

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version 4.2 Revision Date: 08.12.2023 SDS Number: 9372775-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

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

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product
Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom
Telephone : +1-908-740-4000
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version 4.2 Revision Date: 08.12.2023 SDS Number: 9372775-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H315 Causes skin irritation. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P264 Wash skin thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves/ eye protection/ face protection. Response: P332 + P313 If skin irritation occurs: Get medical advice/ attention. P337 + P313 If eye irritation persists: Get medical advice/ attention. P362 + P364 Take off contaminated clothing and wash it before reuse.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Lactic acid	50-21-5 200-018-0	Skin Corr. 1C; H314 Eye Dam. 1; H318 specific concentra- tion limit Eye Irrit. 2; H319 1 - < 3 %	>= 1 - < 3
Halofuginone	82186-71-8	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 1; H310 Skin Irrit. 2; H315 Eye Dam. 1; H318	>= 0.025 - < 0.1

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version 4.2 Revision Date: 08.12.2023 SDS Number: 9372775-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

		Skin Sens. 1B; H317 Repr. 2; H361f STOT RE 1; H372 (Blood) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 <hr/> M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	
--	--	--	--

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- 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 and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Causes skin irritation.
Causes serious eye irritation.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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 vapour or mist.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Gases

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version 4.2 Revision Date: 08.12.2023 SDS Number: 9372775-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Halofuginone	82186-71-8	TWA	5 µg/m ³ (OEB 4)	Internal
Further information: DSEN, Skin				
		Wipe limit	50 µg/100 cm ²	Internal

8.2 Exposure controls

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

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to BS EN 14387

Filter type : Organic vapour type (A)

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	liquid
Colour	:	yellow
Odour	:	odourless
Odour Threshold	:	No data available
pH	:	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
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Lactic acid:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

Acute 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

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version 4.2 Revision Date: 08.12.2023 SDS Number: 9372775-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

Assessment: The substance or mixture has no acute dermal toxicity

Remarks: Based on data from similar materials

Halofuginone:

Acute 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 dermal toxicity : LD50 (Rabbit): 16 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

Lactic acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Corrosive after 1 to 4 hours of exposure
Remarks : Based on data from similar materials

Halofuginone:

Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Lactic acid:

Species : Chicken eye
Remarks : Based on data from similar materials

Result : Irreversible effects on the eye

Halofuginone:

Result : Severe irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version 4.2 Revision Date: 08.12.2023 SDS Number: 9372775-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

Components:

Lactic acid:

Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

Halofuginone:

Exposure routes : Dermal
Species : Guinea pig
Result : Sensitiser

Germ cell mutagenicity

Not classified based on available information.

Components:

Lactic acid:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Halofuginone:

Genotoxicity in vitro : Test Type: Ames test
Result: positive

Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Test system: human lymphoblastoid cells
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Test Type: Cytogenetic assay
Species: Rat
Application Route: Oral
Result: negative

Test Type: DNA Repair
Species: Mouse
Application Route: Oral
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Lactic acid:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative
Remarks : Based on data from similar materials

Halofuginone:

Species : Mouse
Application Route : Oral
NOAEL : 0.24 mg/kg body weight
Result : negative

Species : Rat
Application Route : Oral
Exposure time : 63 weeks
NOAEL : 0.36 mg/kg body weight
Result : negative

Species : Rat
Application Route : Oral
Exposure time : 26 Months
NOAEL : 0.09 - 0.18 mg/kg body weight
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Lactic acid:

Effects on foetal develop- : Test Type: Embryo-foetal development

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

ment
Species: Mouse
Application Route: Ingestion
Result: negative

Halofuginone:

Effects on fertility

: Test Type: Fertility
Species: Mouse
Application Route: Oral
Fertility: NOAEL: 0.126 mg/kg body weight
Result: No effects on fertility

Test Type: Fertility
Species: Dog
Application Route: Oral
Fertility: LOAEL: 0.067 mg/kg body weight
Result: Effects on fertility

Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Oral
General Toxicity F1: LOAEL: 0.063 mg/kg body weight
Symptoms: Reduced body weight
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development

: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 0.34 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 0.67 mg/kg body weight
Result: No embryo-foetal toxicity, No teratogenic effects

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
General Toxicity Maternal: NOAEL: 0.025 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 0.076 mg/kg body weight
Result: No embryo-foetal toxicity, No teratogenic effects

Reproductive toxicity - Assessment

: Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Halofuginone:

Target Organs : Blood

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version 4.2 Revision Date: 08.12.2023 SDS Number: 9372775-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

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 : 886 mg/kg
Application Route : Skin contact
Exposure time : 13 Weeks

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
Exposure time : 13 Weeks
Target Organs : Liver

Species : Dog
NOAEL : 0.067 mg/kg
LOAEL : 0.134 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Blood

Species : Dog
NOAEL : 0.075 mg/kg
LOAEL : 0.16 mg/kg
Application Route : Oral
Exposure time : 26 Weeks
Target Organs : Blood

Aspiration toxicity

Not classified based on available information.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version 4.2 Revision Date: 08.12.2023 SDS Number: 9372775-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

Experience with human exposure

Components:

Halofuginone:

General Information : No human information is available.
Inhalation : Remarks: May cause irritation of respiratory tract.
Skin contact : Remarks: May cause skin irritation and/or dermatitis.
May cause sensitisation by skin contact.
Can be absorbed through skin.
Eye contact : Remarks: May irritate eyes.

SECTION 12: Ecological information

12.1 Toxicity

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

NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 : > 10 - 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Halofuginone:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1.8 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

LC50 (Cyprinus carpio (Carp)): 0.3 mg/l

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

Exposure time: 72 h
Remarks: Based on data from similar materials

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.12 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.02 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Chlorella pyrenoidosa (algae)): 46 mg/l
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 10

M-Factor (Chronic aquatic toxicity) : 10

12.2 Persistence and degradability

Components:

Lactic acid:

Biodegradability : Result: Not readily biodegradable.
Remarks: Based on data from similar materials

Halofuginone:

Biodegradability : Result: Not readily biodegradable.

12.3 Bioaccumulative potential

Components:

Lactic acid:

Partition coefficient: n-octanol/water : log Pow: -0.62

Halofuginone:

Partition coefficient: n-octanol/water : log Pow: 1.18

12.4 Mobility in soil

Components:

Halofuginone:

Distribution among environmental compartments : log Koc: 3.87
Method: FDA 3.08

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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

14.1 UN number

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the following entries should be considered:
Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version 4.2 Revision Date: 08.12.2023 SDS Number: 9372775-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : not.
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable
Control of Major Accident Hazards Regulations 2015 (COMAH) : Not applicable

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H300 : Fatal if swallowed.
H310 : Fatal in contact with skin.
H314 : Causes severe skin burns and eye damage.
H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
H330 : Fatal if inhaled.
H361f : Suspected of damaging fertility.
H372 : Causes damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

Skin Corr. : Skin corrosion
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AICC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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

Further information

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

Classification of the mixture:

Skin Irrit. 2	H315
Eye Irrit. 2	H319
Aquatic Chronic 3	H412

Classification procedure:

Calculation method
Calculation method
Calculation method

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	08.12.2023	9372775-00007	Date of first issue: 27.08.2021

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.

GB / EN