



WEST BENGAL CHEMICAL INDUSTRIES LIMITED

145/1, Jessore Road, Lake Town,

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Email: [webcil@wbcil.com](mailto:webcil@wbcil.com)

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## Section 1 - Chemical Product and Company Identification

**1.1 MSDS Name:** Ferric Carboxymaltose

**1.2 Product Code:** FCM2525

**1.3 Recommended Use:** Treatment of iron deficiency anemia in:

- Adults and pediatric patients ( $\geq 1$  year) intolerant to oral iron or with unsatisfactory response to oral iron.
- Adults with non-dialysis dependent chronic kidney disease.

**1.4 Restrictions on Use:** For medical and pharmaceutical use only.

**1.5 Company Identification:**

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## Section 2 – Hazards Identification

**2.1 Classification of the Substance or Mixture Classification (GHS-US):**

Not classified.

**2.2. Label Elements GHS-US Labeling:**

No labeling applicable.

**2.3 Hazard Classification:**

Skin Irritation: Category 2.

Eye Irritation: Category 2.

STOT SE (Single Exposure): Category 3.

Reproductive Toxicity: Category 2.

STOT RE (Repeated Exposure): Category 2.

**2.4 Signal Word:**

WARNING.

**2.5 Hazard Statements:**

H315: Causes skin irritation.

H319: Causes serious eye irritation.





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H335: May cause respiratory irritation.

H361: Suspected of damaging fertility or the unborn child.

H373: May cause damage to organs through prolonged or repeated exposure.

## 2.6 Precautionary Statement Codes:

### Prevention:

P203: Obtain, read, and follow all safety instructions before use.

P260: Do not breathe dust, fume, gas, mist, vapors, or spray.

P264: Wash hands thoroughly after handling.

P280: Wear protective gloves, clothing, and eye protection.

### Response:

P302+P352: IF ON SKIN – Wash with soap and water.

P305+P351+P338: IF IN EYES – Rinse cautiously with water for several minutes. Remove contact lenses if easy to do. Continue rinsing.

P304+P340: IF INHALED – Remove person to fresh air and keep comfortable for breathing.

### Storage:

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P405: Store locked up.

### Disposal:

P501: Dispose of contents/container in accordance with local regulations.





### 2.7 POTENTIAL ACUTE HEALTH EFFECTS:

Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

### 2.8 POTENTIAL CHRONIC HEALTH EFFECTS:

Hazardous in case of skin contact (irritant).

**2.9 CARCINOGENIC EFFECTS:** No data available.

**2.10 MUTAGENIC EFFECTS:** No data available.

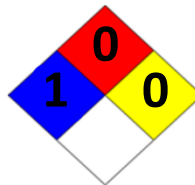
**2.11 TERATOGENIC EFFECTS:** No data available.

**2.12 DEVELOPMENTAL TOXICITY:** No data available

### 2.13 Pictogram:



### 2.14 NFPA SCALE:



NFPA SCALE (0-4)

### 2.15 HMIS RATINGS:

Health	1
Flammability	0
Physical Hazard	0
Personal protection	E

HMIS RATINGS (0-4)





### Section 3 – Composition/Information on Ingredients

**3.1 Ingredient Name:** Ferric Carboxymaltose.

**3.2 Synonyms:**

- Maltofer
- Iron (III) hydroxide polymaltose complex
- Ferric polymaltose (IS)
- Ferromaltose (IS)
- Ferrum Polyisomaltose (IS)
- Ferric Carboxymaltose Complex (IS)

**3.3 Molecular Formula:**  $C_{24}H_{44}FeO_{25}^-$

**3.4 Molecular Weight:** 788.4 g/mol

**3.5 CAS Number:** 9007-72-1

**3.6 EC Number:** 813-933-0

### Section 4 - First Aid Measures

**4.1 Description of First Aid Measures:**

**4.1.1 GENERAL ADVICE**

Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell (show the label where possible).

**4.1.2 IF INHALED**

When symptoms occur: Go into open air and ventilate suspected area. Seek medical attention.

**4.1.3 SKIN CONTACT**

Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Seek medical attention.

**4.1.4 EYE CONTACT**

Rinse thoroughly with plenty of water for 15 minutes and consult a physician.

**4.1.5 IF SWALLOWED**

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.





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#### **4.2. Most important symptoms and effects, both acute and delayed:**

4.2.1 Acute: Respiratory irritation, skin irritation, eye irritation.

4.2.2 Chronic: Hemosiderosis (iron overload disorder) due to prolonged exposure.

#### **4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:**

If you feel unwell, seek medical advice (show the label where possible).

### **Section 5 - Fire-Fighting Measures**

#### **5.1. Extinguishing Media:**

5.1.1 SUITABLE EXTINGUISHING MEDIA: Water spray, dry chemical, foam, Carbon dioxide.

5.1.2 Unsuitable Extinguishing Media: A heavy water stream may spread burning liquid.

#### **5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:**

Carbon oxides, nitrogen oxides (NO<sub>x</sub>), Iron oxides.

#### **5.3 ADVICE FOR FIREFIGHTERS:**

##### **5.3.1 Precautionary Measures Fire**

Exercise caution when fighting any chemical fire. Under fire conditions, hazardous fumes will be present.

##### **5.3.2 Firefighting Instructions**

Use water spray or fog for cooling exposed containers.

##### **5.3.3 Protection During Firefighting**

Do not enter fire area without proper protective equipment, including respiratory protection.

**5.4 FIRE EXTINGUISHING MEDIA:** Use fire-extinguishing media appropriate to the surrounding fire

5.4.1 SMALL FIRE: Use DRY chemical powder.

5.4.2 LARGE FIRE: Use water spray, fog or foam. Do not use water jet.





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## Section 5 - Fire-Fighting Measures

**5.5 FURTHER INFORMATION:** No data available.

## Section 6 - Accidental Release Measures

### 6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT & EMERGENCY PROCEDURES:

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

6.1.1 For Non-emergency Personnel Protective Equipment: Use appropriate personal protection equipment (PPE). Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders Protective Equipment: Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2 ENVIRONMENTAL PRECAUTIONS:

Do not let product enter drains.

### 6.3 METHODS AND MATERIALS FOR CONTAINMENT & CLEANING UP:

Vacuum must be fitted with HEPA filter to prevent release of particulates during clean-up. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Finish cleaning the area with small amounts of soap and water on the spill area.

## Section 7 - Handling and Storage

### 7.1 PRECAUTIONS FOR SAFE HANDLING:

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

7.1.1 Hygiene Measures





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Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

**7.2 CONDITIONS FOR SAFE STORAGE INCLUDING ANY INCOMPATIBILITIES:**

Store in original container. Store in a dry, well-ventilated place. Comply with applicable regulations.

**7.2.1 Technical Measures**

Comply with applicable regulations.

**7.2.2 Storage Conditions**

Store at 20°C to 25°C (68°F to 77°F); Excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature]. Do not freeze.

**7.2.3 Incompatible Products**

Strong acids. Strong bases. Strong oxidizers.

**7.2.4 Storage Temperature**

20 - 25 °C (68 - 77 °F).

## Section 8 - Exposure Controls / Personal Protection

**8.1 APPROPRIATE ENGINEERING CONTROLS:**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

**8.2 Personal Protective Equipment:**

**8.2.1 EYE/FACE PROTECTION**

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**8.2.2 SKIN PROTECTION**

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

**8.2.3 BODY PROTECTION**





## Section 8 - Exposure Controls / Personal Protection

Impervious clothing, the type of protective equipment must be selected according to the concentration and amount of the amount of the dangerous substance at the specific workplace.

### 8.3 EXPOSURE LIMITS:

TWA: 1 STEL: 2 (mg (Fe)/m) [United Kingdom (UK)] TWA: 1 (mg(Fe)/m) from MSHA standard. Consult local authorities for acceptable exposure limits.

## Section 9 - Physical and Chemical Properties

• <b>Appearance (physical state, color, etc.)</b>	Powder
• <b>Upper/lower flammability or explosive limits</b>	No data available
• <b>Color</b>	Brown to deep brown.
• <b>Odor</b>	No data available
• <b>Vapor pressure</b>	No data available
• <b>Odor threshold</b>	No data available
• <b>Vapor density</b>	No data available
• <b>pH</b>	5.0 - 7.0
• <b>Relative density</b>	No data available
• <b>Melting point/freezing point</b>	No data available
• <b>Solubility(ies)</b>	Soluble in water, insoluble in organic solvents
• <b>Initial boiling point and boiling range</b>	No data available
• <b>Flash point</b>	No data available
• <b>Evaporation rate</b>	No data available
• <b>Flammability (solid, gas)</b>	No data available
• <b>Partition coefficient: n-octanol/water</b>	No data available
• <b>Specific Gravity</b>	1.1
• <b>Auto-ignition temperature</b>	No data available
• <b>Decomposition temperature</b>	No data available







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- **Viscosity**

No data available

## Section 10 - Stability and Reactivity

### 10.1 Reactivity:

Hazardous reactions will not occur under normal conditions.

### 10.2 Stability:

Stable under ordinary conditions of use and storage. Reduced to ferrous salt by exposure to light. Very deliquescent; forms a solution on prolonged exposure to air.

### 10.3 Hazardous Decomposition Products:

Burning may produce carbon monoxide, carbon dioxide, nitrogen oxides.

### 10.4 Hazardous Polymerization:

Occurs.

### 10.5 Incompatibilities:

Iodides, Acacia preparation and tannins. Strong oxidizers. Strong acids.

### 10.6 Conditions to avoid:

Heat, Light, moisture.

## Section 11 - Toxicological Information

### 11.1 Acute Toxicity:

LD50 (oral): > 2,000 mg/kg body weight (rat, non-lethal at tested dose levels).

LD50 (intravenous): No mortality at doses up to 200 mg/kg body weight (rat).

11.1.1 Skin Irritation: Ferric Carboxymaltose is not classified as a skin irritant.

Minimal irritation may occur with prolonged exposure or at high concentrations.

11.1.2 Eye Irritation: Slight irritation has been observed in animal models but no significant damage or corrosivity to eye tissue.

11.1.3 Inhalation: Exposure through inhalation is unlikely under normal conditions of use. Inhalation of fine particles may cause mild respiratory irritation, but no significant acute toxicity has been recorded.

### 11.2 Skin corrosion/irritation:





Non-irritant. Ferric Carboxymaltose does not induce skin irritation or corrosion.

**11.3 Serious eye damage/eye irritation:**

Non-irritant. No evidence of eye irritation observed in studies.

**11.4 Respiratory or skin sensitization:**

Studies confirm low potential for hypersensitivity. Rare cases of hypersensitivity reactions have been observed (<1%), including urticaria and anaphylaxis.

**11.5 Germ Cell Mutagenicity:**

Not classified.

**11.6 Non-mutagenic based on:**

Ames test (negative).

Chromosomal aberration assay (negative).

In vivo micronucleus test (negative).

**11.7 Chronic Toxicity:**

**11.7.1 Repeated-Dose Studies**

Long-term administration in rodents and non-rodents shows dose dependent iron accumulation in the liver and spleen, with reversible effects.

**11.7.2 No-Observed-Adverse-Effect Levels (NOAELs)**

Rats: 40 mg iron/kg/day. Dogs: 20 mg iron/kg/day.

LD50 Oral: Not less than 500 mg of iron per kg of body weight.

**11.8 Carcinogenicity:**

No evidence of carcinogenicity in long-term studies in rodents. Ferric carboxymaltose is not classified as a carcinogen.

**11.9 Reproductive Toxicity:**

**11.9.1 Fertility**

No adverse effects on male or female fertility in animal studies.

**11.9.2 Developmental Effects**

No teratogenic effects observed in rats or rabbits at doses up to 100 mg iron/kg.

**11.9.3 Pre- and Post-Natal Development**

No adverse effects on offspring observed in studies.

**11.10 Sign & Symptoms of Exposure:**

Overdose of iron compounds may have a corrosive effect on the gastrointestinal mucosa and be followed by necrosis, perforation, and stricture formation. Several hours may elapse before symptoms that can include epigastric pain, diarrhea,





vomiting, nausea, and hematemesis occur. After apparent recovery a person may experience metabolic acidosis, convulsions, and coma hours or days later. Further complications may develop leading to acute liver necrosis that can result in death due to hepatic coma. Not less than 500 mg of iron per kg of body weight.

**11.11 Specific Target Organ Toxicity – Single Exposure (STOT-SE):**

No specific target organ toxicity observed following single intravenous administration.

**11.12 Specific Target Organ Toxicity – Repeated Exposure (STOT-RE):**

Repeated exposure may cause transient oxidative stress and iron accumulation in the liver, spleen, and kidneys at high doses, reversible upon cessation.

**11.13 Aspiration Hazard:**

Not applicable for intravenous formulations.

**11.14 Sub chronic and Chronic Toxicity:**

NOAEL (rats): 30 mg/kg/day (13-week intravenous study).

NOAEL (dogs): 40 mg/kg/day (13-week intravenous study).

## Section 12 - Ecological Information

**12.1 Routs of entry:**

Inhalation, Ingestion.

**12.2 Environmental toxicity:**

This material is expected to be slightly toxic to aquatic life.

**12.3 Toxicity of the products of biodegradation:**

No data available.

**12.4 Special remarks on the products of biodegradation:**

Not Available.

**12.5 Special remarks on the toxicity of animals:**

Lethal Dose/Conc: LD [Rat] - Route: Oral; Dose: >2000 mg/kg

**12.6 Ecotoxicity:**

12.6.1 Aquatic Toxicity: Ferric carboxymaltose is not highly toxic to aquatic organisms at environmentally relevant concentrations.





12.6.2 Fish: LC50 > 100 mg/L (96 hours).

12.6.3 Daphnia (invertebrates): EC50 > 100 mg/L (48 hours).

12.6.4 Algae: EC50 > 100 mg/L (72 hours).

12.6.5 Terrestrial Toxicity: Non-toxic to terrestrial organisms at expected exposure levels. Iron complexes naturally degrade in soil, becoming part of the iron cycle.

**12.7 Persistence and Degradability:**

Ferric carboxymaltose is not readily biodegradable but degrades through natural environmental processes. In aqueous environments, the compound dissociates into its iron and carboxymaltose components.

**12.8 Bioaccumulative Potential:**

Iron ions are absorbed into natural geochemical cycles. Ferric carboxymaltose has low bioaccumulative potential. The iron released from the complex is metabolized by organisms and does not persist in tissue beyond physiological needs. Carboxymaltose is broken down and eliminated, showing no significant bioaccumulation.

**12.9 Mobility in Soil:**

The carboxymaltose component exhibits moderate mobility in soil due to its water solubility. The iron component binds to soil particles and is largely immobile under natural conditions.

**12.10 Results of PBT and vPvB Assessment:**

12.10.1 PBT (Persistent, Bioaccumulative, Toxic): Ferric carboxymaltose does not meet the criteria for PBT classification.

12.10.2 VPvB (very Persistent, very Bioaccumulative): Ferric carboxymaltose does not meet the criteria for vPvB classification.

## Section 13 - Disposal Considerations

### 13.1 Advice on Disposal:






Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and Exhaust air. Dispose of waste according to laws applicable.

**13.2 Advice on Packaging:**

Not available

**Section 14 - Transport Information**

	Road Transport (ADR/GGVS)	Air Transport (IATA)
14.1 UN number	Not Dangerous Goods	Not Dangerous Goods
14.2 UN proper shipping name	Not Dangerous Goods	Not Dangerous Goods
14.3 transport Hazard Class (es)	Not Dangerous Goods	Not Dangerous Goods
14.4 Packing Group	Not Dangerous Goods	Not Dangerous Goods
14.5 Environmental hazard class (es)	Not Dangerous Goods	Not Dangerous Goods
14.6 Special precautions for User	Not applicable	Not applicable
14.7 Transport in bulk according to Annex 11 of MARPOLE and the IBC Code	Not applicable	Not applicable

DOT Classification	Not a DOT controlled material
Air Transport Goods	Nonhazardous/non-dangerous as per IATA DGR
Special Provision for Transport	Not applicable
ADR/RID	Not dangerous Goods
IMDG	Not dangerous Goods
IATA	Not dangerous Goods
DOT (Pictogram)	

This is NON DGR and NON-HAZARDOUS items as per current IATA DGR





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## Section 15 - Regulatory Information

### International Inventories:

TSCA	Except
DSL	Except
NDSL	Except

### Legend:

**TSCA-** United States Toxic Substances Control Act Section 8(b) inventory

**DSL/NDSL-** Canadian domestic substances List/Non- domestic substances List

### U.S Federal Regulations:

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 40 of the Code of Federal Regulations, Part 372

### SARA 311/312 Hazard Categories:

<b>Acute Health Hazard</b>	No
<b>Chronic Health Hazard</b>	Yes
<b>Fire Hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No
<b>Reactive hazard</b>	No

### Clean Water Act:

This product does not contain any substances regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

### CERCLA

This material as supplied, does not contain any substances regulated as Hazards Substances under the Comprehensive Environmental Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

### U.S State regulations

#### California Proposition 65

This Product does not contain any proposition 65 chemicals.

#### U.S State Right-to-know Regulations

This product does not contain any substances regulated by state right-to-know regulations

#### International Regulations

Mexico -Grade Slight risk, Grade 1





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#### Canada

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

WHMIS Hazard Class

Non-Controlled

### Section 16 - Other Information

#### List of Abbreviations:

LD50 Median lethal dose of a substance required to kill 50% of a test population.

LC50 Medial lethal concentration of a substance required to kill 50% of a test population.

LDLO Lowest known lethal dose

TDLO Lowest known toxic dose

IARC International Agency for Research on Cancer

NTP National Toxicology Program

RTECS Registry of Toxic Effects of Chemical Substances

**Disclaimer:** This material safety data sheet is provided as an information resource only. WEST BENGAL CHEMICAL INDUSTRIES LIMITED believes the information contained herein is accurate and compiled from reliable sources. It is the responsibility of the user to verify its validity. The buyer assumes all responsibility of using and handling the product in accordance with federal, state, and local regulations.

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