SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Isoxazoline (PF-06450567) Chewable Tablet

Trade Name: Simparica
Synonyms: PF-06450567 Chewable Tablets
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary formulation
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: VMIPSrecords@zoetis.com

2. HAZARDS IDENTIFICATION

Appearance: Light brown tablet

Classification of the Substance or Mixture

GHS - Classification

Acute aquatic toxicity: Category 2
Chronic aquatic toxicity: Category 2

Label Elements

Signal Word: Not required
Hazard Statements: H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements: P273 - Avoid release to the environment
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Short Term: May cause mild eye irritation.

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
PF-06450567	1398609-39-6	Not Listed	Acute Tox. 4 (H302) Aq. Acute 1 (H400) Aq. Chronic 1 (H410)	4
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	<1
Magnesium Stearate	557-04-0	209-150-3	Not Listed	<1

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lactose Monohydrate	64044-51-5	Not Listed	Not Listed	*
Flavor	NOT ASSIGNED	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen and products of sulfur chlorine and fluorine

Fire / Explosion Hazards: During processing, dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Avoid dust formation. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean contaminated surface thoroughly.

Additional Consideration for Large Spills: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Avoid generating airborne dust. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Wash thoroughly after handling. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): Veterinary Parasiticide

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

PF-06450567

Zoetis OEL TWA 8-hr	110 µg/m^3

Silicon dioxide, colloidal NF

Australia TWA	2 mg/m^3
Austria OEL - MAKs	4 mg/m^3 0.3 mg/m^3
Czech Republic OEL - TWA	0.1 mg/m^3 4.0 mg/m^3
Estonia OEL - TWA	2 mg/m^3
Finland OEL - TWA	5 mg/m^3
Germany - TRGS 900 - TWAs	4 mg/m^3
Germany (DFG) - MAK	4 mg/m^3
Ireland OEL - TWAs	6 mg/m^3 2.4 mg/m^3
Latvia OEL - TWA	1 mg/m^3
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf Listed
Slovakia OEL - TWA	4.0 mg/m^3
Switzerland OEL -TWAs	4 mg/m^3 0.3 mg/m^3

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Wear impervious gloves if skin contact is possible.
Eyes:	Safety glasses or goggles
Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	**Color:**	Light brown
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
PF-06450567
Measured Log P 3.25
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available
Min. Ignition Energy (mJ):	240

Resistivity (ohm-m): > E+12 @ 50% rH, 24C

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions

Oxidizing Properties:	No data available
Conditions to Avoid:	Avoid dispersion as a dust cloud. Dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions. Keep away from heat and other sources of ignition, including electrostatic discharge.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: eye contact , skin contact

Acute Toxicity: (Species, Route, End Point, Dose)

Lactose Monohydrate
Rat Oral LD 50 29700 mg/kg

PF-06450567
Rat Oral LD50 783 mg/kg
Rat Dermal LD50 > 2020 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

11. TOXICOLOGICAL INFORMATION

PF-06450567
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Minimal
Skin Sensitization - LLNA Mouse Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Magnesium Stearate
13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

PF-06450567

14 Day(s)	Rat	Oral	2.5	mg/kg/day	NOAEL	Adrenal gland
30 Day(s)	Rat	Oral	2.2	mg/kg/day	NOAEL	Adrenal gland, Ovary, Liver
90 Day(s)	Rat	Oral	25	mg/kg/day	NOAEL	Adrenal gland, Ovary, Pancreas

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

PF-06450567

Embryo / Fetal Development	Rat	Oral	3.2	mg/kg/day	NOAEL	Maternal toxicity, Not teratogenic
Embryo / Fetal Development	Rabbit	Oral	3.0	mg/kg/day	NOAEL	Maternal Toxicity, Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Lactose Monohydrate
In Vitro Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

PF-06450567
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vitro Micronucleus Chinese Hamster Ovary (CHO) cells Negative
In Vivo Micronucleus Rat Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Silicon dioxide, colloidal NF
IARC: Group 3 (Not Classifiable)

Product Level Toxicity Data
Acute Toxicity Estimate (ATE), oral >10,000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

PF-06450567
Pseudokirchneriella subcapitata (Green Alga) OECD 201 ErC50 72 Hours > 0.27 mg/L
Daphnia magna (Water Flea) OECD 202 EC50 48 Hours 0.27 mg/L
Fish OECD 203 LC50 96 Hours > 0.54 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

PF-06450567
Measured Log P 3.25

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.

14. TRANSPORT 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.

UN number: UN 3077
UN proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (Isoxazoline)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

DOT / ANTT: Not regulated for transportation

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Non-controlled
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

PF-06450567

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Silicon dioxide, colloidal NF

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4

Lactose Monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed

Flavor

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Magnesium Stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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.

End of Safety Data Sheet