MATERIAL SAFETY DATA SHEET

GastroMARK®
(ferumoxsil oral suspension)

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: GastroMARK®
Synonyms: ferumoxsil oral suspension; Poly[N-(2-aminotethyl)-3-aminopropyl] siloxane-coated non-stoichiometric magnetite
Manufacturer: **Mallinckrodt Inc.**
P.O. Box 5840
St. Louis, MO 63134

Revision Date: January 1, 2003
Information Telephone Number: (888) 744-1414
Emergency Telephone Number: (314) 654-1600
CHEMTREC: 1-800-424-9300
CANUTEC: 613-996-6666

SECTION 2. COMPOSITION, INFORMATION ON INGREDIENTS

Chemical Formula: $FeO_x(C_5H_{13}N_2SiO_2)_y$
Chemical Ingredients:

Component	CAS #	Wt %
Superparamagnetic Iron Oxide	1345-25-1	91%
Silicone	63148-62-9	9%

The formulation contains CML, parabens, orange color, orange flavor, saccharin, sorbitol, NaCl, NaOH, and water.

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW
Read Package Insert Prior to Use

Ensure prompt removal from skin, eyes and clothing. As part of good laboratory and personal hygiene and safety procedure avoid all unnecessary expose to the chemical substance.

POTENTIAL HEALTH EFFECTS

Inhalation:
Not expected to be a health hazard via inhalation.

Ingestion:
Excessive oral doses may produce gastrointestinal disturbances.

Eye Contact:
No adverse effects expected, but spashes may cause mechanical irritation.

Skin Contact:
No adverse effects expected.

Chronic Exposure:
No adverse health effects expected from chronic exposure.

Aggravation of Pre-existing Conditions:
May provoke an allergic reaction in people with hypersensitivity to iron oxides.

SECTION 4. FIRST AID MEASURES

Inhalation:
Not expected to require first aid measures.

Ingestion:
May cause diarrhea and flatulence.

Skin Exposure:
Wash exposed area with soap and water. Get medical advice if irritation develops.

Eye Exposure:
In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician if irritation develops.

SECTION 5. FIRE FIGHTING MEASURES

Flammability: Not a flammable material.

Fire/Explosion Hazards: Not considered to be a fire or explosion hazard.

Fire Extinguishing Media: Use any means suitable for extinguishing surrounding fire.

Special Instructions: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Small spills may be mopped up or flushed to sewer. Large spills may be collected for disposal or absorbed with an inert material and containerized for disposal. Ensure compliance with local, state and federal regulations.

SECTION 7. HANDLING AND STORAGE

Store at 2°C to 25°C (36°F-77°F). ***Do not freeze.***

SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Airborne Exposure Limits:
None established.

Engineering Controls:
Not expected to require any special ventilation.

Respiratory Protection:
Not expected to require personal respirator usage.

Skin Protection:
Wear protective gloves.

Eye/Face Protection:
Safety glasses. Maintain eye wash fountain and quick-drench facilities in work area.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Dark brown to orange brown suspension.

Odor: Odorless.

Solubility: Insoluble in water, alkali and organic solvents. Decomposed in strong acids.

Boiling Point: ca. 100°C (212°F).

Specific Gravity: 1.01.

pH: 5.5-9.0 adjusted with sodium hydroxide.

Osmolality: 250 mOsm/kg.

Melting Point: Not applicable.

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products: None known.

Hazardous Polymerization: Will not occur.

Incompatibilities: No information found.

SECTION 11. TOXICOLOGICAL INFORMATION

Maximum dose level studies in rats and dogs exceeded the anticipated human clinical dose of approximately 2-3 mg Fe/kg by up to 1000 times as the drug substance and 20 times as the drug product.

SECTION 12. ECOLOGICAL INFORMATION

Because this product is intended for use by hospital or clinic patients, it is expected to be treated by standard wastewater treatment facilities with no adverse environmental impacts.

SECTION 13. DISPOSAL CONSIDERATIONS

Collected spills may be flushed to sewer with large amounts of water. Containerized material may be disposed in an approved waste facility.

If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a Biohazard and disposed of accordingly.

If not a biohazard, waste GastroMARK® is considered non-hazardous. Consult local, state and federal regulations for proper disposal.

SECTION 14. TRANSPORT INFORMATION

DOT (Department of Transportation): Not regulated as a hazardous material.

SECTION 15. REGULATORY INFORMATION

OSHA Hazard Communication:
This product is not considered hazardous under the OSHA Communication Standard (29 CFR 1910.1200) guidelines.
CERCLA Reportable Quantities:
Not applicable.
SARA Title III:
302 Extremely Hazardous Substances: None
311/312 Hazard Categories: None
313 Toxic substances subject to annual release reporting requirements: None.
RCRA Hazardous Waste Status
Non-hazardous (See Section 13 for additional details.)
California Proposition 65 Warning:
Not applicable.
Australian Hazchem Code: None allocated.
Australian Poison Schedule: None allocated.
WHMIS: This MSDS has been prepared according to 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

MSDS Status: Revised in accordance with ANSI Guideline Z400.1-1998.
NFPA Ratings: Health: 0 Fire: 0 Reactivity: 0
Product Use: Diagnostic imaging agent
Revision Information: Sections 1 and 15 updated.

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