

SAFETY DATA SHEET

Zoetis New Zealand Limited
Level 5, 8 Mahuhu Crescent, Auckland



Section 1: Identification of the Substance and Supplier

Trade Name:	Simparica®
ACVM Registration No.:	A011219
Classification:	Unrestricted
Recommended Use:	For the treatment and prevention of flea infestations; and for the treatment and control of tick infestations, sarcoptic, demodectic and ear mite infestations.
Company Details:	Zoetis New Zealand Limited
Address:	Level 4, 8 Mahuhu Crescent Auckland Central Auckland 1010 New Zealand
Telephone No.:	0800 650 277 (Business Hours)
Emergency Telephone No.:	National Poisons Centre: 0800 POISON (0800 764 766) Emergency Services: In an emergency dial 111
Date of Preparation:	01 July 2019

Section 2: Hazards Identification

Hazard Classification:	6.9B, 9.1B
Priority Identifier(s):	WARNING KEEP OUT OF REACH OF CHILDREN
Secondary Identifier(s):	6.9B Warning - May cause organ damage from repeated oral exposure at high doses 9.1B Toxic to aquatic organisms with long-lasting effects; Avoid contamination of any water supply with product or empty container

Section 3: Composition / Information on Ingredients

Chemical Identity of Ingredients

Ingredient	CAS No.	Concentration
Sarolaner	1398609-39-6	4.0%
Other ingredients determined not to be hazardous.	-	-

This is a commercial product whose exact ratio of components may vary.
Trace quantities of impurities are also likely.

Section 4: First Aid Measures

Necessary First Aid Measures:	<p>For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately. If the patient is not breathing begin artificial respiration and seek medical advice immediately. Never give fluids or induce vomiting if a patient is unconscious or convulsing, regardless of injury.</p> <p>Ingestion: DO NOT induce vomiting. If the patient is conscious wash mouth out with water. Do not give anything by mouth to an unconscious person. Seek medical advice immediately.</p> <p>Eye Contact: Flush the eye(s) out with running water for at least 15 minutes. Removal of contact lenses should be done with caution within 5 minutes of exposure. If symptoms develop seek medical advice immediately.</p> <p>Skin Contact: Remove any contaminated clothing and wash the affected area immediately with soap and water. If symptoms develop seek medical advice immediately.</p> <p>Inhalation: Move the patient to fresh air. If symptoms develop seek medical advice immediately.</p>
Poisoning Symptoms:	No data available.
Workplace Facilities:	No specific facilities required. Standard emergency equipment must be available.
Hygiene Practices:	Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while using this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Notes for Medical Personnel:	Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient. Note the nature of this product.

Section 5: Fire-Fighting Measures

Type of hazard:	During processing, dust may form explosive mixture in air. Fine particles (such as mists) may fuel fires/explosions.
Fire Hazard Properties:	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.
Regulatory Requirements:	Not applicable.
Extinguishing Media & Methods:	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂). Apply extinguishing media carefully to avoid creating airborne dust. Do not use water jet as an extinguisher, as this will spread the fire.
Hazchem Code:	Not assigned.
Recommended Protective Clothing:	During large-scale fire fighting operations wear approved positive pressure, self-contained breathing apparatus (SCBA) and full protective turn-out gear.

Section 6: Accidental Release Measures

Personal Precautions:	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Ventilate the contaminated area. Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained.
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.
Procedure for Spills:	<ol style="list-style-type: none">1. Non-essential personnel should be evacuated from the affected area.2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage.3. Absorb the spill with an absorbent material (e.g. sand).4. Collect the spilled material into labelled containers for disposal, minimising dust generation.5. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains.
Procedure for Disposal:	Contaminated material must be disposed of at an approved landfill or other approved facility in accordance with local, regional and national requirements. Avoid contamination of any water supply with product or empty container.

Section 7: Handling and Storage

Handling

Precautions for Safe Handling:	When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with skin. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash contaminated clothing before reuse. Wash thoroughly after handling. Avoid release to the environment. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight.
Regulatory Requirements:	Not required.
Handling Practices:	Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Approved Handlers:	Approved handlers are not required for this product.

Storage

Conditions for Safe Storage:	Store below 30°C (Room Temperature) in the original carton. Keep out of reach of children. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Keep away from heat, sparks and open flame. Keep away from food, drink and animal feedingstuffs. Use care in handling/storage.
Store Site Requirements:	No additional requirements.
Packaging:	Store in the original container, away from foodstuffs.

Section 8: Exposure Control / Personal Protection

Always Read and Follow the Label Instructions and Warnings

Workplace Exposure Guidelines

Workplace Exposure Standards:	Sarolaner TWA 110 µg/m ³
Application in the Workplace:	The nature of this product makes it unlikely that this level will be approached during normal handling.
Exposure Standards Outside the Workplace:	None set.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Personal Protection:	<p>The following instructions are for those coming into frequent and / or lengthy contact with this product. For occasional handling employ precautions suitable for the conditions under which the product is being handled.</p> <p>Hands: Impervious gloves are recommended if skin contact is possible and for bulk processing operations.</p> <p>Eyes: It is always prudent to utilise protective eyewear.</p> <p>Skin: When prolonged or frequently repeated contact could occur, utilise chemically protective clothing. Selection of specific items such as a face shield, gloves, boots, or overalls will depend on the situation.</p> <p>Respiratory: Respiratory protection is not normally required; however, if necessary utilise an air-purifying respirator that complies with NZ standards.</p>
General Hygiene:	Change work clothes regularly. Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.

Section 9: Physical and Chemical Properties

Appearance:	Light brown tablet.
Odour:	No data available.
Specific Gravity / Density:	No data available.
Melting Point:	Not applicable.
Boiling Point:	Not applicable.
pH:	No data available.
Solubility in Water:	No data available.
Flashpoint:	Not applicable. This product is not flammable.
Oxidising Properties:	Not applicable. This product is not an oxidiser.
Corrosive Properties:	Not applicable. This product is not corrosive.
Vapour Pressure:	No data available.

Section 10: Stability and Reactivity

Stability of the Substance:	This product is stable under normal conditions.
Conditions to Avoid:	Heat, flames and sparks. Contact with incompatible materials. Protect from sunlight. Avoid dispersion as a dust cloud.
Material to Avoid:	Strong oxidizing agents.
Hazardous Decomposition Products:	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride. May include products of fluorine.
Hazardous Polymerisation:	This product is unlikely to spontaneously polymerise.
Specific Data:	No specific data available.

Section 11: Toxicological Information

HSNO Classifications

6.9B Harmful - May cause organ damage from repeated oral exposure at high doses

Acute Effects (Sarolaner)

Inhalation:	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. <ul style="list-style-type: none">• Dermal (Rat) LD50 > 2020 mg/kg
Eye Contact:	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
Ingestion:	Expected to be a low ingestion hazard. <ul style="list-style-type: none">• Acute: Oral (Rat) LD50 783 mg/kg• Subacute: Oral (Rat) NOAEL 2.5 mg/kg/day, 14 days (adrenal gland)• Subchronic: Oral (Rat) NOAEL 2.5 mg/kg/day, 30 days (adrenal gland, ovary, liver)

Chronic / Long Term Effects (Sarolaner)

Mutagenicity:

- Bacterial Mutagenicity (Ames) Negative *Salmonella, E. coli*
- *In vitro* Chromosome Aberration Negative Human lymphocytes
- *In Vitro* Micronucleus Negative Chinese Hamster Ovary (CHO) cells
- *In Vivo* Micronucleus Negative Rat

Carcinogenicity: This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive Toxicity: This product is not expected to cause reproductive or developmental effects.

- Oral (Rabbit) NOAEL 3 mg/kg/day Embryo/Foetal Development, Maternal Toxicity Not teratogenic
- Oral (Rat) NOAEL 3.2 mg/kg/day Embryo/Foetal Development, Maternal Toxicity Not teratogenic

Section 12: Ecotoxicity Information

HSNO Classifications

9.1B Ecotoxic - Toxic to aquatic organisms with long-lasting effects; Avoid contamination of any water supply with product or empty container

The environmental characteristics of this material have not been fully evaluated.
Avoid contamination of any water supply with product or empty container.

Ecotoxicity Effects (Sarolaner)

Aquatic Toxicity: Species, Method, End Point, Duration, Result

- *Psuedokirchneriella subcaptiata* (Green Alga) OECD 201 ErC50 75 Hrs > 72 mg/L
- *Daphnia magna* (Water Flea) OECD 202 EC50 48 Hrs 0.27 mg/L
- Fish OECD 203 LC50 95 Hrs > 0.54 mg/L

A greater than (>) symbol indicates the acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

- Persistence and Degradability: No data available
- Bio-accumulative Potential: Measured Log P 3.25
- Mobility in Soil: No data available

Environmental Fate

No information available.

Section 13: Disposal Considerations

Product Disposal: Preferably dispose of product by use in accordance with label directions. Otherwise dispose of product at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with product.

Container Disposal: Dispose of empty containers by wrapping in paper and putting in garbage for disposal at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with empty container.

Section 14: Transport Information

Dangerous Goods Classification

UN No.: Not applicable. This product is not a dangerous good.
Class: Not applicable. This product is not a dangerous good.
Packing Group: Not applicable. This product is not a dangerous good.
Proper Shipping Name: Not applicable. This product is not a dangerous good.

Section 15: Regulatory Information

HSNO Approval No.:	HSR100757
HSNO Controls:	See www.epa.govt.nz for controls
ACVM Registration No.:	A011219
ACVM Controls:	See www.foodsafety.govt.nz for registration conditions

Section 16: Other Information

Note: This product is a veterinary medicine and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to the Government health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

CONTACT POINT:	Zoetis New Zealand Limited:	0800 650 277 (Business Hours)
	National Poisons Centre:	0800 POISON (0800 764 766)
	Emergency Services:	Dial 111

This Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products.

PLEASE READ ALL LABELS CAREFULLY BEFORE USING PRODUCT.

If clarification of further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

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