SAFETY DATA SHEET

Section 1: Identification

Product identifier **Simparica™ (Sarolaner) Chewable Tablets**

Other means of identification

Synonyms Simparica * Simparica™ Chews for Dogs * Simparica™ (sarolaner) Chewables * Sarolaner

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product used as antiparasitic

Restrictions on use Not for human use

Details of manufacturer or importer

Company Name (NZ) Zoetis New Zealand Limited
Level 4, 8 Mahuhu Crescent
Auckland Central
Auckland 1010, New Zealand

Telephone No. 0800 963 847 (Business Hours)

Emergency No. (National Poisons Centre) 0800 POISON (0800 764 766)

Emergency No. (Emergency Services) In an emergency dial 111

Section 2: Hazard identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Not classified.	
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 2
	Hazardous to the aquatic environment, long-term hazard	Category 2

Label elements, including precautionary statements

Hazard symbol(s)

Environment

Signal word None.

Hazard statement(s) Toxic to aquatic life with long lasting effects.

Precautionary statement(s)

Prevention Avoid release to the environment.

Response Collect spillage.

Storage Store away from incompatible materials.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards which do not result in classification None.

Supplemental information May form combustible dust concentrations in air. Direct contact with eyes may cause temporary irritation.

Section 3: Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Sarolaner isoxazoline	1398609-39-6	4
Magnesium stearate	557-04-0	<1
Silicon dioxide, colloidal NF	7631-86-9	<1

Flavor	Not assigned
Lactose monohydrate	64044-51-5

Section 4: First-aid measures

Description of necessary first aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists. Wash clothing separately before reuse.
Eye contact	Do not rub eyes. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.
Personal protection for first-aid responders	For personal protection, see section 8 of the SDS. You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.
Symptoms caused by exposure	Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
Medical attention and special treatment	Treat symptomatically.

Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed. Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride. May include products of fluorine.
Special protective equipment and precautions for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazchem code	None.
Hazards from combustion products	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride.
General fire hazards	During processing, dust may form explosive mixture in air. Fine particles (such as mists) may fuel fires/explosions.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away.
For emergency responders	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Keep people away from and upwind of spill/leak. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Do not breathe dust. Avoid dust formation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. Use personal protection recommended in Section 8 of the SDS.
Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Avoid dust formation. Ensure adequate ventilation. Prevent entry into waterways, sewer, basements or confined areas.

Large Spills: Stop the flow of material, if this is without risk. Ground/bond container and equipment. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Prevent release to the environment.

Section 7: Handling and storage

Precautions for safe handling

Observe good industrial hygiene practices. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Wear appropriate personal protective equipment. Avoid contact with skin. When using, do not eat, drink or smoke. Wash thoroughly after handling. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Wash contaminated clothing before reuse. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Use care in handling/storage. Keep away from heat, sparks and open flame. Protect from sunlight. Store in a well-ventilated place. Keep away from food, drink and animal feeding stuffs. Store below 30°C (86°F) Store away from incompatible materials (see Section 10 of the SDS).

Section 8: Exposure controls/personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components	Type	Value
Sarolaner isoxazoline (CAS 1398609-39-6)	TWA	110 µg/m³

New Zealand. OELs (Workplace Exposure Standards and Biological Exposure Indices)

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m3	
Silicon dioxide, colloidal NF (CAS 7631-86-9)	TWA	3 mg/m3	Respirable dust.
		10 mg/m3	Inhalable dust.

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m3	Inhalable dust.
Silicon dioxide, colloidal NF (CAS 7631-86-9)	TWA	2 mg/m3	Respirable dust.

Biological limit values

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

Control banding approach

Not available.

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection	No personal respiratory protective equipment normally required. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely.
Thermal hazards	Not applicable.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Section 9: Physical and chemical properties

Appearance	
Physical state	Solid.
Form	Solid. Tablet.
Colour	Light brown.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Kinematic viscosity	Not available.
Other physical and chemical parameters	
Dust explosion properties	
Minimum Ignition Energy (MIE) - dust cloud	240 mJ
Electrostatic properties	
Resistivity at ambient humidity	>E+12 @ 50% rH, 24C
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

Section 10: Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Protect from sunlight. Contact with incompatible materials. Avoid dispersion as a dust cloud.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride. May include products of fluorine.

Section 11: Toxicological information

Information on likely routes of exposure

Inhalation Prolonged inhalation may be harmful. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact No adverse effects due to skin contact are expected.

Sarolaner isoxazoline — Species: Rabbit; Severity: Non-irritating

Eye contact Direct contact with eyes may cause temporary irritation.

Sarolaner isoxazoline — Species: Rabbit; Severity: Minimal

Ingestion May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

Acute toxicity

Product	Species	Test Results
Simparica™ (Sarolaner) Chewable Tablets		
Acute		
Oral		
LD50		> 10000 mg/kg (Calculated ATE)

Components	Species	Test Results
Lactose monohydrate (CAS 64044-51-5)		
Acute		
Oral		
LD50	Rat	29700 mg/kg
Magnesium stearate (CAS 557-04-0)		
Chronic		
Oral		
LOAEL	Rat	1092 g/kg, 13 weeks Liver
Sarolaner isoxazoline (CAS 1398609-39-6)		
Acute		
Dermal		
LD50	Rat	> 2020 mg/kg
Oral		
LD50	Rat	783 mg/kg
Subacute		
Oral		
NOAEL	Rat	2.5 mg/kg/day, 14 days (Adrenal gland)
		2.2 mg/kg/day, 30 days (Adrenal gland, Ovary, Liver)
Subchronic		
Oral		
NOAEL	Rat	25 mg/kg/day, 90 days (Adrenal gland, Ovary, Pancreas)
Silicon dioxide, colloidal NF (CAS 7631-86-9)		
Acute		
Oral		
LD50	Rat	> 22500 mg/kg

Skin corrosion/irritation Not expected to cause skin irritation.

Irritation Corrosion - Skin

Sarolaner isoxazoline — Result: Non-irritant; Species: Rabbit

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye contact

Sarolaner isoxazoline	Species: Rabbit Severity: Minimal

Respiratory irritation Not available.

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitiser.

Skin sensitisation This product is not expected to cause skin sensitisation.

Skin Sensitisation

Sarolaner isoxazoline	LLNA Species: Mouse Severity: Negative

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Sarolaner isoxazoline	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli
Lactose monohydrate	In Vitro Bacterial Mutagenicity (Ames) Species: Salmonella , E. coli
Sarolaner isoxazoline	In Vitro Chromosome Aberration Result: Negative Species: Human lymphocytes In Vitro Micronucleus Result: Negative Species: Chinese Hamster Ovary (CHO) cells In Vivo Micronucleus Result: Negative Species: Rat

Carcinogenicity Due to partial or complete lack of data the classification is not possible.

ACGIH Carcinogens

Magnesium stearate (CAS 557-04-0)	A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Silicon dioxide, colloidal NF (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Based on available data, the classification criteria are not met.

Developmental effects

Sarolaner isoxazoline	3 mg/kg/day Embryo / Fetal Development, Maternal Toxicity Not Teratogenic Result: NOAEL Species: Rabbit Organ: Oral 3.2 mg/kg/day Embryo / Fetal Development, Maternal toxicity Not teratogenic Result: NOAEL Species: Rat Organ: Oral

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Not an aspiration hazard.

Narcotic effects Due to lack of data the classification is not possible.

Chronic effects Prolonged inhalation may be harmful. Based on available data, the classification criteria are not met.

Section 12: Ecological information

Ecotoxicity Avoid release to the environment. Toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Sarolaner isoxazoline (CAS 1398609-39-6)			
Aquatic			
Algae	EC50	Pseudokirchneriella subcapitata (Green Alga)	> 0.27 mg/l, 72 Hours (ErC50)
Crustacea	EC50	Daphnia magna (Water Flea)	0.27 mg/l, 48 Hours
Fish	LC50	Fish	> 0.54 mg/l, 96 Hours

Persistence and degradability No data available for this product.

Bioaccumulative potential No data available for this product. The following information is available for the individual ingredients.

Partition coefficient n-octanol / water (log Kow)	
Sarolaner isoxazoline	3.25

Mobility in soil No data available for this product.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Section 13: Disposal considerations

Disposal methods Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Special precautions to be taken during disposal Dispose in accordance with all applicable regulations.

Method of disposal that should not be used None known.

Section 14: Transport information

IATA

UN number	UN3077
UN proper shipping name	Environmentally Hazardous Substance, Solid, n.o.s (Isoxazoline)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	No.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Isoxazoline), MARINE POLLUTANT (Isoxazoline)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

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

IATA; IMDG

Marine pollutant

General information

As of January 1, 2015, materials offered for transport that are classified for transportation only as Marine Pollutants and which are packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 Liters or less for liquids or having a net mass per single or inner packaging of 5 kilograms or less for solids are NOT subject to ICAO/IATA, IMDG, or ADR transport regulations provided the general packaging requirements of those regulations are met. Refer to ICAO/IATA A197, IMDG 2.10.2.7, ADR SP 375. Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

Section 15: Regulatory information

Applicable regulations

Registered pursuant to the ACVM Act 1997, No. A11219
See www.foodsafety.govt.nz for registration conditions.
Approved pursuant to the HSNO Act 1996, Code No. HSR100757.
See www.epa.govt.nz for approval controls.

New Zealand Inventory of Chemicals (NZIoC): Registration status

Lactose monohydrate (CAS 64044-51-5)	May be used as a single component chemical under an appropriate group standard
Magnesium stearate (CAS 557-04-0)	May be used as a single component chemical under an appropriate group standard
Silicon dioxide, colloidal NF (CAS 7631-86-9)	May be used as a single component chemical under an appropriate group standard

Section 16: Other information

Issue date 08-September-2023

Version No. 01

Key abbreviations or acronyms used ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).

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Revision information

Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Exposure Controls / Personal Protection: OELs
Physical & Chemical Properties: Multiple Properties
Ecological Information: Ecotox Property Data
Transport Information: Proper Shipping Name/Packing Group
GHS: Classification