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Email: webcil@wbcil.com Website: www.wbcil.com

Section 1 - Chemical Product and Company Identification

1.1 Product Name: Iron Sucrose

1.2 Company Identification: IRS4580

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

Use of the substance/mixture: An iron replacement product indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease (CKD), Industrial and scientific research uses.

1.4 Company Identification:

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Section 2 – Hazards Identification

2.1 Classification of the substance or mixture:

Regulatory List EC1272/08 Regulation (EC) 1272/2008 (GHS/CLP)

Classification under CLP according to (EC) 1272/2008

2.1.1 Hazard classification

Skin Irr. 2

Eye Irr. 2A

2.2 Signal Word:

Warning

2.3 Hazard Statement:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

2.4 Precautionary Statement

Prevention

- **P261**: Avoid breathing dust, fumes, gas, mist, vapors, or spray.
- **P280**: Wear protective gloves, protective clothing, and eye/face protection.

Response

Section 2 – Hazards Identification

- **P302 + P352**: IF ON SKIN: Wash with plenty of soap and water.
- **P304 + P340**: IF INHALED: Remove casualty to fresh air and keep at rest in a position comfortable for breathing.
- **P305 + P351 + P338**: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Disposal

- **P501**: Dispose of contents and container in accordance with local, regional, national, and international regulations.

2.5 Potential Acute Health Effects:
Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.
2.6 Potential Chronic Health Effects:
Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.
2.7 Carcinogenic Effects:
Not Available
2.8 Mutagenic Effects:
Not Available
2.9 Teratogenic Effects:
Not Available
2.10 Developmental Toxicity:
Not Available
2.11 Other Hazards Other Hazards:
Exposure may aggravate individuals with iron overload. The most common adverse reactions are diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremity, arthralgia, back pain, muscle cramp, chest pain, and peripheral edema. Hemosiderosis has been observed following overdosage. Refer to package insert for more information.

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Section 2 – Hazards Identification

2.12 Pictogram:

2.13 HIMS diagram:

Health	2
Flammability	0
Physical Hazard	0
Personal protection	E

Section 3 - Composition / Information on Ingredients

3.1 Chemical Name: Iron Sucrose

3.2 Synonym: Ferric hydroxide sucrose complex, Iron oxide saccharated, iron saccharate

3.3 Molecular Formula: $C_{12}H_{29}Fe_5Na_2O_{23}$

3.4 Molecular Weight: 736.06 g/mol

3.5 CAS Number: 8047-67-4

Section 4 – First Aid Measures

4.1 Description of first aid measures:

4.1.1 General advice:

Consult a physician. Show this safety data sheet to the doctor. Consult a attendance

4.1.2 Eye

Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Consult an ophthalmologist.

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Section 4 – First Aid Measures

4.1.3 If inhaled:

If breathed in, move person into fresh air. If not breathing give artificial respiration.

4.1.4 In case of skin:

In case of eye, rinse with plenty of water, and in case of skin, & eye contact wash with plenty of soap and water.

4.1.5 If swallowed:

Never give anything by mouth to an unconscious person. Rinse Mouth with water.

4.2 Most important symptoms and effects, both acute and delayed:

Hints for Physician: Symptoms

See Section 11 for additional information on health hazards

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

4.3.1 First Aid: Inhalation

Remove casualty to fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration. Call a physician.

4.3.2 Hints for Physician: Treatment Treat symptomatically.

Section 5- Fire-Fighting Measures

5.1 Suitable Extinguishing Media:

Foam, dry extinguishing powder, carbon dioxide (CO2), water spray jet

5.2 Flammability of the Product:

Non-flammable.

5.3 Auto-Ignition Temperature:

Not applicable.

5.4 Flash Points:

Not applicable.

5.5 Flammable Limits:

Not applicable.

5.6 Products of Combustion:

Not available.

5.7 Fire Hazards in Presence of Various Substances:

Not applicable.

5.8 Environmental precautions

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Section 5- Fire-Fighting Measures

Do not discharge into drains or rivers.

5.9 Methods and material for containment and cleaning up:

Clean-up procedures Transfer to a closable, labelled salvage container for disposal by an appropriate method.

5.10 Explosion Hazards in Presence of Various Substances:

Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

5.11 Fire Fighting Media and Instructions:

Wear a self-contained breathing apparatus and chemical protective clothing.

5.12 Special Remarks on Fire Hazards:

Toxic fumes.

5.13 Special Remarks on Explosion Hazards:

Do not inhale explosion and combustion gases. Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Move undamaged containers from immediate hazard area if it can be done safely.

Section 6 – Accidental Release Measures

6.1 Personal Precautions, protective equipment and emergency procedures:

Wear breathing apparatus if exposed to vapours/dusts/aerosols. Provide adequate ventilation.

6.1.1 For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE) as identified in section 8. Emergency Procedures: Evacuate unnecessary personnel.

6.1.2 For Emergency Responders Protective Equipment:

Equip cleanup crew with proper protection. Refer to section 8: "Exposure controls/personal protection" Emergency Procedures: Isolate the hazard area. Ventilate area

6.2 Environmental precautions:

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Ensure all waste water is collected and treated via a waste water treatment plant

6.3 Methods and materials for containment and cleaning up:

Not Available

6.3.1 Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish

Section 6 – Accidental Release Measures

cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

6.3.2 Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7 – Handling & Storage

7.1 Precautions:

Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation. Avoid prolonged or repeated exposure. Remove contaminated clothing and wash before reuse. Wash thoroughly after handling.

7.2 Storage:

7.2.1 Conditions for safe storage, including any incompatibilities

Keep container tightly sealed in cool, well-ventilated area. Keep away from direct sunlight and sources of ignition.

7.2.2 Recommended storage temperature:

Powder -20°C 3 years; 4°C 2 years

In solvent -80°C 6 months; -20°C 1 month

7.3 Specific end use(s): No data available.

Section 8 – Exposure Controls / Personal Protection

8.1 Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

8.2 Exposure controls:

8.2.1 Industrial Hygiene

Mechanical exhaust required. Safety shower and eye shower.

8.3 Personal Protection:

Safety glasses. Lab coat. Dust respirator. Be sure to use an approved / certified respirator or

Section 8 – Exposure Controls / Personal Protection

equivalent. Gloves.

8.3.1 Respiratory Protection

Wear NIOSH/MSHA or European Standard EN 149 approved respirator.

8.3.2 Hand Protection

Wear compatible chemical-resistant gloves to prevent skin exposure.

8.3.3 Eye Protection

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA.

8.3.4 Body Protection

Wear compatible chemical-resistant gloves and clothing to prevent skin exposure.

8.4 Advice on Safe Handling:

Wash contaminated clothing before reuse. Wear appropriate protective clothing to prevent exposure

8.5 Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

8.6 Exposure Limits:

TWA: 1 (mg/m3) from ACG IH Consult local authorities for acceptable exposure limits.

Section 9 – Physical and Chemical

9.1 Information on basic physical and chemical properties

Physical states:	Solid
Appearence	powder
Odor:	No data available
Odor threshold:	No data available
pH:	9.5 – 11.5
Melting/freezing point:	No data available
Boiling point/range:	100 °C (212 °F)
Flash point:	No data available
Evaporation rate:	No data available

Flammability (solid, gas):	No data available
Upper/lower flammability or explosive limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available
Partition coefficient:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available
Specific gravity	App 1.15

9.2 Other Safety information:
No data available

Section 10 - Stability and Reactivity

10.1 Reactivity

Hazardous reactions will not occur under normal conditions.

10.2 Stability:

The product is stable under normal conditions.

10.3 Incompatibilities with other material:

Acids, strong oxidizers.

10.4 Hazardous Polymerization:

Carbon dioxide (CO_2), carbon monoxide.

10.5 Conditions to Avoid:

Direct sunlight. Extremely high or low temperatures.

10.6 Corrosivity:

Non-corrosive in presence of glass.

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Section 11 – Toxicological Information

11.1 Routes of Entry:

Inhalation. Ingestion.

11.2 Toxicity to Animals:

LD50 Oral Rat > 90000 mg/kg

Sodium hydroxide (1310-73-2)

LD50 Dermal Rabbit 1350 mg/kg

11.3 Chronic Effects on Humans:

Not available.

11.4 Other Toxic Effects on Humans:

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

11.5 Special Remarks on Toxicity to Animals:

Not available.

11.6 Special Remarks on Chronic Effects on Humans:

Not available

11.7 Special Remarks on other Toxic Effects on Humans:

11.7.1 Skin

Contact may cause irritation or rash, particularly with moist skin.

11.7.2 Eyes

Dust may cause irritation (abraison) by mechanical action and cause redness, and tearing.

11.7.3 Inhalation

Inhalation high concentrations of dust may cause nasal or lung irritation.

11.7.4 Ingestion

Ingestion can produce gastrointestinal tract irritation. Can cause diarrhoea.

11.7.5 Respiratory or Skin Sensitization

Not classified

11.8 Germ Cell Mutagenicity:

Not classified

11.9 Carcinogenicity:

Not classified

IARC group 3

11.10 Reproductive Toxicity:

Not classified

11.11 Developmental:

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Section 11 – Toxicological Information

US FDA Pharmaceutical Pregnancy Category B: Iron sucrose passes into breast milk of nursing animals.

11.12 Specific Target Organ Toxicity (Single Exposure):

Not classified

11.13 Specific Target Organ Toxicity (Repeated Exposure):

Not classified

11.14 Aspiration Hazard:

Not classified

11.15 Endocrine disrupting properties

This product does not contain known or suspected endocrine disruptors according to REACH or relevant EU Regulations.

11.16 Other information

No additional information

Section 12 - Ecological Information

12.1 Ecotoxicity:

Not available.

12.2 BOD5 and COD:

Not available.

12.3 Products of Biodegradation:

Possibly hazardous short-term degradation products are not likely. However, long term degradation products may arise.

12.4 Toxicity of the Products of Biodegradation:

The product of degradation is more toxic.

12.5 Special Remarks on the Products of Biodegradation:

Not available.

12.6 Bioaccumulative potential:

No data available

12.7 Mobility in soil:

No data available

12.8 Results of PBT and vPvB assessment:

No data available

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Section 12 - Ecological Information

12.9 Other adverse effects:

No data available

Section 13 - Disposal Considerations

13.1 Product related considerations:

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 Contaminated packaging:

Dispose of as unused product.

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 MARPOL and the IBC Code	Not Applicable	Not Applicable

Section 14 - Transport Information

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14.8 D O T Classification	:	Not a DOT controlled material
14.9 Air transport Goods	:	Nonhazardous/non dangerous as per IATA DGR.
14.10 Special Provision for Transport	:	Not applicable
14.11 IATA Specification		Non-dangerous, non-hazardous

14.12 DOT (Pictograms)

AS PER IATA REGULATION SAFE FOR CARRAGE, NON-HAZARDOUS AND NON-RESTRICTED.
NO SPECIAL LABELLING OR TRANSPORT MEASURE HAVE BEEN IDENTIFIED.
THIS IS NOT REGULATED AS PER IATA REGULATION

Section 15 – Regularity Information

15.1 Federal and State Regulations:

TSCA 8(b) inventory: Iron Sucrose

15.2 Other Regulations:

EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

WHMIS (Canada):

Not controlled under

WHMIS (Canada).

DSCL (EEC):

This product is not classified according to the EU regulations. Not applicable.

15.3 HMIS rating:

Health Hazard: 2

Fire Hazard: 0

Reactivity: 0

Personal Protection: E

15.4 Protective Equipment:

Gloves. Lab coat. Dust respirator. Be sure to use an approved / certified respirator or equivalent. Splash goggles

SARA 302 Components:

Section 15 – Regulatory Information

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No chemicals in this are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313

SARA 311/312 hazards:

No SARA Hazards.

Massachusetts Right to know components:

No components are subject to the Massachusetts right to know act

Pennsylvania Right to Know components:

No components are subject to the Pennsylvania right to know act

New Jersey Right to Know components:

No components are subject to the New Jersey right to know act

California Prop. 65 components:

This product does not contain any chemicals known to state of California to cause cancer, birth defects, or any other reproductive harm.

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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