1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Halofuginone Formulation

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Serious eye damage/eye irritation : Category 2A
Short-term (acute) aquatic hazard : Category 3
Long-term (chronic) aquatic hazard : Category 3

GHS label elements
Hazard pictograms :

Signal word : Warning
Hazard statements : 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 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.

**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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lactic acid</strong></td>
<td>50-21-5</td>
<td>&gt;= 1 - &lt; 3</td>
<td>2-1369</td>
<td></td>
</tr>
<tr>
<td><strong>Halofuginone</strong></td>
<td>82186-71-8</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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.

### 5. FIREFIGHTING MEASURES

**Suitable extinguishing media:** Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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Date of first issue: 2016/08/26

Unsuitable extinguishing media: None known.
Specific hazards during firefighting:
Hazardous combustion products: Exposure to combustion products may be a hazard to health.
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.

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.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / 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>Further information: DSEN, Skin</td>
<td></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

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

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
10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity</th>
<th>Not classified as a reactivity hazard.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reac-</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>tions</td>
<td></td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition</td>
<td>No hazardous decomposition products are known.</td>
</tr>
<tr>
<td>products</td>
<td></td>
</tr>
</tbody>
</table>

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
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

Germ cell mutagenicity
Not classified based on available information.

Components:

Lactic acid:
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Method: OECD Test Guideline 471
  - Result: negative
  - Remarks: Based on data from similar materials
  - Test Type: In vitro mammalian cell gene mutation test
  - Method: OECD Test Guideline 476
  - Result: negative
  - Remarks: Based on data from similar materials
  - Test Type: Chromosome aberration test in vitro
  - Method: OECD Test Guideline 473
  - Result: negative
  - Remarks: Based on data from similar materials

Halofuginone:
- Genotoxicity in vitro:
  - Test Type: Ames test
  - Result: positive
  - Test Type: Mouse Lymphoma
    - Result: negative
  - Test Type: Chromosomal aberration
    - Test system: human lymphoblastoid cells
    - Result: negative
  - Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
    - Result: negative
Genotoxicity in vivo:
- Test Type: Micronucleus test
  - 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  
  Application Route: Oral  
  General Toxicity F1: LOAEL: 0.063 mg/kg body weight  
  Symptoms: Reduced body weight  
  Result: No effects on fertility and early embryonic development were detected.

**Effects on foetal development**

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

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

**Reproductive toxicity - Assessment**

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

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Components:**

**Halofuginone:**

- Target Organs: Blood  
  Assessment: Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

Components:

Lactic acid:

Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

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

Halofuginone:

Species: Mouse
NOAEL: 0.07 mg/kg
LOAEL: 0.16 mg/kg
Application Route: Oral
Exposure time: 4 Weeks
Target Organs:  Blood

Species: Rat
NOAEL: 0.13 mg/kg
LOAEL: 0.88 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Liver

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

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Halofuginone:

General Information: No human information is available.
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
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 toxicity): 10
M-Factor (Chronic aquatic toxicity): 10

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

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available
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.

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
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**
Not applicable

**Substances Subject to be Indicated Names**
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

**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
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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

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

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 Sys-
SAFETY DATA SHEET

Halofuginone Formulation

Version 5.0 Revision Date: 2021/08/27 SDS Number: 845719-00015 Date of last issue: 2020/10/10 Date of first issue: 2016/08/26

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

JP / EN