SAFETY DATA SHEET

Section 1: Identification

Product identifier **Simparica Trio**

Other means of identification

Synonyms Simparica Trio Chewable Tablets * Chewable Heartworm Tablets * Isoxazoline/Moxidectin/Pyrantel Pamoate Chewable Tablets

Recommended use of the chemical and restrictions on use

Recommended use Veterinary antiparasitic (ectocide); anti-worm agent (anthelmintic)

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	Acute toxicity, oral	Category 5
	Acute toxicity, dermal	Category 5
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 1
	Hazardous to the aquatic environment, long-term hazard	Category 1

Label elements, including precautionary statements

Hazard symbol(s)

Environment

Signal word Warning

Hazard statement(s) May be harmful if swallowed. May be harmful in contact with skin. Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)

Prevention Avoid release to the environment.

Response Call a POISON CENTRE or doctor/physician if you feel unwell. 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 The mixture contains a substance that is assessed to be a PBT or a vPvB.

Supplemental information None.

Section 3: Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Pyrantel pamoate	22204-24-6	16

Sarolaner	1398609-39-6	1.3
Moxidectin	113507-06-5	0.03
Magnesium stearate	557-04-0	<2
Silica colloidal, Ph. Eur.	112945-52-5	<2
Butylated hydroxytoluene	128-37-0	<1

Composition comments % = w/w

Section 4: First-aid measures

Description of necessary first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. If skin irritation or rash occurs: Get medical advice/attention.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.

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 IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

Symptoms caused by exposure Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort.

Medical attention and special treatment Provide general supportive measures and 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.

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.

Hazchem code None.

Hazards from combustion products None.

General fire hazards No unusual fire or explosion hazards noted.

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 Wear appropriate personal protective equipment.

For emergency responders Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

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 Wear appropriate protective equipment and clothing during clean-up. Avoid the generation of dusts during clean-up. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). 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.

Section 7: Handling and storage

Precautions for safe handling Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not taste or swallow. Avoid contact with skin and eyes. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities Keep tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks and open flame. 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
Moxidectin (CAS 113507-06-5)	TWA	70 µg/m3
Pyrantel pamoate (CAS 22204-24-6)	TWA	300 µg/m3
Sarolaner (CAS 1398609-39-6)	TWA	110 µg/m³

New Zealand. WES. (Workplace Exposure Standards)

Components	Type	Value	Form
Butylated hydroxytoluene (CAS 128-37-0)	TWA	10 mg/m3	
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m3	
Silica colloidal, Ph. Eur. (CAS 112945-52-5)	TWA	3 mg/m3	Respirable dust.
		10 mg/m3	Inhalable dust.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Butylated hydroxytoluene (CAS 128-37-0)	TWA	2 mg/m3	Inhalable fraction and vapour.
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Butylated hydroxytoluene (CAS 128-37-0)	TWA	10 mg/m3

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

Components	Type	Value	Form
Butylated hydroxytoluene (CAS 128-37-0)	TWA	10 mg/m3	
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m3	Inhalable dust.

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

Control banding approach Not available.

Appropriate engineering controls 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 Wear protective gloves.

Other Wear suitable protective clothing.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Not applicable.

Hygiene measures	Keep away from food and drink. 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	Tablet.
Physical state	Solid.
Form	Solid.
Colour	Reddish-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	
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	Contact with incompatible materials. High temperatures. Keep away from heat, sparks and open flame.
Incompatible materials	Peroxides. Phenols. Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

Section 11: Toxicological information

Information on likely routes of exposure

Inhalation	Health injuries are not known or expected under normal use.
Skin contact	May be harmful in contact with skin. Prolonged skin contact may cause temporary irritation.

Moxidectin	Species: Rabbit Severity: Mild
Butylated hydroxytoluene	Species: Rabbit Severity: Moderate

Skin contact

Sarolaner	Species: Rabbit Severity: Non-irritating

Eye contact Direct contact with eyes may cause temporary irritation.

Sarolaner	Species: Rabbit Severity: Minimal
Butylated hydroxytoluene	Species: Rabbit Severity: Moderate
Moxidectin	Species: Rabbit Severity: Moderate

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort.

Information on toxicological effects

Acute toxicity May be harmful in contact with skin. May be harmful if swallowed.

Components	Species	Test Results
Butylated hydroxytoluene (CAS 128-37-0)		
Acute		
Intraperitoneal		
LD50	Mouse	138 mg/kg
Oral		
LD50	Mouse	650 mg/kg
	Rat	1700 mg/kg
		890 mg/kg
Chronic		
Oral		
LOAEL	Mouse	2000 mg/kg, 4 days Liver, Kidney, Ureter, Bladder
	Rat	5185 mg/kg, 4 weeks Liver
Magnesium stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2000 mg/m3
Oral		
LD50	Rat	> 2000 mg/kg
Moxidectin (CAS 113507-06-5)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg
Oral		
LD50	Rat	106 mg/kg
Chronic		
Oral		
NOEL	Mouse	30 mg/kg/day, 2 years (Not carcinogenic)
	Rat	100 mg/kg/day, 2 years (Not carcinogenic)
Subacute		
Oral		
LOEL	Rat	100 mg/kg/day, 28 days (Central Nervous System)
NOEL	Mouse	75 mg/kg/day, 28 days (Central nervous system)

Components	Species	Test Results
Subchronic		
Oral		
NOEL	Dog	10 mg/kg/day, 90 days (Central Nervous System)
	Rat	50 mg/kg/day, 13 weeks (Central Nervous System)
Pyrantel pamoate (CAS 22204-24-6)		
Acute		
Intraperitoneal		
LD50	Mouse	620 mg/kg
	Rat	535 mg/kg
Oral		
LD50	Mouse	> 24 g/kg
	Rat	> 4000 mg/kg
		> 24 g/kg
Subacute		
Oral		
LOAEL	Dog	50 mg/kg/day, 1 months (Target organs: Gastrointestinal system, Liver)
NOAEL	Rat	500 mg/kg/day, 1 months (Target organs: None identified)
Subchronic		
Oral		
NOAEL	Dog	100 mg/kg/day, 13 weeks (Target organs: Gastrointestinal system, Liver)
	Rat	300 mg/kg/day, 13 weeks (Target organs: None identified)
Sarolaner (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)
Silica colloidal, Ph. Eur. (CAS 112945-52-5)		
Acute		
Oral		
LD50	Rat	> 22500 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Moxidectin	Species: Rabbit Severity: Mild

Irritation Corrosion - Skin

Sarolaner	Result: Non-irritant Species: Rabbit

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

Eye contact

Sarolaner	Species: Rabbit Severity: Minimal
Butylated hydroxytoluene	Species: Rabbit Severity: Moderate
Moxidectin	Species: Rabbit Severity: Moderate

Respiratory irritation Not available.

Respiratory or skin sensitisation

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

Skin sensitisation Based on available data, the classification criteria are not met. This product is not expected to cause skin sensitisation.

Skin Sensitisation

Sarolaner	LLNA Species: Mouse Severity: Negative
Moxidectin	Species: Guinea Pig Severity: Negative

Germ cell mutagenicity Based on available data, the classification criteria are not met. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Sarolaner	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli
Pyrantel pamoate	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella
Moxidectin	In Vitro Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli
Sarolaner	In Vitro Chromosome Aberration Result: Negative Species: Human lymphocytes
Moxidectin	In Vitro HGPRT Forward Gene Mutation Assay Result: Negative Species: Chinese Hamster Ovary (CHO) cells
Sarolaner	In Vitro Micronucleus Result: Negative Species: Chinese Hamster Ovary (CHO) cells
Moxidectin	In Vivo Cytogenetics Result: Negative Species: Rat Bone Marrow
Sarolaner	In Vivo Micronucleus Result: Negative Species: Rat
Moxidectin	In Vivo Unscheduled DNA Synthesis Result: Negative Species: Rat Hepatocyte

Carcinogenicity Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

ACGIH Carcinogens

Butylated hydroxytoluene (CAS 128-37-0)	A4 Not classifiable as a human carcinogen.
Magnesium stearate (CAS 557-04-0)	A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Butylated hydroxytoluene (CAS 128-37-0)	3 Not classifiable as to carcinogenicity to humans.

Silica colloidal, Ph. Eur. (CAS 112945-52-5)	3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Based on available data, the classification criteria are not met. This product is not expected to cause reproductive or developmental effects.

Developmental effects

Moxidectin	1 mg/kg/day Embryo / Fetal Development, (Maternal toxicity, Not teratogenic) Result: NOEL Species: Rabbit Organ: Oral route
Pyrantel pamoate	250 mg/kg Embryo / Fetal Development, Not Teratogenic Result: NOAEL Species: Rabbit Organ: Oral 250 mg/kg Embryo / Fetal Development, Not Teratogenic Result: NOAEL Species: Rat Organ: Oral 250 mg/kg Prenatal & Postnatal Development, No effects at maximum dose Result: NOAEL Species: Rat Organ: Oral
Sarolaner	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
Moxidectin	5 mg/kg/day Embryo / Fetal Development, (Negative) Result: NOEL Species: Rat Organ: Oral route 5 mg/kg/day Embryo / Fetal Development, (Not Teratogenic, Embryotoxicity, Maternal Toxicity) Result: NOEL Species: Rat Organ: Oral route
Butylated hydroxytoluene	6 g/kg Embryo / Fetal Development, teratogenic Result: LOEL Species: Rat Organ: Oral

Reproductivity

Pyrantel pamoate	250 mg/kg Reproductive & Fertility, No effects at maximum dose 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 Based on available data, the classification criteria are not met. Not an aspiration hazard.

Narcotic effects Not available.

Section 12: Ecological information

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

Components		Species	Test Results
Moxidectin (CAS 113507-06-5)			
Aquatic			
Algae	ErC50	Green algae (Selenastrum capricornutum)	> 87 ppb, 72 Hours
Crustacea	EC50	Daphnia magna (Water Flea)	30 ppt, 48 Hours
Fish	LC50	Lepomis macrochirus (Bluegill Sunfish)	0.62 ppb, 96 Hours
		Oncorhynchus mykiss (rainbow trout)	0.16 ppb, 96 Hours
Sarolaner (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 is available on the degradability of 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)	
Moxidectin	4.77
Sarolaner	3.25

Mobility in soil No data available for this product. The following information is available for the individual ingredients.

Adsorption	
Soil/Sediment Sorption - Log Koc	
Moxidectin	4.3 - 4.6

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 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 (Moxidectin, Sarolaner)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	Yes
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 (Moxidectin, Sarolaner), MARINE POLLUTANT
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. A11870. See www.foodsafety.govt.nz for registration conditions. Approved pursuant to the HSNO Act, No. HSR100757. See www.epa.govt.nz for approval controls.

New Zealand Inventory of Chemicals (NZIoC): Registration status

Butylated hydroxytoluene (CAS 128-37-0)	HSNO Approved
Magnesium stearate (CAS 557-04-0)	May be used as a single component chemical under an appropriate group standard
Moxidectin (CAS 113507-06-5)	HSNO Approved
Pyrantel pamoate (CAS 22204-24-6)	HSNO Approved
Silica colloidal, Ph. Eur. (CAS 112945-52-5)	May be used as a single component chemical under an appropriate group standard

Section 16: Other information

Issue date	17-March-2022
Revision date	20-April-2022
Version No.	02
Key abbreviations or acronyms used	Not available.

Disclaimer	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	Section 15: Regulatory information: Applicable regulations