

## 1. Identification

<b>Product identifier</b>	<b>Simparica™ (Sarolaner) Chewable Tablets</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Simparica * Simparica™ Chews for Dogs * Simparica™ (sarolaner) Chewables * Sarolaner
<b>Recommended use</b>	Veterinary product used as antiparasitic
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	
<b>Company Name (US)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison and Drug Center</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300  International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	VMIPSrecords@zoetis.com
<b>Company Name (EU)</b>	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	VMIPSrecords@zoetis.com

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Hazardous to the aquatic environment, acute hazard Category 2  Hazardous to the aquatic environment, long-term hazard Category 2
<b>OSHA defined hazards</b>	Not classified.
<b>Label elements</b>	



<b>Signal word</b>	None.
<b>Hazard statement</b>	Toxic to aquatic life with long lasting effects.
<b>Precautionary statement</b>	
<b>Prevention</b>	Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Avoid release to the environment. Observe good industrial hygiene practices.
<b>Response</b>	Collect spillage.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)** None known.  
**Supplemental information** Direct contact with eyes may cause temporary irritation.

### 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** Rinse mouth. Do not induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

**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 (CO<sub>2</sub>). 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. Avoid dust formation. 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.

**Methods and materials for containment and cleaning up**

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. 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 feedingstuffs. 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/m<sup>3</sup>

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

**Components**

**Type**

**Value**

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

TWA

0.8 mg/m<sup>3</sup>

20 mppcf

**US. ACGIH Threshold Limit Values**

**Components**

**Type**

**Value**

Magnesium Stearate (CAS  
557-04-0)

TWA

10 mg/m<sup>3</sup>

**US. NIOSH: Pocket Guide to Chemical Hazards**

**Components**

**Type**

**Value**

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

TWA

6 mg/m<sup>3</sup>

**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**

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.

**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

**Physical state** Solid.

**Form** Tablet.

**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

#### Electrostatic properties

**Resistivity at ambient humidity** >E+12 @ 50% rH, 24C

**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.

<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Heat, flames and sparks. Contact with incompatible materials. Protect from sunlight. Avoid dispersion as a dust cloud.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	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)		
<b>Chronic</b>		
<b>Oral</b>		
LOAEL	Rat	1092 g/kg, 13 weeks Liver
Silicon dioxide, colloidal NF (CAS 7631-86-9)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	> 15000 mg/kg
	Rat	> 22500 mg/kg
<b>Skin corrosion/irritation</b>	Not expected to cause skin irritation.	
<b>Irritation Corrosion - Skin</b>		
Isoxazoline (PF-06450567)		Result: Non-irritant Species: Rabbit
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye Contact</b>		
Isoxazoline (PF-06450567)		Species: Rabbit Severity: Minimal
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Not a respiratory sensitizer.	
<b>Skin sensitization</b>	This product is not expected to cause skin sensitization.	
<b>Skin sensitization</b>		
Isoxazoline (PF-06450567)		LLNA Species: Mouse Severity: Negative
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Mutagenicity</b>		
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
<b>Carcinogenicity</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Silicon dioxide, colloidal NF (CAS 7631-86-9)		3 Not classifiable as to carcinogenicity to humans.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Not listed.		
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Not available.		
<b>Reproductive toxicity</b>	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)		
EC50	Daphnia magna (Water Flea)	0.27 mg/L, 48 Hours
	Pseudokirchneriella subcapitata (Green Alga)	> 0.27 mg/L, 72 Hours (ErC50)
<b>Aquatic</b>		
Fish	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** None known.

**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 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.

**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.





**Revision date** 10-03-2016  
**Version #** 03  
**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** This document has undergone significant changes and should be reviewed in its entirety.