

SAFETY DATA SHEET



Revision date: 28-Jan-2014

Version: 3.0

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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: VMIPRecords@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

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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.

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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 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.
- 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.

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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/m³ Sensitizer

Magnesium Stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

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

| | | | |
|-------------------------------------|--------------------|--------------------------|--------------------|
| Physical State: | Tablets | Color: | Orange |
| 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 | | |
| Boiling Point (°C): | No data available. | | |

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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.

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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.

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12. ECOLOGICAL INFORMATION

| | |
|---------------------------------------|--|
| Environmental Overview: | Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. |
| Toxicity: | No data available |
| Persistence and Degradability: | No data available |
| Bio-accumulative Potential: | No data available |
| 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

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



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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

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