Species : Dog NOAEL : 0.134 mg/kg LOAEL : 0.134 mg/kg Application Route : Oral				
Application Route       :       Skin contact         Exposure time       :       13 Weeks         Benzoic acid:				
Benzoic acid:         Species       :       Rat         LOAEL       :       < 0.025 mg/l			: Skin contact	
Species       :       Rat         LOAEL       :       < 0.025 mg/l	Expos	sure time	: 13 Weeks	
LÓAEL : < 0.025 mg/l Application Route : inhalation (dust/mist/fume) Exposure time : 28 Days Halofuginone: Species : Mouse NOAEL : 0.07 mg/kg LOAEL : 0.16 mg/kg Application Route : 0 ral Exposure time : 4 Weeks Target Organs : Blood Species : Rat NOAEL : 0.13 mg/kg LOAEL : 0.88 mg/kg Application Route : 0 ral Exposure time : 13 Weeks Target Organs : Liver Species : Dog NOAEL : 0.067 mg/kg LOAEL : 0.134 mg/kg Application Route : 0 ral	Benz	oic acid:		
Application Route       : inhalation (dust/mist/fume)         Exposure time       : 28 Days         Halofuginone:				
Exposure time       : 28 Days         Halofuginone:       Species         Species       : Mouse         NOAEL       : 0.07 mg/kg         LOAEL       : 0.16 mg/kg         Application Route       : Oral         Exposure time       : 4 Weeks         Target Organs       : Blood         Species       : Rat         NOAEL       : 0.13 mg/kg         LOAEL       : 0.08 mg/kg         Application Route       : Oral         Exposure time       : 13 Weeks         Target Organs       : Liver         Species       : Dog         NOAEL       : 0.067 mg/kg         LOAEL       : 0.134 mg/kg         Application Route       : Oral				
Species       :       Mouse         NOAEL       :       0.07 mg/kg         LOAEL       :       0.16 mg/kg         Application Route       :       Oral         Exposure time       :       4 Weeks         Target Organs       :       Blood         Species       :       Rat         NOAEL       :       0.13 mg/kg         LOAEL       :       0.88 mg/kg         Application Route       :       Oral         Exposure time       :       13 Weeks         Target Organs       :       Liver         Species       :       Dog         NOAEL       :       0.067 mg/kg         LOAEL       :       0.134 mg/kg         Application Route       :       Oral				
NOAEL       : 0.07 mg/kg         LOAEL       : 0.16 mg/kg         Application Route       : Oral         Exposure time       : 4 Weeks         Target Organs       : Blood         Species       : Rat         NOAEL       : 0.13 mg/kg         LOAEL       : 0.13 mg/kg         LOAEL       : 0.88 mg/kg         Application Route       : Oral         Exposure time       : 13 Weeks         Target Organs       : Liver         Species       : Dog         NOAEL       : 0.067 mg/kg         LOAEL       : 0.134 mg/kg         Application Route       : 0.134 mg/kg	Halof	uginone:		
LOAEL       : 0.16 mg/kg         Application Route       : Oral         Exposure time       : 4 Weeks         Target Organs       : Blood         Species       : Rat         NOAEL       : 0.13 mg/kg         LOAEL       : 0.88 mg/kg         Application Route       : Oral         Exposure time       : 13 Weeks         Target Organs       : Liver         Species       : Dog         NOAEL       : 0.067 mg/kg         LOAEL       : 0.134 mg/kg         Application Route       : Oral				
Application Route       :       Oral         Exposure time       :       4 Weeks         Target Organs       :       Blood         Species       :       Rat         NOAEL       :       0.13 mg/kg         LOAEL       :       0.88 mg/kg         Application Route       :       Oral         Exposure time       :       13 Weeks         Target Organs       :       Liver         Species       :       Dog         NOAEL       :       0.067 mg/kg         LOAEL       :       0.134 mg/kg         Application Route       :       Oral				
Target Organs       :       Blood         Species       :       Rat         NOAEL       :       0.13 mg/kg         LOAEL       :       0.88 mg/kg         Application Route       :       Oral         Exposure time       :       13 Weeks         Target Organs       :       Liver         Species       :       Dog         NOAEL       :       0.067 mg/kg         LOAEL       :       0.134 mg/kg         Application Route       :       Oral	Applic	cation Route		
Species       : Rat         NOAEL       : 0.13 mg/kg         LOAEL       : 0.88 mg/kg         Application Route       : Oral         Exposure time       : 13 Weeks         Target Organs       : Liver         Species       : Dog         NOAEL       : 0.067 mg/kg         LOAEL       : 0.134 mg/kg         Application Route       : Oral				
NOAEL       : 0.13 mg/kg         LOAEL       : 0.88 mg/kg         Application Route       : Oral         Exposure time       : 13 Weeks         Target Organs       : Liver         Species       : Dog         NOAEL       : 0.067 mg/kg         LOAEL       : 0.134 mg/kg         Application Route       : Oral		0	5 BIOOD	
LOAEL       : 0.88 mg/kg         Application Route       : Oral         Exposure time       : 13 Weeks         Target Organs       : Liver         Species       : Dog         NOAEL       : 0.067 mg/kg         LOAEL       : 0.134 mg/kg         Application Route       : Oral	Speci	ies		
Application Route       :       Oral         Exposure time       :       13 Weeks         Target Organs       :       Liver         Species       :       Dog         NOAEL       :       0.067 mg/kg         LOAEL       :       0.134 mg/kg         Application Route       :       Oral				
Target Organs       :       Liver         Species       :       Dog         NOAEL       :       0.067 mg/kg         LOAEL       :       0.134 mg/kg         Application Route       :       Oral	Applic	cation Route	: Oral	
Species       : Dog         NOAEL       : 0.067 mg/kg         LOAEL       : 0.134 mg/kg         Application Route       : Oral				
NOAEL       : 0.067 mg/kg         LOAEL       : 0.134 mg/kg         Application Route       : Oral		-		
LOAEL : 0.134 mg/kg Application Route : Oral				
Application Route : Oral				
13 / 21				
			13/21	



Version 10.0	Revision Date: 2024/09/28		DS Number: 5719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26
	sure time		13 Weeks	
	et Organs	:	Blood	
NOAI LOAE Applie Expos	Species:NOAEL:LOAEL:Application Route:Exposure time:Target Organs:		Dog 0.075 mg/kg 0.16 mg/kg Oral 26 Weeks Blood	
Not c	ration toxicity lassified based on ava			
-	rience with human e	exposi	lre	
	ponents:			
	fuginone: eral Information	:	No human infor	mation is available.
Inhala	ation	:	Remarks: May o	cause irritation of respiratory tract.
Skin o	contact	:		cause skin irritation and/or dermatitis. sitisation by skin contact. d through skin.
Eye c	contact	:	Remarks: May i	rritate eyes.
12. ECOL	OGICAL INFORMAT	ION		

## Ecotoxicity

### Components:

### Lactic acid:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials



ersion ).0	Revision Date: 2024/09/28		0S Number: 5719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26
			mg/l Exposure time: 72 Method: OECD T	rchneriella subcapitata (green algae)): > 1 2 h est Guideline 201 on data from similar materials
Toxici	ty to microorganisms	:		
Benzo	pic acid:			
Toxici	ty to fish	:	LC50 (Lepomis m Exposure time: 90	acrochirus (Bluegill sunfish)): 44.6 mg/l 6 h
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 44 Method: EPA-660	
Toxici plants	ty to algae/aquatic	:	ErC50 (Pseudoki mg/l Exposure time: 7: Method: OECD T	
			EC10 (Pseudokin mg/l Exposure time: 7: Method: OECD T	
	ty to daphnia and other ic invertebrates (Chron- city)	:	Exposure time: 2	magna (Water flea)): 25 mg/l 1 d est Guideline 211
Toxici	ty to microorganisms	:	IC50: > 1,000 mg Exposure time: 3 Method: OECD T	
Halof	uginone:			
Toxici	ty to fish	:	Exposure time: 9	shus 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: 9	acrochirus (Bluegill sunfish)): 0.12 mg/l 5 h on data from similar materials
Toxici	ty to daphnia and other	:	EC50 (Daphnia m	nagna (Water flea)): 0.02 mg/l



Version 10.0	Revision Date: 2024/09/28	-	OS Number: 5719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26
aquat	tic invertebrates		Exposure time: 48 Remarks: Based	3 h on data from similar materials
Toxic plants	ity to algae/aquatic S	:	Method: OECD T	yrenoidosa (algae)): 46 mg/l est Guideline 201 on data from similar materials
	ctor (Acute aquatic tox-	:	10	
icity) M-Fa toxicit	ctor (Chronic aquatic ty)	:	10	
Persi	stence and degradabil	ity		
Com	ponents:			
	c acid:			
Biode	egradability	:	Result: Not readily Remarks: Based	y biodegradable. on data from similar materials
Benz	oic acid:			
Biode	egradability	:	Result: rapidly de Biodegradation: 8 Exposure time: 35	39.5 %
Halof	uginone:			
Biode	egradability	:	Result: Not readily	y biodegradable.
Bioad	ccumulative potential			
Com	ponents:			
Partit	<b>c acid:</b> ion coefficient: n- ol/water	:	log Pow: -0.62	
Partit	<b>oic acid:</b> ion coefficient: n- ol/water	:	log Pow: 1.88	
Partit	i <b>uginone:</b> ion coefficient: n- ol/water	:	log Pow: 1.18	
Mobi	lity in soil			
<u>Com</u>	ponents:			
Halof	uginone:			
	bution among environ- al compartments	:	log Koc: 3.87 Method: FDA 3.08	3



rsion .0	Revision Date: 2024/09/28	SDS Number: 845719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26
	r <b>dous to the ozone lay</b> oplicable	er	
	<b>adverse effects</b> Ita available		
. DISPO	SAL CONSIDERATIO	NS	
Dispo	osal methods		
Waste	e from residues		ccordance with local regulations. of waste into sewer.
Conta	minated packaging	: Empty containe dling site for re	ers should be taken to an approved waste han cycling or disposal. e specified: Dispose of as unused product.
. TRAN	SPORT INFORMATION	l	
Interr	national Regulations		
UNRT			
	umber	: Not applicable : Not applicable	
Class	er shipping name	: Not applicable	
	diary risk	: Not applicable	
	ng group	: Not applicable	
Label		: Not applicable	
Enviro	onmentally hazardous	: no	
IATA-	DGR		
UN/IC	No.	: Not applicable	
	er shipping name	: Not applicable	
Class		: Not applicable	
	diary risk ng group	: Not applicable : Not applicable	
Label		: Not applicable	
	ng instruction (cargo	: Not applicable	
	ng instruction (passen-	: Not applicable	
	-Code	<b>.</b>	
		: Not applicable	
Prope Class	er shipping name	: Not applicable : Not applicable	
	diary risk	: Not applicable	
	ng group	: Not applicable	
Label		: Not applicable	
	Code	: Not applicable	
	e pollutant	: Not applicable	



Version	Revision Date:	SDS Number:
10.0	2024/09/28	845719-00022

Date of last issue: 2023/12/08 Date of first issue: 2016/08/26

#### **National Regulations**

Refer to section 15 for specific national regulation.

#### Special precautions for user

Not applicable

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

#### **Related Regulations**

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

### Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Lactic acid	>=1 - <10	From April 1st, 2025
benzoic acid	>=0.1 - <1	From April 1st, 2025

### Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Lactic acid	From April 1st, 2025

#### Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Chemical name

Lactic acid (DL-, L-, D-)

## Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable





ersion .0	Revision Date: 2024/09/28	SDS Number: 845719-00022	Date of last issue: 2023/12/08 Date of first issue: 2016/08/26
Ordin	ance on Preventior	n of Hazards Due to S	pecified Chemical Substances
Not ap	oplicable		
	ance on Preventior	n of Lead Poisoning	
	ance on Preventior	n of Tetraalkyl Lead P	oisoning
	ance on Preventior	n of Organic Solvent F	Poisoning
Subst	cement Order of th ances) oplicable	e Industrial Safety an	d Health Law - Attached table 1 (Dangerou
	nous and Deleteric	ous Substances Contr	ol Law
viron			of Specific Chemical Substances in the E the Management Thereof
High	Pressure Gas Safet	y Act	
-	oplicable	-	
Explo	sive Control Law		
Not ap	oplicable		
Vesse	el Safety Law		
Not re	gulated as a danger	ous good	
	on Law		
	gulated as a danger	-	
Marin	e Pollution and Sea	a Disaster Prevention	etc Law
Bulk t	ransportation	: Noxious liquid	substance(Category Z)
Pack	transportation	: Not classified a	as marine pollutant
	otics and Psychotro	-	
		Raw Material (Export / In	mport Permission)
Speci	oplicable fic Narcotic or Psych oplicable	otropic Raw Material (E	Export / Import permission)
	e Disposal and Pub rial waste	lic Cleansing Law	
The c	omponents of this	product are reported	in the following inventories:
AICS		: not determined	3
DSL		: not determined	1
IECS		: not determined	1



## **Halofuginone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/08
10.0	2024/09/28	845719-00022	Date of first issue: 2016/08/26

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

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

#### **Further information**

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data		eChem Portal search results and European Chemicals Agen-
Sheet		cy, http://echa.europa.eu/

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

Date format	:	уууу/	mm/dd					
Full text of other abbreviations								

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA	:	8-hour, time-weighted average

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



Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/08
10.0	2024/09/28	845719-00022	Date of first issue: 2016/08/26

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.

JP / EN