



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 Chewable Tablets

Trade Name:	Pepcid Duo
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***
Calcium carbonate	1317-65-3	215-279-6	*
Starch	9005-25-8	232-679-6	*
Sucrose	57-50-1	200-334-9	*
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	*
Lactose Monohydrate	64044-51-5	Not listed	*
Magnesium hydroxide	1309-42-8	215-170-3	*
Peppermint flavor	8006-90-4	Not listed	*
Sodium Lauryl Sulfate	151-21-3	205-788-1	*
Cellulose Acetate	9004-70-0	Not listed	*
Flavor blend	NOT ASSIGNED	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, round tablet

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)

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Known Clinical Effects:	Adverse effects most commonly reported in clinical use include headache, nausea and gastrointestinal disturbances. 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.
EU Indication of danger:	Not classified
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

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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 as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Calcium carbonate

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Starch

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Sucrose

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Ferric oxide red

OSHA - Final PELs - TWAs: = 10 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA
Australia TWA = 5 mg/m³ 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:

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

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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/m³

Starch

Mouse IP LD50 6600 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

Magnesium hydroxide

Rat Oral LD50 8500 mg/kg
Rat Intraperitoneal LD50 2780 mg/kg

Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

Sodium Lauryl Sulfate

Rat Oral LD 50 1288 mg/kg
Rat Intraperitoneal LD 50 210 mg/kg

Sucrose

Rat Oral LD50 29.7 g/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)

Magnesium hydroxide

Eye Irritation Rabbit Moderate

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

Sodium Lauryl Sulfate

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

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

Ferric oxide red

IARC: Group 3

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.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified
EU Risk Phrases:

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R64 - May cause harm to breastfed babies.

OSHA Label:

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

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

Calcium carbonate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-279-6

Starch

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

Sucrose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9

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

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EU EINECS List	209-150-3
Lactose Monohydrate	
Australia (AICS):	Present
Magnesium hydroxide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-170-3
Peppermint flavor	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Sodium Lauryl Sulfate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1
Cellulose Acetate	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
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 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet