Section 1: Identification

Product name: Halofuginone Formulation

Manufacturer or supplier’s details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908 Upper Hutt - New Zealand
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

Section 2: Hazard identification

GHS Classification

Serious eye damage/eye irritation: Category 2A

GHS label elements

Hazard pictograms:

Signal word: Warning

Hazard statements: H319 Causes serious eye irritation.

Precautionary statements:

Prevention:
P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.

Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients
SAFETY DATA SHEET

Halofuginone Formulation

Version 3.11 Revision Date: 27.08.2021
SDS Number: 845723-00014 Date of last issue: 10.10.2020
Date of first issue: 26.08.2016

Substance / Mixture : Mixture

### Components

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

### 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.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

**In case of eye contact**
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

**If swallowed**
If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed**
Causes serious eye irritation.

**Protection of first-aiders**
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

**Notes to physician**
Treat symptomatically and supportively.

### 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 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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 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.

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.
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

Section 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>

Further information: DSEN, Skin

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: 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.

Section 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
Section 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.

Section 11: Toxicological information

**Exposure routes**: Inhalation, Skin contact, Ingestion, Eye contact.

**Acute toxicity**

Not classified based on available information.

**Components**:

**Lactic acid**:
- **Acute oral toxicity**: LD50 (Rat): > 2,000 mg/kg
- **Remarks**: Based on data from similar materials

**Acute inhalation toxicity**: LC50 (Rat): > 5 mg/l
- **Exposure time**: 4 h
- **Test atmosphere**: dust/mist
- **Method**: OECD Test Guideline 403
- **Remarks**: Based on data from similar materials

**Acute dermal toxicity**: LD50 (Rabbit): > 2,000 mg/kg
- **Assessment**: The substance or mixture has no acute dermal toxicity
- **Remarks**: Based on data from similar materials

**Halofuginone**:
- **Acute oral toxicity**: LD50 (Rat): 30 mg/kg
- **LD50 (Mouse)**: 5 mg/kg

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

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

**Skin corrosion/irritation**

Not classified based on available information.

**Components**:

**Lactic acid**:
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Date of first issue: 26.08.2016

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Halofuginone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Skin irritation</td>
</tr>
</tbody>
</table>

**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

**Lactic acid:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Chicken eye</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Guinea pig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Halofuginone:**

Exposure routes: Dermal
Species: Guinea pig
Result: Sensitiser

**Chronic toxicity**

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Lactic acid:**
### Genotoxicity in vitro

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>OECD Test Guideline 471</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>OECD Test Guideline 476</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>OECD Test Guideline 473</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### 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
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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.

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: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100
plants

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

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:
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Halofuginone Formulation

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

Section 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.

Section 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
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Packing group: Not applicable
Labels: Not applicable
EmS Code: Not applicable
Marine pollutant: Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433
UN number: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable
Hazchem Code: Not applicable

Special precautions for user
Not applicable

Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

Section 16: Other information

Further information
Date format: dd.mm.yyyy
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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 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.

NZ / EN