



# MATERIAL SAFETY DATA SHEET

Revision date: 26-Jul-2013

Version: 2.0

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

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### Material Name: Cefpodoxime Proxetil Oral Suspension

Trade Name:	VANTIN Oral Suspension
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antibiotic agent

## 2. HAZARDS IDENTIFICATION

Appearance: White to off-white powder  
Signal Word: DANGER

Statement of Hazard: May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.  
May cause allergic skin reaction.

Additional Hazard Information:  
Short Term: 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. Serious allergic reactions, including anaphylaxis, have been reported. 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.

EU Indication of danger: Xn - Harmful

EU Hazard Symbols:  
Xn



EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.  
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification  
(NOHSC):

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## 2. HAZARDS IDENTIFICATION

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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	%
Cefpodoxime Proxetil	87239-81-4	Not Listed	Xn;R42/43	1-2
Citric acid	77-92-9	201-069-1	Xi; R36	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Starch	9005-25-8	232-679-6	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Butylated hydroxyanisole	25013-16-5	246-563-8	Not Listed	*
Carboxymethylcellulose sodium	9004-32-4	Not Listed	Not Listed	*
Carrageenan	9000-07-1	232-524-2	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Flavoring agents	Not assigned	Not Listed	Not Listed	*
Hydrogenated vegetable oil	68334-00-9	269-804-9	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*
Maltodextrin	9050-36-6	232-940-4	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Propylene glycol alginate	9005-37-2	Not Listed	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	*
Sodium Citrate	6132-04-3	Not Listed	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

## 4. 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.

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**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.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide and oxides of nitrogen.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**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.

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

**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.

### 7. HANDLING AND STORAGE

**General Handling:** Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. 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.

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<b>Butylated hydroxyanisole</b>	
Germany - TRGS 900 - TWAs	20 mg/m <sup>3</sup>
Germany (DFG) - MAK	20 mg/m <sup>3</sup>
<b>Cefpodoxime Proxetil</b>	
Pfizer OEL TWA-8 Hr:	100µg/m <sup>3</sup> , Sensitizer
<b>Colloidal silicon dioxide</b>	
Australia TWA	2 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.1 mg/m <sup>3</sup>
	4.0 mg/m <sup>3</sup>
Estonia OEL - TWA	2 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
Ireland OEL - TWAs	6 mg/m <sup>3</sup>
	2.4 mg/m <sup>3</sup>
Latvia OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m <sup>3</sup>
<b>Microcrystalline cellulose</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
<b>Starch</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
<b>Sucrose</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

<b>Engineering Controls:</b>	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. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Wear impervious gloves to prevent skin contact.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Wear impervious protective clothing to prevent skin contact - consider use of disposable clothing where appropriate.
<b>Respiratory protection:</b>	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>	Powder	<b>Color:</b>	White to off-white
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solubility:</b>	Soluble: Water		

### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients.
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#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Cefpodoxime Proxetil**

Mouse	Oral	LD 50	> 8000 mg/kg
Mouse	Sub-tenon injection (eye)	LD 50	2535 mg/kg
Mouse	Subcutaneous	LD 50	> 10,000 mg/kg
Rat	Intravenous	LD 50	> 4000 mg/kg

##### **Sucrose**

Rat	Oral	LD50	29.7 g/kg
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### 11. TOXICOLOGICAL INFORMATION

#### Butylated hydroxyanisole

Rat Oral LD50 2000 mg/kg  
Mouse Oral LD 50 1100 mg/kg  
Rat Intraperitoneal LD 50 881 mg/kg

#### Carboxymethylcellulose sodium

Mouse Oral LD50 > 27,000 mg/kg  
Rat Oral LD50 27,000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

#### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

#### Citric acid

Rat Oral LD50 3000 mg/kg

#### Lactose

Rat Oral LD50 > 10 g/kg

#### Sodium benzoate

Rat Oral LD50 4,070 mg/kg  
Mouse Oral LD50 1600 mg/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.

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

##### Cefpodoxime Proxetil

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit No effect

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

##### Citric acid

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

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

##### Butylated hydroxyanisole

12 Day(s) Rat Oral 3300 mg/kg LOAEL Liver, Blood

##### Carboxymethylcellulose sodium

13 Week(s) Rat Oral 227 g/kg LOAEL Liver, Kidney, Ureter, Bladder

##### Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood  
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

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### 11. TOXICOLOGICAL INFORMATION

#### 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

##### **Butylated hydroxyanisole**

Embryo / Fetal Development	Rat	Oral	30 g/kg	LOEL	Teratogenic
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##### **Sodium benzoate**

Embryo / Fetal Development	Rat	Oral	44 g/kg	LOEL	Developmental toxicity
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#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Cefpodoxime Proxetil**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Chromosome Aberration	Negative	
Unscheduled DNA Synthesis	Negative	
<i>In Vivo</i> Micronucleus	Negative	

##### **Sucrose**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
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##### **Butylated hydroxyanisole**

<i>In Vivo</i> Micronucleus	Bone Marrow	Negative
<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Butylated hydroxyanisole**

Two Year(s)	Rat	Oral	728 g/kg/day	Gastrointestinal system, Tumors
Two Year(s)	Rat	Oral	874 g/kg/day	Gastrointestinal system, Endocrine system, Tumors

**Carcinogen Status:** See below

##### **Butylated hydroxyanisole**

<b>IARC:</b>	Group 2B (Possibly Carcinogenic to Humans)
<b>NTP:</b>	Reasonably Anticipated To Be A Human Carcinogen
<b>OSHA:</b>	Listed

##### **Carrageenan**

<b>IARC:</b>	Group 3 (Not Classifiable)
<b>OSHA:</b>	Listed

##### **Colloidal silicon dioxide**

<b>IARC:</b>	Group 3 (Not Classifiable)
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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

### 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

**EU Indication of danger:** Xn - Harmful

**EU Risk Phrases:** R42/43 - May cause sensitization by inhalation and skin contact.

**EU Safety Phrases:**  
S22 - Do not breathe dust.  
S24 - Avoid contact with skin.  
S37 - Wear suitable gloves.

**OSHA Label:**  
DANGER  
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.  
May cause allergic skin reaction.

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A





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## 15. REGULATORY INFORMATION

### Butylated hydroxyanisole

California Proposition 65	carcinogen initial date 1/1/90
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	246-563-8

### Carboxymethylcellulose sodium

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

### Carrageenan

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-524-2

### Cefpodoxime Proxetil

California Proposition 65	Not Listed
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### Citric acid

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

### Colloidal silicon dioxide

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

### Croscarmellose sodium

California Proposition 65	Not Listed
Australia (AICS):	Present

### Flavoring agents

California Proposition 65	Not Listed
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### Hydrogenated vegetable oil

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	269-804-9

### Hydroxypropyl cellulose

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

### Lactose

California Proposition 65	Not Listed
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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-559-2
<b>Maltodextrin</b>	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-940-4
<b>Microcrystalline cellulose</b>	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9
<b>Propylene glycol alginate</b>	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
<b>Sodium benzoate</b>	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8
<b>Sodium Citrate</b>	
California Proposition 65	Not Listed
Australia (AICS):	Present
<b>Starch</b>	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6
<b>Sucrose</b>	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9
<b>Water</b>	
California Proposition 65	Not Listed

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R36 - Irritating to eyes.

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

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information. Updated Section 3 - Composition / Information on Ingredients.

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

Pfizer 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**