

Halofuginone Formulation

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|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | 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 chemical product

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Hazard pictograms : 

Signal word : Warning

Hazard statements : H315 Causes skin irritation.

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

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:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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 | > 0 - < 10 | 2-1369 |
| Benzoic acid | 65-85-0 | > 0 - < 10 | 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 advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

| | | |
|---|---|---|
| | | 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. |
| Most important symptoms and effects, both acute and delayed | : | Causes skin irritation. Causes serious eye irritation. |
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician | : | Treat symptomatically and supportively. |

5. FIREFIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides |
| 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. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. |

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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.

Avoidance of contact : Oxidizing agents

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.

Storage

Conditions for safe storage : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types: Strong oxidizing agents

Packaging material : Unsuitable material: None known.

Halofuginone Formulation

Version 9.0 Revision Date: 2023/12/08 SDS Number: 845719-00021 Date of last issue: 2023/09/30
 Date of first issue: 2016/08/26

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 parameters / Reference concentration / Permissible concentration | Basis |
|--------------|---------------------------------|------------------------------------|--|----------|
| Benzoic acid | 65-85-0 | TWA (Inhalable fraction and vapor) | 0.5 mg/m ³ | ACGIH |
| Halofuginone | 82186-71-8 | TWA | 5 µg/m ³ (OEB 4) | Internal |
| | Further information: DSEN, Skin | | | |
| | | Wipe limit | 50 µg/100 cm ² | Internal |

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

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| Physical state | : | liquid |
| Colour | : | yellow |
| Odour | : | odourless |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Boiling point, initial boiling point and boiling range | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Lower explosion limit and upper explosion limit / flammability limit | : | |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | 2.1 - 3 |
| Evaporation rate | : | No data available |
| Auto-ignition temperature | : | No data available |
| Viscosity | : | |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | : | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |
| Density and / or relative density | : | |
| Density | : | No data available |
| Relative vapour density | : | No data available |
| Explosive properties | : | Not explosive |

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

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

Molecular weight : No data available

Particle characteristics
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Benzoic acid:

Acute oral toxicity : LD50 (Rat): 2,250 mg/kg
Method: OECD Test Guideline 401

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

| | | |
|---------------------------|---|---|
| Acute inhalation toxicity | : | LC50 (Rat): > 12.2 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity |

Halofuginone:

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| 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 |

Benzoic acid:

| | | |
|---------|---|-----------------|
| Species | : | Guinea pig |
| Result | : | Skin irritation |

Halofuginone:

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|---------|---|-----------------|
| 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 |

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| Result | : | Irreversible effects on the eye |
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Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

Benzoic acid:

| | |
|---------|-----------------------------------|
| Species | : Rabbit |
| Result | : Irreversible effects on the eye |

Halofuginone:

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|--------|---------------------|
| 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 |

Benzoic acid:

| | |
|-----------------|---------------------------------|
| Test Type | : Local lymph node assay (LLNA) |
| Exposure routes | : Skin contact |
| Species | : Mouse |
| Result | : negative |

Halofuginone:

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|-----------------|--------------|
| 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 |

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

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

Benzoic acid:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
 Result: equivocal

Test Type: in vitro micronucleus test
 Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
 Species: Rat
 Application Route: Ingestion
 Result: negative

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
 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

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

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 development | : Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative |
|-------------------------------|--|

Benzoic acid:

| | |
|----------------------|--|
| Effects on fertility | : Test Type: Four-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative |
|----------------------|--|

Halofuginone:

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| Effects on fertility | : Test Type: Fertility Species: Mouse |
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Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

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| | 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:**Benzoic acid:**

| | |
|-----------------|---|
| Exposure routes | : inhalation (dust/mist/fume) |
| Target Organs | : Lungs |
| Assessment | : Shown to produce significant health effects in animals at concentrations of 0.02 mg/l/6h/d or less. |

Halofuginone:

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| Target Organs | : Blood |
| Assessment | : Causes damage to organs through prolonged or repeated |

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

|| exposure.

Repeated dose toxicity**Components:****Lactic acid:**

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| 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 | : Rat |
| LOAEL | : < 0.025 mg/l |
| Application Route | : inhalation (dust/mist/fume) |
| Exposure time | : 28 Days |

Halofuginone:

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|-------------------|--------------|
| 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 |

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

|| Target Organs : Blood

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Halofuginone:

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| 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. |

12. ECOLOGICAL INFORMATION

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 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 |

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Benzoic acid:

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| Toxicity to fish | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): 44.6 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: EPA-660/3-75-009 |
| Toxicity to algae/aquatic plants | : | ErC50 (Pseudokirchneriella subcapitata (green algae)): > 33.1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| | | EC10 (Pseudokirchneriella subcapitata (green algae)): 3.4 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 25 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 |
| Toxicity to microorganisms | : | IC50: > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 |

Halofuginone:

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| 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- | : | 10 |

Halofuginone Formulation

Version 9.0 Revision Date: 2023/12/08 SDS Number: 845719-00021 Date of last issue: 2023/09/30
Date of first issue: 2016/08/26

icity)
M-Factor (Chronic aquatic toxicity) : 10

Persistence and degradability**Components:****Lactic acid:**

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

Benzoic acid:

Biodegradability : Result: rapidly degradable
Biodegradation: 89.5 %
Exposure time: 35 d

Halofuginone:

Biodegradability : Result: Not readily biodegradable.

Bioaccumulative potential**Components:****Lactic acid:**

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

Benzoic acid:

Partition coefficient: n-octanol/water : log Pow: 1.88

Halofuginone:

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

Mobility in soil**Components:****Halofuginone:**

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

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

- UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR

- UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

- UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

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 | >0 - <10 | From April 1st, 2025 |
| benzoic acid | >0 - <10 | 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 |

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

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION**Further information**

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 Agen-

Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

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

Date format : yyyy/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

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.

SAFETY DATA SHEET



Halofuginone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
| 9.0 | 2023/12/08 | 845719-00021 | Date of first issue: 2016/08/26 |

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