



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

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ChemSafe (24 hours): +44 (0)208 762 8322

### Material Name: Famotidine tablets

**Trade Name:** Pepcid F/C  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used for gastrointestinal disorders.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Famotidine	76824-35-6	Not listed	10 mg***
Microcrystalline cellulose	9004-34-6	232-674-9	*
Starch	9005-25-8	232-679-6	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Titanium dioxide	13463-67-7	236-675-5	*
Magnesium stearate	557-04-0	209-150-3	*
Ferric oxide red	1309-37-1	215-168-2	*

Ingredient	CAS Number	EU EINECS List	%
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Hypromellose	9004-65-3	Not listed	*

**Additional Information:** \* Proprietary  
\*\*\* per tablet/capsule/lozenge/suppository  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Pink tablet  
**Signal Word:** None required

**Statement of Hazard:** May cause harm to breastfed babies.

### Additional Hazard Information:

**Short Term:** Not acutely toxic ; Not an eye irritant ; Not a skin irritant (based on components) .  
**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include headache, gastrointestinal disturbances, dizziness. Occasional, transient changes reported in liver function tests, but no liver damage seen. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Secreted in human breast milk.

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**EU Indication of danger:** Not classified  
**EU Hazard Symbols:**

**EU Risk Phrases:**  
R64 - May cause harm to breastfed babies.

**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.

### 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.

### 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

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

**Fire / Explosion Hazards:** Not applicable

### 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:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

**Storage Conditions:** Store at controlled room temperature. Protect from moisture.

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Storage Temperature: <30°C

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Microcrystalline cellulose

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Starch

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA  
ACGIH Threshold Limit Value (TWA) = 2 mg/m<sup>3</sup> TWA  
Australia TWA = 2.5 mg/m<sup>3</sup> TWA containing no asbestos fibers

### Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Ferric oxide red

OSHA - Final PELs - TWAs: = 10 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 5 mg/m<sup>3</sup> TWA  
Australia TWA = 5 mg/m<sup>3</sup> TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.  
**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.  
**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.  
**Respiratory protection:** Not required for the normal use of this product. 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:

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Physical State:	Tablet	Color:	Pink
Molecular Formula:	Mixture	Molecular Weight:	Mixture

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** None known  
**Incompatible Materials:** None identified

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

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

#### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

#### Microcrystalline cellulose

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

#### Starch

Mouse IP LD50 6600 mg/kg

#### Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

#### Titanium dioxide

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 50 mg/kg

#### Famotidine

Rat Oral LD50 4049 mg/kg  
Rat Intravenous LD50 254 mg/kg  
Rat Intraperitoneal LD50 800 mg/kg  
Mouse Oral LD50 4686 mg/kg  
Mouse Intravenous LD50 254 mg/kg

#### Hypromellose

Rat Oral LD50 > 10,000 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)

#### Microcrystalline cellulose

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

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

#### Famotidine

Reproductive & Fertility	Rat	Intravenous	200 mg/kg/day	NOAEL	Fertility
Reproductive & Fertility	Rat	Oral	2000 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Rabbit	Intravenous	200 mg/kg/day	LOAEL	Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral	500 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Oral	2000 mg/kg/day	NOAEL	Not Teratogenic

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

#### Famotidine

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative with activation
<i>In Vivo</i> Micronucleus	Mouse	Negative
<i>In Vivo</i> Chromosome Aberration	Mouse	Negative

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

#### Famotidine

92 Week(s)	Mouse	Oral	2000 mg/kg/day	NOAEL	Not carcinogenic
106 Week(s)	Rat	Oral	2000 mg/kg/day	NOAEL	Not carcinogenic

**Carcinogen Status:** See below

#### Ferric oxide red

**IARC:** Group 3

#### Talc (non-asbestiform)

**IARC:** Group 3

#### Titanium dioxide

**IARC:** Group 2B

**OSHA:** Present

## 12. ECOLOGICAL INFORMATION

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

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

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

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## 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified  
**EU Risk Phrases:** R64 - May cause harm to breastfed babies.

**OSHA Label:**  
None required  
May cause harm to breastfed babies.

### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
None required  
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### **Famotidine**

<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 2 Schedule 4

#### **Microcrystalline cellulose**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	232-674-9

#### **Starch**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	232-679-6

#### **Talc (non-asbestiform)**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	238-877-9

#### **Titanium dioxide**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	236-675-5

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### Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

### Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

### Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

### Ferric oxide red

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-168-2

## 16. OTHER INFORMATION

### Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

### Prepared by:

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**