



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.3

Page 1 of 6

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

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

**Material Name: Ferrous Fumarate Tablets, 75 mg (Packaged with Estrostep Fe and Loestrin Fe)**

**Trade Name:** Not established  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical active used as dietary supplement

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ferrous fumarate	141-01-5	205-447-7	60.8
Microcrystalline cellulose	9004-34-6	232-674-9	*
Sucrose	57-50-1	200-334-9	*
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Maltodextrin	9050-36-6	232-940-4	*
Sodium starch glycolate	9063-38-1	Not listed	*
Povidone	9003-39-8	Not listed	*

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** Brown tablets

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

### Additional Hazard Information:

**Short Term:** Dust may cause irritation . Not acutely toxic (based on animal data)  
**Known Clinical Effects:** The most immediate effect seen after ingestion of iron is GI irritation which may lead to nausea, vomiting, and other GI effects. Excessive ingestion/overdose may result in more serious side effects, including death.

**EU Indication of danger:** Not classified

## MATERIAL SAFETY DATA SHEET

Material Name: Ferrous Fumarate Tablets, 75 mg (Packaged with Estrostep Fe and Loestrin Fe)  
Revision date: 02-Jan-2007

Page 2 of 6

Version: 1.3

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

### 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** No data available

**Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

**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 in a cool, dry place away from direct sunlight.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ferrous fumarate



## MATERIAL SAFETY DATA SHEET

Material Name: Ferrous Fumarate Tablets, 75 mg (Packaged with Estrostep Fe and Loestrin Fe)

Page 4 of 6

Revision date: 02-Jan-2007

Version: 1.3

### Povidone

Rat Oral LD50 100 g/kg

### Sucrose

Rat Oral LD50 29.7 g/kg

### 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

### Ferrous fumarate

Rat Oral LD50 3850 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.

#### Inhalation Acute Toxicity

Ferrous fumarate may be irritating to the respiratory system.

#### Ingestion Acute Toxicity

See Acute toxicity table. In humans 20 mg/kg of elemental iron may cause GI irritation and 60 mg/kg may lead to systemic toxicity.

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

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

##### Eye Irritation / Sensitization

Ferrous fumarate may be irritating to the eyes.

##### Skin Irritation / Sensitization

No data available

##### Chronic Toxicity

Chronic ingestion of iron preparations may cause GI tract irritation with nausea, vomiting, heartburn, anorexia, constipation, and diarrhea. Chronic excessive iron intake may cause damage to the liver and pancreas.

#### Reproductive Effects

High level exposures to iron (maternally toxic doses) have been associated with spontaneous abortions and preterm delivery. Data on these exposures are equivocal and limited. Iron overload has been associated with reduced spermatogenesis in male rats.

#### Teratogenicity

Large dose dietary iron supplements were not teratogenic when tested in mice and rats. Pregnant rabbits fed maternally toxic doses of an iron supplement had offspring with an increased incidence of defects of the CNS and skeleton.

#### Mutagenicity

No data available

#### Carcinogen Status:

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

### Povidone

IARC:

Group 3

## 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

## MATERIAL SAFETY DATA SHEET

Material Name: Ferrous Fumarate Tablets, 75 mg (Packaged  
with Estrostep Fe and Loestrin Fe)  
Revision date: 02-Jan-2007

Page 5 of 6

Version: 1.3

### 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

**OSHA Label:**

Non-hazardous in accordance with international standards for workplace safety.

**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.

**Ferrous fumarate**

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4 Schedule 5 Schedule 6
EU EINECS List	205-447-7

**Maltodextrin**

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-940-4

**Sodium starch glycolate**

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

**Microcrystalline cellulose**

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

## MATERIAL SAFETY DATA SHEET

Material Name: Ferrous Fumarate Tablets, 75 mg (Packaged  
with Estrostep Fe and Loestrin Fe)

Page 6 of 6

Revision date: 02-Jan-2007

Version: 1.3

---

EU EINECS List	232-674-9
<b>Sucrose</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9
<b>Magnesium stearate</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3
<b>Povidone</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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

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 a warranty of any kind, expressed or implied.

**End of Safety Data Sheet**