



WEST BENGAL CHEMICAL INDUSTRIES LIMITED

145/1, Jessore Road, Lake Town,

Kolkata – 700 089, India.

Phone: +9133 4025 1700 Fax: +9133 2574 7410

Email: webcil@webcil.com

Website: www.webcil.com

Section 1 - Chemical Product and Company Identification

1.1 MSDS Name: Iron Isomaltoside

1.2 Product Code: IIM2525

1.3 Relevant identified uses of the substance or mixture and uses advised against:

1.3.1 Recommended Use:

Pharmaceutical ingredient (Injectable Grade), used for iron replacement therapy

1.3.2 Restrictions on Use:

Not intended for personal consumption.

1.4 Company Identification:

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Section 2 - Hazards Identification

2.1 Classification:

Not classified as hazardous under standard regulatory guidelines (GHS, OSHA, EU).

2.2 Label Elements (GHS Classification)

2.2.1 Pictograms: None required

2.2.2 Signal Word: Not applicable

2.2.3 Hazard Statements: Not classified as hazardous

2.2.4 Precautionary Statements: Avoid prolonged exposure to dust; use protective measures if necessary

2.3 Potential Health Effects:

2.3.1 Eye Contact

May cause mild irritation. Flush with water if irritation occurs

2.3.2 Skin contact

May cause mild irritation in sensitive individuals. Wash with soap and water if needed.

2.3.3 Inhalation

Inhalation of dust may cause slight respiratory discomfort. Use protective equipment if airborne dust is present.

2.3.4 Ingestion

Large amounts may cause mild gastrointestinal discomfort.





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Section 2 - Hazards Identification

2.4 Chronic Effects:

No significant long-term health hazards identified.

2.5 Medical Conditions Aggravated by Exposure:

Individuals with respiratory sensitivities may experience slight irritation from airborne dust.

2.6 Environmental Impact:

Not expected to cause environmental harm or bioaccumulate.

Section 3 - Composition / Information on Ingredients

3.2 Substance Name: Iron Isomaltoside (Injectable Grade)

3.2 Chemical Name: Iron (III)-Hydroxide Isomaltoside 1000

3.3 CAS Number: 1370654-58-2

3.4 EINECS Number: Not available

3.5 Molecular Formula: C₁₄H₂₆O₁₀Fe

3.6 Molecular Weight: 410.25 g/mol

Section 4 - First Aid Measures

4.1. Description of first aid measures:

4.1.1 General Information:

In case of exposure, provide immediate medical attention if symptoms persist. Ensure that the affected individual is in a well-ventilated area. Remove contaminated clothing and wash exposed skin areas with water.

4.1.2 Eye Contact:

Rinse immediately with plenty of water for at least 15 minutes, keeping the eyelids open. Avoid rubbing the eyes. Seek medical attention if irritation persists.

4.1.3 Skin Contact:

Wash the affected area thoroughly with soap and water. Remove any contaminated clothing and footwear. If irritation develops or persists, seek medical attention.

4.1.4 Inhalation:

Remove the affected person from the exposure area to fresh air. If breathing is difficult, administer oxygen and seek medical help immediately. If not breathing, provide artificial respiration and seek emergency medical assistance.

4.1.5 Ingestion:

Rinse mouth thoroughly with water. Do not induce vomiting unless advised by medical personnel. If large amounts are ingested, seek medical advice immediately. Provide the victim with water or milk if they are





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Section 4 - First Aid Measures

conscious.

4.2 Most important symptoms and effects:

No information available.

4.3 Indication of any immediate medical attention and special treatment needed:

Treat symptomatically

Section 5 - Fire-Fighting Measures

5.1 Flammability:

Iron Isomaltoside is not classified as flammable or explosive.

5.2 Extinguishing media:

5.2.1 Suitable Extinguishing Media:

Use water spray, foam, carbon dioxide (CO₂), dry chemical powder

5.2.2 Unsuitable Extinguishing Media:

Do not use a high-pressure water jet, as it may spread the material.

5.3 Flash Point:

Not applicable

5.4 Auto-Ignition Temperature:

Not applicable

5.5 Explosion Limits:

Not available

5.6 Hazardous decomposition products:

Non-combustible

5.7 Special hazards arising from the substance or mixture:

In case of fire, toxic fumes may be generated, including **iron oxides**.

5.8 Incompatible with:

Avoid contact with strong oxidizing agents (e.g., peroxides, chlorates, nitrates), strong acids. Do not store near flammable materials or reactive metals.

5.9 Fire Hazards in Presence of Various Substances:

While the substance itself is not combustible, decomposition in a fire may release iron oxides, carbon monoxide (CO) and carbon dioxide (CO₂). May cause mild respiratory irritation if inhaled in large amounts.

5.10 Special Fire-Fighting Procedures:

Firefighters should wear self-contained breathing apparatus (SCBA) and full protective gear. Avoid direct contact with released fumes. Keep unprotected personnel away from the fire scene. Use water spray to cool





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Section 5 - Fire-Fighting Measures

containers exposed to heat.

5.11 Protective Equipment for Firefighters:

Wear self-contained breathing apparatus (SCBA) with full-face protection. Use fire-resistant clothing, gloves, and protective boots. Avoid direct exposure to fire or smoke fumes.

5.12 Emergency Fire Response:

Evacuate personnel to a safe area. Notify emergency services immediately. Prevent run-off water from contaminating drains or waterways. Use water mist or foam to control flames and smoke spread.

Section 6 - Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedure:

Wear protective gloves, safety goggles, and a dust respirator to avoid skin and eye contact. Avoid inhalation of dust or fine particles. Remove unprotected personnel from the spill area. Wash hands thoroughly after handling the material.

6.2 Environmental Precautions:

Prevent entry into drains, sewers, or waterways. Avoid contamination of soil and groundwater. If a large spill occurs near a water body, notify local environmental authorities immediately.

6.3 Methods and material for containment and cleaning up:

Pick up and arrange disposal without creating dust. Sweep up and keep in suitable, closed containers for disposal.

6.3.1 Small Spills:

Use a clean, dry brush or vacuum to collect spilled material. Place the collected material in a sealed container for disposal. Wipe the area with a damp cloth to remove residual dust. Ensure proper ventilation in the area.

6.3.2 Large Spills:

Contain the spill by covering it with a plastic sheet to prevent dust spread. Use an industrial vacuum with a HEPA filter or damp sweeping to remove bulk material. Collect the material in an appropriate waste container for disposal. If the spill occurs in a confined space, ensure proper ventilation before entering.

6.4 Prevention of Secondary Hazards:

Do not allow spilled material to dry completely, as it may form fine dust that can become airborne. Avoid using compressed air for cleaning, as this may cause dust dispersion. Dispose of any contaminated clothing properly before reuse.

6.5 Emergency Response Contacts:

If a major spill occurs, notify local environmental agencies and follow proper hazardous material protocols. In case of accidental exposure, refer to Section 4.





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Section 7 - Handling and Storage

7.1 Handling Precautions:

Avoid direct contact with skin, eyes, and clothing. Prevent dust generation and inhalation by handling in a controlled environment. Use local exhaust ventilation or fume hoods if handling generates airborne dust. Wear appropriate PPE (gloves, safety goggles, and a dust mask). Wash hands thoroughly after handling, especially before eating, drinking, or smoking. Avoid prolonged exposure and minimize handling in open spaces. Ensure spilled material is cleaned immediately to prevent contamination.

7.2 Storage Conditions:

Store in a cool, dry, and well-ventilated area. Keep away from moisture. Protect from direct sunlight and heat





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Section 7 - Handling and Storage

sources. Store in sealed containers to prevent dust contamination. Do not store near oxidizing agents, acids, or reactive chemicals. Maintain storage temperature within recommended limits (ambient temperature unless otherwise specified).

7.2.1 Storage Incompatibilities:

Do not store near strong acids, oxidizing agents, highly reactive metals

7.2.2 Storage Packaging:

Use high-density polyethylene (HDPE) or glass containers for storage. Label all containers clearly and properly according to regulatory standards. Ensure that damaged or leaking containers are replaced immediately.

Section 8 - Exposure Controls / Personal Protection

8.1 Exposure Limits:

No established occupational exposure limits for Iron Isomaltoside. General guidelines for handling dust-forming substances should be followed. Keep airborne concentrations as low as possible using proper ventilation controls.

8.2 Engineering Controls: Use local exhaust ventilation (LEV) or fume hoods to reduce airborne dust exposure. Ensure proper air filtration systems in closed processing areas. Implement enclosed material handling systems for large-scale operations. Maintain negative pressure in storage and handling areas to prevent dust escape.

8.3 Personal Protective Equipment (PPE):

8.3.1 Eye and Face Protection:

Wear safety goggles or full-face shields to prevent eye contact with airborne dust. Use chemical splash goggles if working with solutions containing Iron Isomaltoside.

8.3.2 Skin Protection:

Wear protective gloves made of nitrile, latex, or other chemical-resistant materials. Use lab coats or protective clothing to prevent skin exposure. Avoid prolonged skin contact; wash thoroughly after handling.

8.3.3 Respiratory Protection:

Use a NIOSH-approved dust mask or respirator if airborne dust concentration is high. In confined spaces or heavy exposure, use a full-face respirator with HEPA filters. Do not use a standard face mask, as it may not provide adequate protection.

8.3.4 Hand Protection:

Use chemical-resistant gloves when handling the material for extended periods. Regular work gloves may not provide sufficient protection against prolonged exposure.

8.4 Personal Hygiene Measures:

Wash hands and face thoroughly after handling the material. Do not eat, drink, or smoke in areas where the





Section 8 - Exposure Controls / Personal Protection

substance is handled. Change contaminated clothing immediately and wash before reuse. Use an emergency eyewash station and safety shower in case of accidental exposure.

8.5 Exposure Guidelines for Large-Scale Handling:

Install dust collection systems to minimize airborne particles. Ensure proper air exchange rates in industrial settings. Conduct routine air quality monitoring in storage and processing areas. Provide safety training for all personnel handling the material.

8.6 Environmental Exposure Controls:

Prevent the release of dust into the environment. Ensure proper waste management (refer to Section 13 - Disposal Considerations). Follow local and national environmental regulations for air and water discharge.

Section 9 - Physical and Chemical Properties

Appearance	:	Powder.
Colour	:	Brown to deep brown powder.
Odour	:	No information available.
Flammability (solid, gas)	:	Not applicable.
Solubility	:	Highly soluble in water.
Flash point	:	Not applicable.
pH	:	Not available.
Explosive properties	:	Not applicable.
Freezing Point	:	No data available
Autoignition temperature	:	Not applicable.
Odour threshold	:	No data available
Melting point:	:	Not available.
Initial boiling point	:	Not available.
Relative Vapour Density	:	No data available
Decomposition temperature	:	Not available.
Fat Solubility	:	No data available
Vapour pressure	:	No data available
Evaporation rate	:	No data available
Density	:	Not available.
Partition coefficient (P)	:	No data available
Viscosity	:	No data available
Oxidising properties	:	No data available





Section 10 - Stability and Reactivity

10.1. Stability:

Iron Isomalto-side is stable under normal storage and handling conditions. It does not decompose spontaneously at room temperature. Stability is maintained when stored in a dry, well-ventilated environment.

10.2 Reactivity:

Non-reactive under normal conditions of use, storage, and transport. Does not polymerize or undergo hazardous reactions under standard conditions.

10.3 Conditions to Avoid:

Excessive heat, moisture exposure, direct sunlight.

10.4 Incompatible Materials:

Strong oxidizing agents (e.g., peroxides, nitrates, chlorates), strong acids, strong base, reactive metals.

10.5 Hazardous Decomposition Products:

In case of extreme heat or combustion, decomposition may release iron oxides (Fe_2O_3 , Fe_3O_4), carbon monoxide (CO), carbon dioxide (CO_2), other unidentified decomposition gases

10.6 Possibility of Hazardous Reactions:

Stable under recommended storage conditions.

10.7 Hazardous polymerization:

Does not undergo hazardous polymerization.

10.8 Conditions to avoid:

Strong acids or oxidizers, leading to decomposition.

10.9 Corrosivity:

Not available.

Section 11 - Toxicological Information

11.1 Routes of Exposure:

Inhalation, skin, eye, ingestion

11.2 Acute Toxicity Data:

Toxicity Type	Test Species	Route	Dose	Results/Effects
LD50 (Oral)	Rat	Ingestion	>1000 mg Fe/kg	No mortality; mild coat roughness at high doses.
LD50 (Dermal)	Not available	Skin	Not available	No significant toxicity data available.





Section 11 - Toxicological Information

LC50 (Inhalation)	Not available	Inhalation	Not available	No data available; dust inhalation may cause mild irritation.
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11.3 Chronic Toxicity:

Repeated exposure to high dust concentrations may cause mild respiratory discomfort. Animal studies suggest oxidative stress and inflammatory responses at high doses.

11.4 Skin corrosion/inhalation:

Prolonged exposure may cause mild irritation, but no severe dermal toxicity observed.

11.5 Serious eye damage/eye irritation:

Dust exposure may cause mild irritation or redness.

11.6 Sensitization Effects:

No known allergic reactions reported from handling Iron Isomaltoside.

11.7 Carcinogenic Effects:

Not classified as carcinogenic (IARC, NTP, OSHA).

11.8 Mutagenic Effects:

No data available; not expected to be mutagenic.

11.9 Reproductive Toxicity (Rats):

80 mg Fe/kg (3x per week) caused testicular and prostate effects at high doses.

11.10 Teratogenicity:

No information available.

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

No significant effects known.

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

High-dose subacute exposure in rats led to body weight loss and reproductive organ effects.

Dogs tolerated similar doses better, but cumulative exposure over 250 mg/kg caused toxicity.

11.13 Chronic Effects on Humans:





Section 11 - Toxicological Information

Not available.

11.14 Other Toxic Effects on Humans:

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

11.15 Aspiration Hazard: Not classified

Section 12 - Ecological Information

12.1 Ecotoxicity

Iron Isomalto-side is not classified as highly toxic to the environment; however, excessive release into aquatic systems may cause localized effects due to iron accumulation.

Test Type	Species	Exposure Time	Results
LC50 (Lethal Concentration, 50%)	Fish (Species not specified)	96 hours	Not available
EC50 (Effective Concentration, 50%)	Daphnia magna (Water Flea)	48 hours	Not available
Chronic Toxicity	Aquatic organisms	Long-term	No data available
Terrestrial Toxicity	Soil organisms	Long-term	No data available

12.2 Persistence and Degradability:

Expected to degrade over time but may persist under certain environmental conditions.

12.3 Bio-accumulative Potential:

Low potential for bioaccumulation due to its high-water solubility and complex formation.

12.4 Mobility in Soil:

Highly soluble in water, indicating potential mobility in soil and groundwater.

12.5 Environmental Precautions:

Prevent uncontrolled discharge into water bodies, soil, and sewage systems. Dispose of in accordance with local and national environmental regulations. Use spill containment measures to avoid environmental contamination.

12.6 Other Adverse Effects

Not classified as an ozone-depleting substance.

No known contribution to global warming potential (GWP).

Excessive accumulation in water bodies may lead to iron enrichment, affecting aquatic ecosystems.

Section 13 - Disposal Considerations

It is the responsibility of the waste generator to determine the toxicity and physical properties of the





material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

Section 14 - Transport Information

14.1 UN Number:

Not classified as a hazardous material for transport.

14.2 UN Proper Shipping Name:

Not regulated as a dangerous good

14.3 Transport Hazard Class(es):

Regulatory Body	Classification
DOT (U.S. Department of Transportation)	Not regulated
IATA (International Air Transport Association)	Non-hazardous, non-dangerous
IMDG (International Maritime Dangerous Goods Code)	Not classified as dangerous
ADR/RID (EU Road/Rail Transport)	Not restricted

14.4 Packing Group:

Not assigned a packing group classification since it is not classified as hazardous for transport.

14.5 Environmental Hazards:

Not classified as a marine pollutant. Not expected to pose significant environmental risks under normal transport conditions.

14.6 Special Precautions for Transport:

Ensure containers are tightly sealed to prevent spills and contamination. Avoid exposure to moisture and excessive heat during transport. Use standard packaging that protects the product from environmental factors.

14.7 Transport in Bulk According to Annex II of MARPOL and the IBC

Code:

Not listed under MARPOL or IBC Code for bulk transport



Section 15 - Regulatory Information





15.1 Safety, Health, and Environmental Regulations/Legislation Specific for the Substance or Mixture
United States (U.S.) Regulations

Regulatory Body	Status/Compliance
TSCA (Toxic Substances Control Act)	Not listed
OSHA (Occupational Safety and Health Administration) Hazard Classification	Not classified as hazardous
SARA Title III (Superfund Amendments and Reauthorization Act)	Not listed under Sections 302, 304, 313
CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act)	Not listed
RCRA (Resource Conservation and Recovery Act)	Not considered hazardous waste
Clean Air Act (CAA)	Does not contain hazardous air pollutants (HAPs)
Clean Water Act (CWA)	Not listed as a hazardous substance

European Union (EU) Regulations

Regulatory Body	Status/Compliance
REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals)	Not classified as a hazardous substance
CLP (Classification, Labeling, and Packaging Regulation - EC 1272/2008)	Not classified as hazardous
EINECS (European Inventory of Existing Commercial Chemical Substances)	Not listed
SVHC (Substances of Very High Concern)	Not applicable

International Regulations

Country/Regulatory Body	Status/Compliance
Canada (WHMIS Classification)	Not controlled under WHMIS
Canada (DSL/NDSL - Domestic/Non-Domestic Substances List)	Not listed
Australia (AICS - Australian Inventory of Chemical Substances)	Not listed
Japan (ENCS - Existing and New Chemical Substances)	Not listed
China (IECSC - Inventory of Existing Chemical Substances in China)	Not listed





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Korea (KECI - Korean Existing Chemicals Inventory)	Not listed
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15.2 Chemical Safety Assessment:

Product is not classified as hazardous under GHS, REACH, or other global regulatory frameworks.

Section 16 - Other Information

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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