SAFETY DATA SHEETS

This SDS packet was issued with item:

078945512

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078939202 078939203 078939204 078939205 078939206 078939207 078945509 078945510

SAFETY DATA SHEET

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	Veterinary antiparasitic (ectocide); anti-worm agent (anthelmintic)
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Not classified.	
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 1
	Hazardous to the aquatic environment, long-term hazard	Category 1
OSHA defined hazards	Not classified.	

Label elements

Signal word	Warning
Hazard statement	Very toxic to aquatic life with long lasting effects.
Precautionary statement	
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.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
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
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. 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 center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

General information

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.

5. Fire-fighting measures

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 firefighters

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.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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. Local authorities should be advised if significant spillages cannot be contained.

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.

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.

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).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known 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

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
Silica colloidal, Ph. Eur. (CAS 112945-52-5)	TWA	0.8 mg/m3
		20 mppcf

US. ACGIH Threshold Limit Values

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

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Butylated hydroxytoluene (CAS 128-37-0)	TWA	10 mg/m3
Silica colloidal, Ph. Eur. (CAS 112945-52-5)	TWA	6 mg/m3

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, such as personal protective equipment

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.

General hygiene considerations	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.

9. Physical and chemical properties

Appearance	Tablet.
Physical state	Solid.
Form	Solid.
Color	Reddish-brown.
Odor	Not available.
Odor 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	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor 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.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials. High temperatures. Keep away from heat, sparks and open flame.
Incompatible materials	Peroxides. Phenols. Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Health injuries are not known or expected under normal use.

Skin contact	No adverse effects due to skin contact are expected. Prolonged skin contact may cause temporary irritation.
Moxidectin	Species: Rabbit Severity: Mild
Butylated hydroxytoluene	Species: Rabbit Severity: Moderate
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 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
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)

Components	Species	Test Results
	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)
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)

Components	Species	Test Results
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 or skin sensitization

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

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

Skin sensitization

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

Mutagenicity

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.

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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

Developmental effects

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 Not an aspiration hazard.

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.

13. Disposal considerations

Disposal instructions	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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	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 (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

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
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

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.

DOT; 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.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 07-01-2019

Version # 01

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Revision information This document has undergone significant changes and should be reviewed in its entirety.