SAFETY DATA SHEET

Halofuginone Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Halofuginone Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Skin corrosion/irritation : Category 3
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 : H316 Causes mild 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 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.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lactic acid</td>
<td>50-21-5</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td></td>
<td>Halofuginone</td>
<td>82186-71-8</td>
<td>&gt;= 0.025 - &lt; 0.1</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:**
Causes mild skin irritation.
Halofuginone Formulation

5. FIREFIGHTING 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.
- 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 and personal protective equipment recommendations.

Environmental precautions
- Discharge into the environment must be avoided.
- 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 drying or other appropriate containment to keep material from spreading. If dyed 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

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.
- 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.

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

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:
- Material: Chemical-resistant gloves

Eye protection:
- Remarks: Consider double gloving.
- 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.

**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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>2.1 - 3</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
## 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.

**Product:**
- **Acute oral toxicity**: Acute toxicity estimate: > 5,000 mg/kg
  Method: Calculation method

**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:
   Causes mild skin irritation.

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
   Result: Irreversible effects on the eye
   Remarks: Based on data from similar materials

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
  - 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
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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
  - 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:
12. ECOLOGICAL INFORMATION

Ecotoxicity

Component:

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 (aglae)): 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

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
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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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
Date format : dd.mm.yyyy

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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
SAFETY DATA SHEET

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<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>

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; 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.

IN / EN