SAFETY DATA SHEET
Halofuginone Formulation

Version 3.10 Revision Date: 10.10.2020 SDS Number: 845723-00013 Date of last issue: 13.09.2019 Date of first issue: 26.08.2016

Section 1: Identification

Product name: Halofuginone Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908 Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

Section 2: Hazard identification

GHS Classification
Serious eye damage/eye irritation: Category 2A

GHS label elements
Hazard pictograms: ⚠️
Signal word: Warning
Hazard statements: H319 Causes serious eye irritation.
Precautionary statements: Prevention:
P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.

Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Other hazards which do not result in classification
None known.
SAFETY DATA SHEET

Halofuginone Formulation

Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactic acid</td>
<td>CAS-No. 50-21-5 Concentration (≥ 1 - &lt; 3)</td>
</tr>
<tr>
<td>Halofuginone</td>
<td>CAS-No. 82186-71-8 Concentration (&lt; 1)</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

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

In case of skin contact: In case of contact, immediately flush skin with plenty of water. Remove 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.

Most important symptoms and effects, both acute and delayed: Causes serious eye irritation.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

Section 5: Fire-fighting measures

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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.
Section 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.

- **Methods and materials for containment and cleaning up**: Soak up with inert absorbent material. For large spills, provide diking 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.

Section 7: Handling and storage

- **Technical measures**: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

- **Local/Total ventilation**: Use only with adequate ventilation.

- **Advice on safe handling**: Do not get on skin or clothing. Avoid inhalation of 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
Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halofuginone</td>
<td>82186-71-8</td>
<td>TWA</td>
<td>5 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 50 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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: Chemical-resistant gloves

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 facemask 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.

Section 9: 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

### Flammability (liquids)
- No data available

### 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.

### Molecular weight
- No data available

### Particle size
- No data available
SAFETY DATA SHEET

Halofuginone Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

Section 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.

Section 11: Toxicological information

Exposure routes : 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
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
Not classified based on available information.
Components:

Lactic acid:
Species: Rabbit
Result: Skin irritation
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.

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

Chronic toxicity

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

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

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

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
### Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>General Toxicity Maternal</th>
<th>NOAEL: 0.076 mg/kg body weight</th>
<th>Embryo-foetal toxicity: NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL: 0.34 mg/kg body weight</td>
<td></td>
<td></td>
<td>No embryo-foetal toxicity, No teratogenic effects</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>NOAEL: 0.025 mg/kg body weight</td>
<td></td>
<td></td>
<td>No embryo-foetal toxicity, No teratogenic effects</td>
</tr>
</tbody>
</table>

### 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:***

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

### Repeated dose toxicity

#### Components:

**Lactic acid:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 100 mg/kg</td>
<td>Ingestion</td>
<td>13 Weeks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>886 mg/kg</td>
<td>Skin contact</td>
<td>13 Weeks</td>
</tr>
</tbody>
</table>

**Halofuginone:**

<table>
<thead>
<tr>
<th>Species</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td></td>
</tr>
</tbody>
</table>
Halofuginone Formulation

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.

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

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 : EC50 (Daphnia magna (Water flea)): > 100 mg/l
aquatic invertebrates
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
  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

**Persistence and degradability**

**Components:**

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

**Halofuginone:**
Biodegradability: Result: Not readily biodegradable.
Bioaccumulative potential

Components:

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

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

Other adverse effects
No data available

Section 13: Disposal considerations

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

Section 14: Transport information

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture
SAFETY DATA SHEET

Halofuginone Formulation

Version 3.10 Revision Date: 10.10.2020 SDS Number: 845723-00013 Date of last issue: 13.09.2019
Date of first issue: 26.08.2016

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

Section 16: Other information

Further information
Sources of key data used to compile the Safety Data Sheet:

Date format: dd.mm.yyyy

Full text of other abbreviations

AIC - 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 Substanc-
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NZ / EN