

SAFETY DATA SHEET



1. Identification

Product identifier Simparica™ (Sarolaner) Chewable Tablets

Other means of identification

Synonyms Sarolaner * Simparica * PF-06450567 Chewable Tablets

Recommended use Veterinary product used as antiparasitic

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company Name (US) Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (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

Contact E-Mail VMIPSrecords@zoetis.com

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 2
Hazardous to the aquatic environment, long-term hazard Category 2

OSHA defined hazards Not classified.

Label elements



Signal word None.

Hazard statement Toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Precautionary statement

Prevention Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Avoid release to the environment. Observe good industrial hygiene practices.

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	%
Isoxazoline (PF-06450567)	PF-06450567 Sarolaner Sarolaner API	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	

Composition comments 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	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	If swallowed, do NOT induce vomiting. Rinse mouth thoroughly. Call a physician or poison control center immediately.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). 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 firefighters	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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	During processing, dust may form explosive mixture in air. Fine particles (such as mists) may fuel fires/explosions.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. 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.

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**

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.

Conditions for safe storage, including any incompatibilities

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 feedstuffs. Use care in handling/storage.

8. Exposure controls/personal protection**Occupational exposure limits****Zoetis****Components****Type****Value**

Isoxazoline (PF-06450567)
(CAS 1398609-39-6)

TWA

110 µg/m³

US. OSHA Table Z-3 (29 CFR 1910.1000)**Components****Type****Value**

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

TWA

0.8 mg/m³

20 mppcf

US. ACGIH Threshold Limit Values**Components****Type****Value**

Magnesium Stearate (CAS
557-04-0)

TWA

10 mg/m³

US. NIOSH: Pocket Guide to Chemical Hazards**Components****Type****Value**

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

TWA

6 mg/m³

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, such as personal protective equipment**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

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.
General hygiene considerations	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	Tablet
Physical state	Solid.
Form	Solid.
Color	Light 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

Dust explosion properties

Minimum ignition energy (MIE) - dust cloud	240 mJ
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Electrostatic properties

Resistivity at ambient humidity	>E+12 @ 50% rH, 24C
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Explosive properties	Not explosive.
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Oxidizing properties	Not oxidizing.
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10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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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. Protect from sunlight. Avoid dispersion as a dust cloud.
Incompatible materials	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.

11. Toxicological information

Information on likely 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.
Isoxazoline (PF-06450567) Species: Rabbit
Severity: Non-irritating

Eye contact Direct contact with eyes may cause temporary irritation.
Isoxazoline (PF-06450567) Species: Rabbit
Severity: Minimal

Ingestion Expected to be a low ingestion hazard.

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

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
Isoxazoline (PF-06450567) (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)

Lactose Monohydrate (CAS 64044-51-5)

Acute

Oral

LD50 Rat 29700 mg/kg

Components	Species	Test Results
Magnesium Stearate (CAS 557-04-0)		
<u>Chronic</u>		
Oral		
LOAEL	Rat	1092 g/kg, 13 weeks Liver
Silicon dioxide, colloidal NF (CAS 7631-86-9)		
<u>Acute</u>		
Oral		
LD50	Mouse	> 15000 mg/kg
	Rat	> 22500 mg/kg
Skin corrosion/irritation	Not expected to cause skin irritation.	
Irritation Corrosion - Skin		
Isoxazoline (PF-06450567)		Result: Non-irritant Species: Rabbit
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye Contact		
Isoxazoline (PF-06450567)		Species: Rabbit Severity: Minimal
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Skin sensitization		
Isoxazoline (PF-06450567)		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		
Isoxazoline (PF-06450567)		Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli
Lactose Monohydrate		In Vitro Bacterial Mutagenicity (Ames) Species: Salmonella , E. coli
Isoxazoline (PF-06450567)		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	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Silicon dioxide, colloidal NF (CAS 7631-86-9)		3 Not classifiable as to carcinogenicity to humans.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not available.		
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.	

Developmental effects

Isoxazoline (PF-06450567)

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
Isoxazoline (PF-06450567) (CAS 1398609-39-6)		
Aquatic Fish	EC50	Daphnia magna (Water Flea) 0.27 mg/L, 48 Hours
		Pseudokirchneriella subcapitata (Green Alga) > 0.27 mg/L, 72 Hours (ErC50)
	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)

Isoxazoline (PF-06450567) 3.25

Mobility in soil No data available.

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 Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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.

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. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

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** 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 (Isoxazoline), MARINE POLLUTANT**Transport hazard class(es)****Class** 9**Subsidiary risk** -**Packing group** III**Environmental hazards****Marine pollutant** Yes**EmS** Not available.**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.**Transport in bulk according to** Not applicable.**Annex II of MARPOL 73/78 and
the IBC Code****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 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
 Delayed Hazard - No
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

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**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. Massachusetts RTK - Substance List

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

US. New Jersey Worker and Community Right-to-Know Act

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

US. Pennsylvania Worker and Community Right-to-Know Law

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

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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, including date of preparation or last revision

Issue date 02-12-2016

Revision date	06-13-2016
Version #	02
List of abbreviations	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	Toxicological Information: Toxicological Data