

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 03.08.2019

Revision date: 06.07.2024

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SECTION 1: Identification

Product identifier

Product name: CaleGastro

Recommended use of the product and restriction on use:

Relevant identified uses: VETERINARY USE: Treatment and prevention of gastric ulcers in horses.

Uses advised against: Not for human use

Reasons why uses advised against: Veterinary product.

Manufacturer or supplier details

Supplier:

Dechra Veterinary Products NZ Limited

PO Box 1604,

Paraparaumu Beach, 5252

New Zealand

Phone: 0800 479 838

Email: info.nz@dechra.com

Website: <http://www.dechra.co.nz/>

Emergency telephone number:

National Poisons Centre, New Zealand

0800 764 766

SECTION 2: Hazards identification

Not Classified as a Dangerous Good according to NZS 5433:2012 Transport of Dangerous Goods on Land.

Classified in accordance with the relevant criteria of the HSNO Act 1996, the Hazardous Substances (Classification) Notice 2017 and the Hazardous Substances (Minimum Degrees of Hazard) Notice 2017, New Zealand.

HSNO Classification or Subclasses – Physical hazards: Not applicable

HSNO Classification or Subclasses – Health hazards:

Class	GHS Category	HSNO Category
Skin irritation	Category 2	6.3A
Serious eye damage	Category 1	8.3A
Skin sensitization	Category 1	6.5B

HSNO Classification or Subclasses – Environmental hazards: Not applicable

GHS classification:

Skin irritation, category 2

Serious eye damage, category 1

Skin sensitization, category 1

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Label elements

Hazard pictogram(s):



Signal word: Danger

Hazard statements:

H315 Causes skin irritation

H318 Causes serious eye damage

H317 May cause an allergic skin reaction

Precautionary statements:

P280 Wear protective gloves, protective clothing, eye protection and face protection

P264 Wash face, hands and any exposed skin thoroughly after handling

P261 Avoid breathing dust, fumes, gas, mist, vapours or spray

P272 Contaminated work clothing should not be allowed out of the workplace

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310 Immediately call a POISON CENTER or doctor

P302+P352 IF ON SKIN: Wash with plenty of soap and water

P362 Take off contaminated clothing and wash before reuse

P321 Specific treatment (see Sections 4-8 of this SDS and any supplemental information on the product label)

P333+P313 If skin irritation or rash occurs: Get medical advice and attention

P501 Dispose of contents and container in accordance with local regulations

Hazards not otherwise classified:

None.

SECTION 3: Composition/information on ingredients

Mixture:

Identification	Name	Weight %
CAS number: 67762-27-0	Cetearyl alcohol	15-20
CAS number: 151-21-3	Sodium lauryl sulphate	4-9
CAS number: 73590-58-6	Omeprazole	3

Additional information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret under the provisions of sections 55 (7) of the HSNO Act.

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SECTION 4: First-aid measures

For advice, contact a Poisons Information Center (e.g. phone Australia 131 126, New Zealand 0800 764 766) or a doctor.

Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance.

After inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. Keep person at rest. If breathing is difficult, administer oxygen. If breathing has stopped, provide artificial respiration. If experiencing respiratory symptoms, seek medical advice/attention.

After skin contact:

Remove contaminated clothing and shoes. Rinse skin with copious amounts of water [shower] for several minutes. Launder contaminated clothing before reuse. If symptoms develop or persist, seek medical advice/attention.

After eye contact:

Immediately rinse eyes with plenty of gently flowing lukewarm water for 15 minutes. Remove contact lenses if present and easy to do so. Protect unexposed eye. Seek immediate medical attention, preferably from an ophthalmologist.

After swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most important symptoms and effects, both acute and delayed:

Acute symptoms and effects:

Eye contact may result in irritation, redness, pain, inflammation, itching, burning, tearing, corneal damage and loss of vision.

Dermal exposure may cause an allergic skin reaction. Symptoms may include irritation, redness, pain, rash, inflammation, itching, burning and dermatitis.

Delayed symptoms and effects:

Effects are dependent on exposure (dose, concentration, contact time).

Immediate medical attention and special treatment:

Specific treatment:

In case of eye contact, seek prompt medical attention while rinsing is continued.

Notes for the doctor:

Treat symptomatically.

Workplace Facilities:

No additional information.

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SECTION 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media:

Water mist/fog, carbon dioxide, dry chemical or alcohol-resistant foam.

Unsuitable extinguishing media:

Do not use water jet.

Specific hazards during fire-fighting:

Thermal decomposition may produce irritating/toxic fumes/gases like carbon oxides and hydrocarbons.

Special protective equipment for firefighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

Hazchem or Emergency Action Code:

Not Applicable.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Methods and material for containment and cleaning up:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and storage precautions

Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Do not get in eyes. Avoid contact with skin and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Container Type: HDPE syringe.

Storage conditions: Store below 25°C in a dry place.

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Conditions for safe storage, including any incompatibilities:

Store below 25°C in a cool, dry, well-ventilated location out of direct sunlight in an HDPE syringe. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Keep out of reach of children. Store away from incompatible materials (See Section 10).

Safe packaging material

Suitable material:

Not determined or not applicable.

Unsuitable material:

Not determined or not applicable.

SECTION 8: Exposure controls and personal protection

Occupational Exposure limit values:

No occupational exposure limits noted for the ingredient(s).

Biological limit value:

No biological exposure limits noted for the ingredient(s).

Information on monitoring procedures:

Not determined or not applicable

Appropriate engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal protection equipment

Eye and face protection:

Use safety glasses with side shields or goggles. Consider the use of a face shield for splash protection. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Full body protection should be worn. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

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General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and chemical properties

Appearance	Viscous liquid; thick ointment with cream to pink pellets
Odour	Odourless
Odour threshold	Not determined or not available.
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.
Flammability (solid, gas)	Non flammable
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapour pressure	Not determined or not available.
Vapour density	Not determined or not available.
Relative density	0.95 - 1.05
Solubilities	Not determined or not available.
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Particle characteristics	Not determined or not available.

Other information: No additional information.

SECTION 10: Stability and reactivity

Reactivity:

Not reactive under recommended handling and storage conditions.

Chemical stability:

Stable under recommended handling and storage conditions.

Possibility of hazardous reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to avoid:

None known.

Incompatible materials:

Oxidising agents (e.g. hypochlorites), acids (e.g. nitric acid) and alkalis (e.g. sodium hydroxide).

Hazardous decomposition products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced. May evolve carbon oxides and hydrocarbons when heated to decomposition.

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SECTION 11: Toxicological information

Acute toxicity:

Assessment: Based on available data, the classification criteria are not met.

Product data:

Route	Result
Oral ATE	LD50 Rat: 3446.86 mg/kg
Dermal ATE	LD50 Rabbit: 2341.42 mg/kg
Inhalation ATE	LC50 Rat: 37.3 mg/L

Substance data:

Name	Route	Result
Omeprazole	Oral ATE	LD50 Rat: 500 mg/kg
	Dermal ATE	LD50 Rabbit: 1100 mg/kg
	Inhalation ATE	LC50 Rat: 11 mg/L (4 hr [Vapour])
Cetearyl alcohol	oral	LD50 Rat: >10,000 mg/kg
	dermal	LD50 Rabbit: >10,000 mg/kg
Sodium lauryl sulphate	oral	LD50 Rat: 977 mg/kg
	Dermal ATE	LD50 Rat: 1100 mg/kg
	Inhalation ATE	LC50 Rat: 1.5 mg/L (4 hr [dust, mist])

Skin corrosion/irritation

Assessment:

Causes skin irritation.

Product data: No data available.

Substance data:

Name	Result
Omeprazole	Causes skin irritation.
Cetearyl alcohol	Causes skin irritation.
Sodium lauryl sulphate	Causes skin irritation.

Serious eye damage/irritation:

Assessment:

Causes serious eye damage.

Product data: No data available.

Substance data:

Name	Result
Omeprazole	Causes serious eye irritation.
Cetearyl alcohol	Causes serious eye irritation.
Sodium lauryl sulphate	Causes serious eye damage.

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Respiratory or skin sensitization:

Assessment:

May cause an allergic skin reaction.

Product data: No data available.

Substance data:

Name	Result
Omeprazole	May cause an allergic skin reaction.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Reproductive toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Specific target organ toxicity (single exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Omeprazole	May cause respiratory irritation.
Sodium lauryl sulphate	May cause respiratory irritation.

Specific target organ toxicity (repeated exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Information on likely routes of exposure:

Ingestion, skin and eye contact.

Symptoms related to the physical, chemical and toxicological characteristics:

See section 4 of this SDS.

Other information:

No data available.

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SECTION 12: Ecological information

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Cetearyl alcohol	Fish LC50 Oncorhynchus mykiss: >0.4 mg/L (96 hr)
	Aquatic Invertebrates EC50 Daphnia magna: 3.2 mg/L (48 hr [mobility])
	Aquatic Plants EC50 Desmodemus subspicatus: 0.66 mg/L (72 hr [growth rate])
Sodium lauryl sulphate	Fish LC50 Pimephales promelas: 29 mg/L (96 hr)
	Aquatic Invertebrates EC50 Ceriodaphnia dubia: 5.55 mg/L (48 hr [mortality])
	Aquatic Plants EC50 Desmodemus subspicatus: >120 mg/L (72 hr [growth rate])

Chronic (long-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Cetearyl alcohol	Fish NOEC Pimephales promelas: 0.26 mg/L (33 d [growth based on total length, Read-across substance data])
	Aquatic Invertebrates NOEC Daphnia magna: 1 mg/L (21 d [Mortality, reproduction rate, and appearance of offspring, Read-across substance data])
Sodium lauryl sulphate	Fish NOEC Pimephales promelas: >1.36 mg/L (42 d [mortality])
	Aquatic Invertebrates NOEC Ceriodaphnia dubia: 0.88 mg/L (7 d [reproduction])

Persistence and degradability

Product data: No data available.

Substance data:

Name	Result
Cetearyl alcohol	The substance is readily biodegradable. 81% degradation measured by test mat. analysis after 28 days.
Sodium lauryl sulphate	The substance is readily biodegradable. 95% degradation in water, measured by CO2 evolution, after 28 days.

Bioaccumulative potential

Product data: No data available.

Substance data:

Name	Result
Cetearyl alcohol	The substance has the potential to bioaccumulate (BCF: 544.4 L/kg, Specie: fish, basis: whole body w.w., QSAR substance data).
Sodium lauryl sulphate	The substance is not expected to bioaccumulate (log Pow: <= -2.03 at 20°C).

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Mobility in soil

Product data: No data available.

Substance data:

Name	Result
Cetearyl alcohol	The substance is slightly mobile, therefore, adsorption to soil and sediment is expected (Koc at 20 °C: 4658, QSAR substance data).
Sodium lauryl sulphate	The substance is moderately mobile, therefore, there is moderate potential for adsorption to soil and sediment (Koc: 316 - 446 at 25 °C).

Hazard to the ozone layer

Product data: No data available.

Substance data: No data available.

Other adverse effects: No data available.

SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory agencies. Dispose of in accordance with all applicable local, regional, state and federal regulations.

Contaminated packages:

Not determined or not applicable.

Disposal methods that should not be used:

No additional information.

SECTION 14: Transportation information

Road/Rail transport: (NZS 5433:1999)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Air Transport Association Dangerous Goods Regulations (IATA-ICAO)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

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International Maritime Dangerous Goods (IMDG)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

Transport in bulk according to Annex II of MARPOL and the IBC Code: Not Applicable

SECTION 15: Regulatory information

New Zealand Inventory of Chemicals (NZIoC): All Ingredients are listed.

HSNO Classification or Subclasses:

Class	GHS Category	HSNO Category
Skin irritation	Category 2	6.3A
Serious eye damage	Category 1	8.3A
Skin sensitization	Category 1	6.5B

HSNO Group Standard Name:	HSNO Approval Number:
Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard 2017	HSR100757

HSNO Controls: Not determined.

Approved handler test certificate: Not determined.

Tracking: Not determined.

Controlled substance license requirements: Not applicable.

Agricultural Compounds and Veterinary Medicines Act 1997:

ACVM number	A010625
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Montreal Protocol (Ozone Depleting Substances): None of the ingredients are listed.

Stockholm Convention (Persistent Organic Pollutants): None of the ingredients are listed.

Rotterdam Convention (Prior Informed Consent): None of the ingredients are listed.

Basel Convention (Hazardous Waste): None of the ingredients are listed.

SECTION 16: Other information

Abbreviations and Acronyms:

ATE	Acute Toxicity Estimate
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
EC50	Effective Concentration of 50%
GHS	Globally Harmonized System
HSNO	Hazardous Substances and New Organisms

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IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%
MARPOL	International Convention for the Prevention of Pollution from Ships
NZIoC	New Zealand Inventory of Chemicals
TWA	Time Weighted Average
UN	United Nations
VOC	Volatile Organic Compounds

Disclaimer:

The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

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Revision Notes:

Revision Date	Notes
2024-06-07	Version 2; Supersedes (Version 1: 03.08.2019)

End of Safety Data Sheet