according to the Globally Harmonized System



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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 : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

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

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 2

Serious eye damage/eye irri-

tation

Category 2A

Short-term (acute) aquatic

hazard

Category 3

Long-term (chronic) aquatic

hazard

Category 3

GHS label elements

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Hazard pictograms :

!

Signal word : Warning

Hazard statements : H315 + H319 Causes skin irritation and serious eye irritation.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P264 Wash hands 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 + P317 If skin irritation occurs: Get medical help. P337 + P317 If eye irritation persists: Get medical help.

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 - < 0.1

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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.

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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, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

s : Causes skin irritation and 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 prod- :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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.

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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 deter-

mine 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
Advice on safe handling

Use only with adequate ventilation.

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 as-

sessment

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 cm ²	Internal	

Engineering measures : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Essentially no open handling permitted.

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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 expo-

Chemical-resistant gloves

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Material

: Organic vapour type

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 : No data available

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range

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 characteristics

Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous d

products

No hazardous decomposition products are known.

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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

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist 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

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:

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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:

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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 syn-

thesis 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

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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: RatApplication Route: OralExposure 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 develop- : Test Type: Embryo-foetal development

ment 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

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Symptoms: Reduced body weight

Result: No effects on fertility and early embryonic develop-

ment were detected.

Effects on foetal develop-

ment

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 - As-

sessment

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

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

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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

M-Factor (Acute aquatic tox- :

icity)

10

M-Factor (Chronic aquatic

toxicity)

10

Persistence and degradability

Components:

Lactic acid:

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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 environ- : log Koc: 3.87

mental 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 han-

dling 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

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Transport in bulk according to IMO instruments

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

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

not determined

DSL not determined

IECSC not determined

16. OTHER INFORMATION

Revision Date 28.09.2024

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 Agen-

cy, http://echa.europa.eu/

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

Date format dd.mm.yyyy

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

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Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

IN / EN