

SAFETY DATA SHEET



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 (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
Tel	1800 814 883
Fax	(02) 8876 0444
Email	australia.animalhealth@zoetis.com
Emergency Phone	1800 814 883 (all hours)
Police and Fire Brigade	Dial 000
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) 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 known.

Supplemental information

Direct contact with eyes may cause temporary irritation.

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	

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.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Do not induce vomiting. Call a physician or poison control centre immediately. Never give anything by mouth to an unconscious person.
Personal protection for first-aid responders	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.
Symptoms caused by exposure	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
Medical attention and special treatment	Treat symptomatically.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂). Apply extinguishing media carefully to avoid creating airborne dust.
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	In case of fire and/or explosion do not breathe fumes. Use water spray to cool unopened containers. Move containers from fire area if you can do so without risk. During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazchem Code	None.
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.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.
For emergency responders	Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Avoid dust formation. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not breathe dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see 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

Ensure adequate ventilation. Avoid dust formation. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Prevent product from entering drains.

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 contaminated surface thoroughly. Prevent release to the environment.

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.

7. Handling and storage**Precautions for safe handling**

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

Conditions for safe storage, including any incompatibilities

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

8. Exposure controls and personal protection**Control parameters**

Follow standard monitoring procedures.

Occupational exposure limits**Zoetis****Components**

Components	Type	Value
Sarolaner (CAS 1398609-39-6)	TWA	110 µg/m ³

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

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m ³	Inhalable dust.
Silicon dioxide, colloidal NF (CAS 7631-86-9)	TWA	2 mg/m ³	Respirable dust.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)**Components**

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m ³	Inspirable dust.
Silicon dioxide, colloidal NF (CAS 7631-86-9)	TWA	2 mg/m ³	Respirable fraction.

US. ACGIH Threshold Limit Values**Components**

Components	Type	Value
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m ³

UK. EH40 Workplace Exposure Limits (WELs)**Components**

Components	Type	Value	Form
Silicon dioxide, colloidal NF (CAS 7631-86-9)	TWA	6 mg/m ³	Inhalable dust.
		2.4 mg/m ³	Respirable dust.

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)**Components**

Components	Type	Value	Form
Silicon dioxide, colloidal NF (CAS 7631-86-9)	TWA	4 mg/m ³	Inhalable fraction.

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	Wear impervious gloves if skin contact is possible.
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. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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.
Thermal hazards	Not applicable.
Hygiene measures	When using, do not eat, drink or smoke. 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	
Physical state	Solid.
Form	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	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
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.
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.

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 Heat, flames and sparks. Contact with incompatible materials. Avoid dispersion as a dust cloud. Protect from sunlight.

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.

11. Toxicological information

Information on possible routes of exposure

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.
Sarolaner Species: Rabbit
Severity: Non-irritating

Eye contact Direct contact with eyes may cause temporary irritation.
Sarolaner Species: Rabbit
Severity: Minimal

Ingestion Expected to be a low ingestion hazard.

Symptoms related to exposure Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

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 (CAS 1398609-39-6)		
Acute		
Dermal		
LD50	Rat	> 2020 mg/kg

Components	Species	Test results
Oral LD50	Rat	783 mg/kg
<u>Subacute</u> Oral NOAEL	Rat	2.5 mg/kg/day, 14 days (Adrenal gland) 2.2 mg/kg/day, 30 days (Adrenal gland, Ovary, Liver)
<u>Subchronic</u> Oral NOAEL	Rat	25 mg/kg/day, 90 days (Adrenal gland, Ovary, Pancreas)
Skin corrosion/irritation	Not expected to cause skin irritation.	
Irritation Corrosion - Skin Sarolaner		Result: Non-irritant Species: Rabbit
Serious eye damage/irritation	Direct contact with eyes may cause temporary irritation.	
Eye contact Sarolaner		Species: Rabbit Severity: Minimal
Respiratory or skin sensitisation		
Respiratory sensitisation	Not a respiratory sensitizer.	
Skin sensitisation	This product is not expected to cause skin sensitisation.	
Skin sensitisation Sarolaner		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		Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella , E. coli
Lactose Monohydrate		In Vitro Bacterial Mutagenicity (Ames) Species: Salmonella , E. coli
Sarolaner		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	This product is not expected to cause reproductive or developmental effects.	

Developmental effects

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

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.

Chronic effects Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity Toxic to aquatic life with long lasting effects. Releases to the environment should be avoided.

Components	Species	Test results
Sarolaner (CAS 1398609-39-6)	EC50	Daphnia magna (Water Flea) 0.27 mg/l, 48 Hours
		Pseudokirchneriella subcapitata (Green Alga) > 0.27 mg/l, 72 Hours (ErC50)
Aquatic		
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.

**Partition coefficient
n-octanol / water (log Kow)**

Sarolaner 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.

13. Disposal considerations

Disposal methods Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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 (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

ADG

Not regulated as dangerous goods.

RID

UN number 3077
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 MARINE POLLUTANT (Isoxazoline)
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IATA

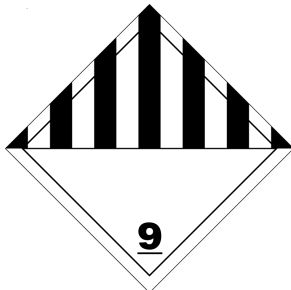
UN number 3077
UN proper shipping name Environmentally Hazardous Substance, Solid, n.o.s (Isoxazoline)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards No.
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IMDG

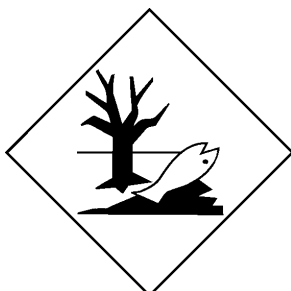
UN number 3077
UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Isoxazoline), MARINE POLLUTANT (Isoxazoline)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards
Marine pollutant Yes
EmS F-A, S-F
Special precautions for user Read safety 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; RID



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

Safety, health and environmental regulations

National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA Numbers: 80943 (For dogs 40.1-60kg), 80945 (For dogs 20.1-40kg), 80948 (For dogs 10.1-20kg), 80949 (For dogs 5.1-10kg), 80950 (For dogs 2.6-5kg), 80951 (For dogs 1.3-2.5kg)

High Volume Industrial Chemicals (HVIC)

Silicon dioxide, colloidal NF (CAS 7631-86-9)

10000 - 99999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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
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

Issue date 12-February-2016

Revision date 29-November-2016

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

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

Product and Company Identification: Synonyms
Composition / Information on Ingredients: Disclosure Overrides
First-aid measures: Personal protection for first-aid responders
Accidental release measures: Methods and materials for containment and cleaning up
Accidental release measures: For emergency responders
Handling and storage: Precautions for safe handling
Handling and storage: Conditions for safe storage, including any incompatibilities
Toxicological Information: Toxicological Data
Disposal considerations: Disposal methods
Transport Information: Proper Shipping Name/Packing Group
Regulatory information: National regulations