according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

Skin irritation, Category 2 H315: Causes skin irritation.

Eye irritation, Category 2 H319: Causes serious eye irritation.

Long-term (chronic) aquatic hazard, Cat-H412: Harmful to aquatic life with long lasting ef-

egory 3 fects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal word : Warning

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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.

Ecological information: 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.

Toxicological information: 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.

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 EUH071	>= 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
6.1		862942-00024	Date of first issue: 26.08.2016
			Skin Sens. 1B; H317 Repr. 2; H361f STOT RE 1; H372 (Blood) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10 Acute toxicity estimate Acute dermal toxicity: 16 mg/kg

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 ad-

vice 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 862942-00024 Date of first issue: 26.08.2016 6.1

> 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.

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 prod- : Carbon oxides

ucts

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 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 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 pro-

tective equipment recommendations (see section 8).

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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.

Local authorities should be advised if significant spillages

cannot be contained.

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 absor-

bent.

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 deter-

mine 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 as-

sessment

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 contami-

nated 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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

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/m3 (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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to NS EN 14387

Filter type : Organic vapour type (A)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : yellow

Odour : odourless

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

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

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 2,1 - 3

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 6.1
 28.09.2024
 862942-00024
 Date of first issue: 26.08.2016

Vapour pressure : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : 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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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.

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 862942-00024 Date of first issue: 26.08.2016 6.1

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 syn-

thesis in mammalian cells (in vitro)

Result: negative

Genotoxicity in vivo Test Type: Micronucleus test

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 Oral Application Route

NOAEL 0,24 mg/kg body weight

Result negative

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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-

ment

Test Type: Embryo-foetal development

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 develop-

ment were detected.

Effects on foetal develop-

ment

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 6.1
 28.09.2024
 862942-00024
 Date of first issue: 26.08.2016

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 - As-

sessment

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

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

Target Organs : Liver

Species : Dog

NOAEL : 0,067 mg/kg LOAEL : 0,134 mg/kg Application Route : Oral

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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered 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.

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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/I

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

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 tox-

icity)

10

M-Factor (Chronic aquatic

toxicity)

: 10

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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

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 consid-

ered 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID 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
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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Conditions of restriction for the following entries should be considered: Number on list 3

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

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

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EC) on substances that deplete the ozone

layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

: Not applicable

Not applicable

Not applicable

Not applicable

: Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

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.

EUH071 : Corrosive to the respiratory tract.

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
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; AIIC - 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 La-

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Halofuginone Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.1 28.09.2024 862942-00024 Date of first issue: 26.08.2016

boratory 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

Sheet

Skin Irrit. 2

Eye Irrit. 2

Aquatic Chronic 3

Sources of key data used to compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Classification procedure:

Classification of the mixture:

H315 Calculation method
H319 Calculation method
H412 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 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.

NO / EN