

Material Safety Data Sheet ANSI Format

Ferrous Fumarate Tablets

Preparation Date 08-Dec-2006 Revision Date 25-Feb-2008 Revision Number 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Ferrous Fumarate Tablets

Common NameNot availableChemical NameNot applicableSynonymsDuofem, ForvitalProduct UsePharmaceutical productClassificationIron Preparations

Supplier Wyeth

P.O. Box 8299

Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400

Emergency Telephone Number Chemtrec USA, Puerto Rico, Canada 1-800-424-9300

Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical tabletPhysical StateSolidOdor Not available

Potential Physical Hazards Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes May cause irritation
Skin May cause irritation

Inhalation May cause mucous membrane and upper respiratory tract irritation

Ingestion The most common effects may include constipation, diarrhea, dark stools, nausea and/or

epigastric pain.

Therapeutic Target Organ(s) Blood system

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects See Section 12

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Ferrous Fumarate	141-01-5	75 mg/tablet
Inactive Ingredients	Not applicable	Remainder

4. FIRST AID MEASURES

Eye Contact In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek

medical advice.

Skin ContactTake off contaminated clothing and shoes immediately. Wash off immediately with soap and

plenty of water. If skin irritation persists, call a physician.

Inhalation Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist,

call a physician.

Ingestion If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never

give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties Presumed to be a combustible particulate solid.

Extinguishing Media

Suitable Extinguishing Media

Unsuitable Extinguishing

Media

Use water spray, foam, dry chemical or carbon dioxide.

Do NOT use water jet.

Fire Fighting Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with

water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters

In the event of fire, wear self-contained breathing apparatus and special protective equipment

for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions Prevent product from entering drains. Local authorities should be advised if a significant spill

cannot be contained.

Methods for Containment Not available

Methods for Cleaning up Take up mechanically and collect in suitable container for disposal. Clean contaminated

surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling For personal protection see Section 8. Handle in accordance with good industrial hygiene and

safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Exposure Guideline

Inactive Ingredients 250 mg/m³

Revision Date 25-Feb-2008

Engineering Controls Ensure adequate ventilation.

Personal Protective Equipment

Eye/face ProtectionProvide eye protection based on risk assessment.Skin ProtectionWear nitrile or latex gloves. Wear protective garment.Respiratory ProtectionBase respirator selection on a risk assessment.

General Hygiene Considerations When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands

before breaks and at the end of workday.

Other Limit access to only personnel trained in the safe handling of this material. Consult a health

and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance Pharmaceutical tablet Physical State Solid

Color Brown Odor Not available

Odor Threshold Not available

pH Not applicable

Specific GravityNot applicableWater SolubilityNot availableSolubilityNot applicableEvaporation RateNot applicablePartition CoefficientNot availableVapor PressureNot applicable

(n-octanol/water)

Boiling PointNot applicableAutoignition TemperatureNot applicableFlash PointNot availableMethodNone

Flash Point Not available Melting Point Not available

Flammability Limits Upper Not applicable Lower Not applicable

in Air

Explosion Limits Upper Not applicable Lower Not applicable

10. STABILITY AND REACTIVITY

Chemical Stability Stable at room temperature.

Conditions to Avoid No data available

Materials to Avoid Strong oxidizing agents

Hazardous Decomposition Products None under normal use

Possibility of Hazardous Reactions None under normal use

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Ferrous Fumarate

LD50 Oral 3850 mg/kg rats

1570 mg/kg mice

Acute Dermal IrritationNot applicablePrimary Eye IrritationNot applicableSensitizationNot applicable

Multiple Dose Toxicity

Ferrous Fumarate

No Toxicologic Effect Not applicable

Dose/Species/Study Length:

Maximum Tolerated Dose (MTD), Oral

Ferrous Fumarate

CarcinogenicityNo data availableGenetic ToxicityNo data availableReproductive ToxicityNo data availableDevelopmental ToxicityNo data available

Ferrous Fumarate

Target Organ(s) of Toxicity No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Ferrous Fumarate

Mobility Not available

Biodegradability Readily biodegradable.

Stability in Water Not available Bioaccumulation Not available

Ecotoxicity

Ferrous Fumarate

MicroorganismsNot availableAlgaeNot availableDaphniaNot availableFishNot available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information

This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT)

Canadian Transport of Dangerous Goods (TDG)

International Civil Aviation Organization (ICAO)

Not regulated International Air Transport Association (IATA)

Not regulated International Maritime Dangerous Goods (IMDG)/International

Not regulated

Maritime Organization (IMO)

Transport of Dangerous Goods by Rail (RID)

Transport of Dangerous Goods by Road (ADR)

Not regulated

Not regulated

Not regulated

Not regulated

(ADN)

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard

Chronic Health Hazard

No
Fire Hazard

No
Sudden Release of Pressure Hazard

No
Reactive Hazard

No

This product does not contain any HAPs.

State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

Canada

Not classified

WHMIS Hazard Class

Non-controlled

European Union

In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety

Format This MSDS was prepared in accordance with ANSI Z400.1-2004.

List of References See Patient Package Insert for more information.

Revision Summary Administrative

Disclaimer:

The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS