

# SAFETY DATA SHEET



Revision date: 28-Jan-2014

Version: 3.0

Page 1 of 9

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

### Product Identifier

**Material Name:** Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg

**Trade Name:** SIMPLICEF  
**Synonyms:** Cefpodoxime Proxetil Tablets  
**Chemical Family:** Mixture

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

**Intended Use:** Veterinary product used as antibiotic agent

### 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 Control 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  
**Contact E-Mail:** VMIPSrecords@zoetis.com

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

## 2. HAZARDS IDENTIFICATION

**Appearance:** Orange tablets

### Classification of the Substance or Mixture

#### GHS - Classification

Respiratory Sensitization: Category 1  
Skin Sensitization: Category 1

#### EU Classification:

EU Indication of danger: Xn - Harmful  
Irritant; (Xi)

EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H317 - May cause an allergic skin reaction

## SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**  
Revision date: 28-Jan-2014

Page 2 of 9

Version: 3.0

**Precautionary Statements:**

- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P284 - Wear respiratory protection
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
- P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
- P321 - Specific treatment (see supplemental first aid instructions on this label)
- P362 - Take off contaminated clothing and wash before reuse
- P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

#### Short Term:

May cause stomach irritation, diarrhea, nausea, or vomiting. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

#### Known Clinical Effects:

Hypersensitivity reactions may also occur in susceptible individuals. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

### Australian Hazard Classification (NOHSC):

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	EU Classification	GHS Classification	%
Cefpodoxime Proxetil	87239-81-4	Not Listed	Xn;R42/43	Resp.Sens.1,H334 Skin Sens. 1,H317	30.3
Sodium Lauryl Sulfate	151-21-3	205-788-1	Not Listed	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	Not Listed	*

### Additional Information:

\* Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**  
Revision date: 28-Jan-2014

Page 3 of 9

Version: 3.0

For the full text of the R phrases and 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 CO<sub>2</sub>, 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.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

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 spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
- Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**  
Revision date: 28-Jan-2014

Page 4 of 9

Version: 3.0

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Keep away from heat, sparks, and flame.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Cefpodoxime Proxetil

**Zoetis OEL TWA 8-hr** 100µg/m<sup>3</sup> Sensitizer

#### Magnesium Stearate

**ACGIH Threshold Limit Value (TWA)** 10 mg/m<sup>3</sup>

**Lithuania OEL - TWA** 5 mg/m<sup>3</sup>

**Sweden OEL - TWAs** 5 mg/m<sup>3</sup>

#### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**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

<b>Physical State:</b>	Tablets	<b>Color:</b>	Orange
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		

## SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**  
Revision date: 28-Jan-2014

Page 5 of 9

Version: 3.0

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Partition Coefficient: (Method, pH, Endpoint, Value)**

No data available

**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

**Flammability:**

**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

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable at normal conditions

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** The information included in this section describes the potential hazards of the individual ingredients. Toxicological properties of the formulation have not been investigated.

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

**Cefpodoxime Proxetil**

Mouse Oral LD 50 > 8000 mg/kg

Mouse Sub-tenon injection (eye) LD 50 2535mg/kg

Mouse Subcutaneous LD 50 > 10,000mg/kg

Rat Intravenous LD 50 > 4000mg/kg

**Lactose Monohydrate**

Rat Oral LD 50 29700 mg/kg

**Sodium Lauryl Sulfate**

Rat Oral LD 50 1288 mg/kg

Rat Sub-tenon injection (eye) LD 50 210mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

## SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**  
Revision date: 28-Jan-2014

Page 6 of 9

Version: 3.0

### 11. TOXICOLOGICAL INFORMATION

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

##### **Cefpodoxime Proxetil**

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit No effect

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

##### **Magnesium Stearate**

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

##### **Sodium Lauryl Sulfate**

3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

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

##### **Cefpodoxime Proxetil**

Reproductive & Fertility Rat Oral >500 mg/kg/day NOAEL Fertility  
Reproductive & Fertility Rabbit Oral > 500 mg/kg/day NOAEL Fertility  
Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity  
Embryo / Fetal Development Rabbit Oral 30 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity

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

##### **Cefpodoxime Proxetil**

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Chromosome Aberration Negative  
Unscheduled DNA Synthesis Negative  
*In Vivo* Micronucleus Negative

##### **Lactose Monohydrate**

*In Vitro* Bacterial Mutagenicity (Ames) Negative

##### **Water**

Bacterial Mutagenicity (Ames) Negative  
*In Vivo* Dominant Lethal Assay *Drosophila* Negative  
*In Vivo* Micronucleus Mouse Rat Negative

#### Carcinogen Status:

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

## SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**  
Revision date: 28-Jan-2014

Page 7 of 9

Version: 3.0

### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	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

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

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

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B



## SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100 and 200 mg**  
Revision date: 28-Jan-2014

Page 8 of 9

Version: 3.0

### 15. REGULATORY INFORMATION

#### Cefpodoxime Proxetil

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

#### Sodium Lauryl Sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	205-788-1

#### 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 R phrases and GHS Classification abbreviations mentioned in Section 3

H317 - May cause an allergic skin reaction

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Xn - Harmful

Xi - Irritant

R42/43 - May cause sensitization by inhalation and skin contact.

**Data Sources:** The data contained in this MSDS 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 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material 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**



## SAFETY DATA SHEET

Material Name: **Simplicef (Cefpodoxime Proxetil) Tablets - 100  
and 200 mg**  
Revision date: **28-Jan-2014**

Page 9 of 9

Version: 3.0

---