SAFETY DATA SHEET

Halofuginone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
5.2	2023/12/08	845716-00020	Date of first issue: 2016/08/26

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Halofuginone Formulation

Other means of identification : HALOCUR (A009802)
HALOCUR ORAL SOLUTION FOR TREATMENT OF CALVES (57163)

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2A

Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

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)
Lactic acid	50-21-5	>= 1 -< 3
Halofuginone	82186-71-8	>= 0.025 -< 0.25

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.
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 (CO2) 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.
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 absor-

bent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to 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. 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.
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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Halofuginone	82186-71-8	TWA	5 µg/m3 (OEB 4)	Internal
	Further information: DSEN, Skin			
		Wipe limit	50 µg/100 cm²	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.
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

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

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

Halofuginone:

Acute oral toxicity : LD50 (Rat): 30 mg/kg

LD50 (Mouse): 5 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0.053 mg/l
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): 16 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

Lactic acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Corrosive after 1 to 4 hours of exposure
Remarks : Based on data from similar materials

Halofuginone:

Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

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.
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 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

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
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.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

Revision Date	:	2023/12/08

Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
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 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 Recom-

mendations 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.

ID / EN