

# **Halofuginone Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.2
 08.12.2023
 862857-00019
 Date of first issue: 26.08.2016

**SECTION 1. 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 : Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 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

**SECTION 2. HAZARDS IDENTIFICATION** 

**GHS Classification** 

Skin corrosion/irritation : Category 2

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 : H315 Causes skin irritation.

H319 Causes serious eye irritation.



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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/ atten-

tion.

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention.

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.

### **SECTION 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

### **SECTION 4. FIRST AID MEASURES**

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

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

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

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.



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Get medical attention.

Causes skin irritation.

If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

Causes serious eye irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES** 

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

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 fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

**SECTION 6. ACCIDENTAL RELEASE MEASURES** 

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or

oil barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.



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> Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### **SECTION 7. HANDLING AND STORAGE**

Technical measures See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Use only with adequate ventilation. Advice on safe handling Do not get on skin or clothing.

Avoid inhalation of vapor 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.

Keep in properly labeled containers. Conditions for safe storage

Store in accordance with the particular national regulations.

Do not store with the following product types: Materials to avoid

Strong oxidizing agents

Gases

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis	
		exposure)	concentration		
Halofuginone	82186-71-8	TWA	5 μg/m3 (OEB 4)	Internal	
	Further information: DSEN, Skin				
		Wipe limit	50 μg/100 cm <sup>2</sup>	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.



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Filter type : Organic vapor 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.

### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : yellow

Odor : odorless

Odor 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 : No data available



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flammability limit

Lower explosion limit / Lower :

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition 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

#### **SECTION 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 : Oxidizing agents

products

: No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 



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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:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Corrosive after 1 to 4 hours of exposure Remarks : Based on data from similar materials

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Species : Rabbit Result : Skin irritation



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#### 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 sensitization

#### Skin sensitization

Not classified based on available information.

### Respiratory sensitization

Not classified based on available information.

### **Components:**

### Lactic acid:

Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Remarks : Based on data from similar materials

Halofuginone:

Routes of exposure : Dermal Species : Guinea pig Result : Sensitizer

#### 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



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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
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



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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 fetal development : Test Type: Embryo-fetal development

Species: Mouse

Application Route: Ingestion

Result: negative

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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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: LOAEL: 0,34 mg/kg body weight Embryo-fetal toxicity.: NOAEL: 0,67 mg/kg body weight Result: No embryo-fetal toxicity., No teratogenic effects.

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

General Toxicity Maternal: NOAEL: 0,025 mg/kg body weight



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Embryo-fetal toxicity.: NOAEL: 0,076 mg/kg body weight Result: No embryo-fetal 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
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



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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 sensitization by skin contact.

Can be absorbed through skin.

Eye contact : Remarks: May irritate eyes.

#### **SECTION 12. ECOLOGICAL INFORMATION**

### **Ecotoxicity**

#### Components:

Lactic acid:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

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



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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): 46 mg/l Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox-

icity)

M-Factor (Chronic aquatic

toxicity)

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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

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Partition coefficient: n-

octanol/water

log Pow: 1,18



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Mobility in soil

**Components:** 

Halofuginone:

Distribution among environ- : log Koc: 3,87 mental compartments : Method: FDA 3.08

Other adverse effects

No data available

**SECTION 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.

**SECTION 14. TRANSPORT INFORMATION** 

**International Regulations** 

**UNRTDG** 

Not regulated as a dangerous good

**IATA-DGR** 

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

Not applicable

**SECTION 15. REGULATORY INFORMATION** 

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

mixture

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the

preparation of drugs.

Not applicable

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

AICS : not determined

DSL : not determined



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IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

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**Further information** 

**Data Sheet** 

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

#### 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 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



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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.

AR / Z8