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SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

· Trade name: Iron saccharate **Iron Sucrose**

· Article number: 101791

· CAS Number: 8047-67-4 · EC number: 232-464-7

· 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.

· Application of the substance / the mixture Additive for cosmetic or pharmaceutic preparations

· 1.3 Details of the supplier of the safety data sheet

Fagron UK Ltd 4B Coquet St Newcastle upon Tyne England NE1 2QB Tel. 0845 6522525

· Further information obtainable from:

Emergency response telephone number:

+44 (0) 845 652 2525

1.4 Emergency telephone number:

Emergency response telephone number:

+44 (0) 845 652 2525

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Acute Tox. 3 H301 Toxic if swallowed.

- 2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the GB CLP regulation.

· Hazard pictograms



GHS06

· Signal word Danger

· Hazard statements

H301 Toxic if swallowed.

· Precautionary statements

P264 Wash thoroughly after handling.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P321 Specific treatment (see on this label).

P330 Rinse mouth. P405 Store locked up.

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P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.1 Substances

· CAS No. Description

CAS: 8047-67-4 Iron saccharate

Iron Sucrose

· Identification number(s)

EC number: 232-464-7

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- General information:

Immediately remove any clothing soiled by the product.

In case of irregular breathing or respiratory arrest provide artificial respiration.

- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

After eye contact:

Rinse opened eye for several minutes under running water. Then consult a doctor.

- · After swallowing: Call for a doctor immediately.
- · 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

Water spray

Fire-extinguishing powder

Carbon dioxide

Foam

· 5.2 Special hazards arising from the substance or mixture

No further relevant information available.

- · 5.3 Advice for firefighters
- Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

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SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Ensure adequate ventilation

Wear protective equipment. Keep unprotected persons away.

- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Pick up mechanically.

Dispose of the material collected according to regulations.

Dispose contaminated material as waste according to item 13.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Thorough dedusting.

Ensure good ventilation/exhaustion at the workplace.

- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Keep container tightly sealed.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

CAS: 8047-67-4 Iron saccharate Iron Sucrose

t-term value: 2 mg/m

WEL Short-term value: 2 mg/m³ Long-term value: 1 mg/m³

as Fe

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

• **Respiratory protection:** Suitable respiratory protective device recommended.

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· Hand protection



Protective gloves

Rubber gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- · Eye/face protection Safety glasses
- · Body protection: Protective work clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

Physical stateColour:SolidBrown

Odour: Characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: Undetermined.

· Boiling point or initial boiling point and

boiling range Undetermined.

• Flammability Product is not flammable.

Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.

· **pH** 10–11

· Viscosity:

Kinematic viscosity
 Dynamic:
 Not applicable.
 Not applicable.

Solubility

· water: Not determined.

· Partition coefficient n-octanol/water (log

value) Not determined.
· Vapour pressure: Not applicable.

Density and/or relative density

Density: Not determined.
Relative density Not determined.
Vapour density Not applicable.

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9.2 Other information

· Appearance:

· Form: Powder

Important information on protection of health and environment, and on safety.

· Auto-ignition temperature: Not determined.

• Explosive properties: Product does not present an explosion hazard.

Change in condition

· Evaporation rate Not applicable.

Information with regard to physical hazard classes

Void Explosives · Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void Flammable liquids Void Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void · Pyrophoric solids Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit

Substances and mixtures, which emit flammable gases in contact with water
 Oxidising liquids
 Oxidising solids
 Organic peroxides
 Corrosive to metals
 Desensitised explosives

SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- Acute toxicity Toxic if swallowed.
- · LD/LC50 values relevant for classification:

Oral LD50 236 mg/kg (mouse) 140 mg/kg (rat)

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- · 11.2 Information on other hazards
- · Endocrine disrupting properties Substance is not listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN number or ID number · ADR, IMDG, IATA	UN2811
14.2 UN proper shipping name	
ADR, IMDG	TOXIC SOLID, ORGANIC, N.O.S. (Iron saccharate Iron Sucrose)
IATA	Toxic solid, organic, n.o.s. (Iron saccharate Iron Sucrose)

- · 14.3 Transport hazard class(es)
- · ADR, IMDG, IATA



· Class 6.1 Toxic substances.

· Label 6.1

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14.4 Packing group ADR, IMDG, IATA	III
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user Hazard identification number (Kemler code): EmS Number: Stowage Category	Warning: Toxic substances. 60 F-A,S-A A
14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
Transport/Additional information:	
ADR Limited quantities (LQ) Excepted quantities (EQ) Transport category Tunnel restriction code	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g 2 E
IMDG Limited quantities (LQ) Excepted quantities (EQ)	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
UN "Model Regulation":	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (IRON SACCHARATE IRON SUCROSE), 6.1, III

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · Seveso category H2 ACUTE TOXIC
- Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing SDS:

Fagron UK

Quality Assurance

· Contact: quality@fagron.co.uk

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Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Acute Tox. 3: Acute toxicity - Category 3

GB

