APOTEX
ADVANCING GENERICS

# Material Safety Data Sheet

## Section 1. Product Identification and Uses

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|---|---|
| **Common/Trade name** | **FERRIPROX®**<br>**500 mg and 1000 mg** |
| **Synonyms** | Deferiprone Tablets |
| **Chemical name** | Not applicable. |
| **Chemical family** | Pyridinone |
| **Supplier** | ApoPharma USA, Inc.,<br>Rockville, MD, USA 20850 |
| **Material uses** | Pharmaceutical industry:Dosage form<br>Therapeutic category: Iron Chelating Agent |
| **Emergency phone** | United States/Canada (Chemtrec) 1-800-424-9300 or<br>+1 703-527-3887 (24 hours)<br>For general information call:<br>1-(416)-749-9300 ext. 8483 (8 AM-4 PM) |

| | |
|---|---|
| **DSL#** | Not on the DSL list. |
| **CAS#** | Mixture. |
| **Molecular weight** | Not applicable. |
| **Chemical formula** | Not applicable. |
| **Chemical structure** | Not applicable |
| **Manufacturer** | Apotex Inc.<br>150 Signet Drive<br>Toronto, Ontario<br>M9L 1T9<br>416-749-9300 |
| **DIN** | Not available. |

## Section 2. Hazards Identification

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|---|---|
| **Potential Acute Health Effects** | Not expected to be hazardous under normal handling conditions. |
| **Potential Chronic Health Effects** | Possible teratogen (animal studies only) |
| **Apotex Hazard Classification (For Apotex internal practices only)** | This material has been assigned hazard class: **2** |

## Section 3. First Aid Measures

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| **Eye contact** | Flush with copious quantities of water. If irritation persists, obtain medical advice. |
| **Skin contact** | Not expected to result in hazardous effects. |
| **Hazardous skin contact** | Flush with copious amounts of water. Seek medical attention if irritation persist. |
| **Slight inhalation** | Not expected to result in hazardous effects. |
| **Hazardous inhalation** | Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen. |
| **Slight ingestion** | Not expected to be hazardous. It is good practice to rinse mouth thoroughly with water and drink a cup of water to minimize discomfort. |
| **Hazardous ingestion** | Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention. |

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## *Section 4. Hazardous Ingredients*

| Name | CAS # | % (w/w) |
|---|---|---|
| Deferiprone | 30652-11-0 | 70 - 90 |

**Toxicity values of the hazardous ingredients**

Refer to Sec. 11.

**TLV** Not available.

## *Section 5. Fire Fighting Measures*

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| **The product is:** | May be combustible at high temperature. |
| **Autoignition temperature** | Not available. |
| **Fire degradation products** | Decomposition products may include the following materials:carbon oxides (CO, $CO_2$), nitrogen oxides (NO, $NO_2$ etc.). |
| **Flash points** | Not applicable. |
| **Flammable limits** | Not available. |
| **Fire extinguishing procedures** | Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.<br>Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| **Flammability** | Emits toxic fumes under fire conditions. |
| | **Remark**<br>No additional remark. |
| **Risks of explosion** | Not available. |
| | **Remark**<br>No additional remark. |

## *Section 6. Accidental Release Measures*

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| **Spill and leak** | Vacuum or sweep up spillage. Avoid dust. Place spillage into an appropriate labeled waste disposal container. Wash contaminated clothing before reuse. Ventilate area and wash spill site. Follow appropriate safe work practices. |

***Protective Clothing Pictograms in case of large spill and/or high exposure levels***

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|---|---|
| **Protective clothing in case of large spill** | Covering uniform. Gloves. Half facepiece Air Purifying Respirator with combination particulate/organic vapour cartridge. Splash goggles. |

## *Section 7. Handling and Storage*

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| **Precautions** | Avoid breathing dust. Pregnant women should avoid exposure to this product. |
| **Storage** | Store at room temperature 15 to 30ºC (59° to 86°F). |

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## Section 8. Exposure Controls/Personal Protection

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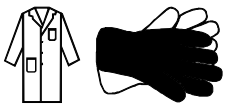
| **Engineering Controls** | The engineering control measures appropriate for a particular worksite depend on how this material is handled and on the extent of exposure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Control measures can include mechanical ventilation (local or general) and process enclosure. Administrative controls and personal protective equipment may also be required. |
| **Personal Protection**<br>**Protective Clothing (Pictograms)** | Covering uniform. Gloves.<br>  |

PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES :
Under normal work conditions, the use of respiratory protective equipment is not expected to be required. For major spills refer to Section 6. Have appropriate equipment available for use in emergencies such as spills or fire.
If the physical state of the finished product is altered by crushing, grinding or breakage, appropriate PPE may be required including half facepiece Air Purifying Respirator with combination particulate/organic vapour cartridges. The respirator use limitations specified by the approving agency and the manufacturer must be observed.
EYE/FACE PROTECTION : Not required under normal working conditions.
SKIN PROTECTION : The use of nitrile gloves is required for Good Manufacturing Practices (GMP) compliance.
RESISTANCE OF MATERIALS FOR PROTECTIVE CLOTHING : Resistance of specific materials can vary from product to product. Evaluate resistance under conditions of use and maintain clothing carefully.
EXPOSURE CONTROLS/PERSONAL PROTECTION COMMENTS: In the event clothing becomes contaminated, remove promptly. Launder before use. Inform laundry personnel of contaminant's hazards. Do not eat, drink or smoke in work areas. Wash hands thoroughly after handling this material. Maintain good housekeeping.
**PREGNANCY PRECAUTION:**
Pregnant women should avoid exposure to this product unless:
True Barrier Technology or appropriate engineering controls exists or PPE as specified.

## Section 9. Physical and Chemical Properties

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|---|---|---|---|
| **Physical state and appearance** | FERRIPROX® (deferiprone) tablets are white to off-white, capsule-shaped tablets, film-coated, and have a functional score imprinted with “APO” score “500” on one side and are plain on the other. | | |
| **pH** | Not available. | **Taste** | Not available. |
| **Odor threshold** | Not available. | **Odor** | Not available. |
| **Volatility** | Not available | | |
| **Melting point/ Freezing point** | Not available. | | |
| **Boiling point** | Not available. | | |
| **Specific gravity** | Not available. | | |
| **Vapor density** | Not available. | | |
| **Vapor pressure** | Not available. | | |
| **Partition Coefficient:** | Not available. | | |
| **Ionicity (surface active agent)** | Not available. | | |
| **Critical temperature** | Not available. | | |
| **Instability temperature** | Not available. | | |
| **Conditions of instability** | No additional remark. | | |
| **Dispersion properties** | See solubility. | | |
| **Evaporation rate** | Not available. | | |
| **Solubility** | Not available. | | |

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## *Section 10. Stability and Reactivity*

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| **Stability** | Normally stable. |
| **Hazardous decomp. products** | When heated to decomposition material emits toxic fumes. |
| **Degradability** | Not available. |
| **Corrosivity** | Not available. |
| | **Remark**<br>No additional remark. |
| **Reactivity/ Incompatibility** | Avoid exposure to moisture. |
| | **Remark**<br>No additional remark. |

## *Section 11. Toxicological Information*

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| **Routes of entry** | As the product is a solid dosage form, the major route of entry is ingestion. Other routes of entry, including inhalation, skin and eye contact may occur only under certain circumstances. |
| **Toxicity data** | Deferiprone:<br>LD50: 2000 - 3000 mg/kg (oral-rat)<br>LD50: 983 and 650 mg/kg (injection - rat and mice) |
| **Long-term effects** | Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA. No rodent carcinogenicity studies have been conducted with deferiprone. In a 12 month rat toxicology study, reversible mammary gland hyperplasia occurred in female animals of all deferiprone-treated groups, irrespective of iron loading. The incidence of mammary tumors (1 of 65 males, 1 of 65 females) in deferiprone-treated animals was not statistically significantly different from that in controls.<br>Fertility and Reproduction: Pregnancy Category: D. Based on evidence of genotoxicity and developmental toxicity in animal studies, deferiprone can cause fetal harm when administered to a pregnant woman. In animal studies, administration of deferiprone during the period of organogenesis resulted in embryofetal death and malformations at doses lower than equivalent human clinical doses.<br>Mutagenicity: Deferiprone was not mutagenic in a bacterial reverse mutation assay. It was positive in an in vitro L5178Y/TK+/- mouse lymphoma mutagenesis assay in the absence or presence of metabolic activation. Evidence of clastogenic effect was observed in a bone marrow micronucleus test in non-iron-loaded mice and after iron loading. There was no difference in the frequencies of lymphocyte chromosomal aberrations in thalassemia patients treated with deferiprone and deferoxamine in a clinical trial conducted to a crossover design. |
| | **Remark**<br>Concentrations: Hypersensitivity to deferiprone. |
| **Short-term effects and Signs & Symptoms of overexposure** | The most common adverse reactions reported during clinical trials with deferiprone were chromaturia, nausea, vomiting, abdominal pain, alanine aminotransferase increased, arthralgia and neutropenia. The most serious reaction was agranulocytosis. |
| | **Remark**<br>Adverse affects based on clinical studies. |

## *Section 12. Ecological Information*

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| **Ecological Information** | Not available. |

## *Section 13. Disposal Considerations*

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| **Waste Disposal** | For internal Apotex (Ontario) waste disposal: Collect in sealed containers and place in appropriate labeled pharmaceutical solid waste class 261A.<br>For external waste disposal: Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies. |

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## *Section 14. Transport information*

| Regulatory information | UN number | Proper shipping name | Class | Packing group | Label | Additional information |
|---|---|---|---|---|---|---|
| **TDG- road Canada/U.S.** | | | Not regulated. | | | |
| **ICAO-Air** | | | Not regulated. | | | |
| **ADR** | | | Not regulated. | | | |
| **IMDG Class** | | | Not regulated. | | | |

## *Section 15. Other Regulatory Information and Pictograms*

**WHMIS**

WHMIS CLASS D-2A: Material causing other toxic effects (VERY TOXIC).

**Remark**

Covered by Food & Drug Act and therefore not regulated under WHMIS.

**EU Classification and Labelling**

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device. R40- Possible risks of irreversible effects. R63- Possible risk of harm to the unborn child.

**Other Regulations**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

## *Section 16. Other Information*

**References**

RTECS Database
Apotex Product Monograph

**MSDS:**

**Validation date: (year.month)**

**Revision date: 4/20/2015.**

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