




1 IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Identification of the preparation

Commercial product name: REF 37478 Iron - REF 40034 Iron

1.2 Use of the preparation

For the quantitative *in vitro* determination of Iron in serum and plasma. The product REF 37478 is suitable for use on the

 instruments and the product REF 40034 is suitable for use on the FALCOR 350 instrument.

1.3 Company / undertaking identification

Manufacturer:

A. Menarini Diagnostics S.r.l.

Via Sette Santi, 3 – 50131 Firenze – Italy

Phone +39 055 56801 – Fax +39 055 5680902

E-mail: diagintmkt@menarini.it

Distributor in Italy:

A. Menarini Diagnostics S.r.l.

Via Sette Santi, 3 – 50131 Firenze – Italy

Phone +39 055 56801 – Fax +39 055 5680902

1.4 Emergency telephone

For emergencies and chemical support call:

A. Menarini Manufacturing Logistics and Services

Diagnostics Quality Control Department

Via Livornese 897, 56010 S. Piero a Grado - Pisa - Italy

Telephone: +39 050 9710215

Fax: +39 050 960054

E-mail: alippi@menarini.it

2 HAZARDS IDENTIFICATION

• **Classification**

Xn; Harmful

• **Warnings**

For *in vitro* diagnostic use only. Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice.

May cause irritation to skin and eyes, may be irritating to mucous membranes and upper respiratory tract. Avoid contact with skin and eyes, avoid inhalation and ingestion.

• **Risk phrases**

R22; Harmful if swallowed

R36/38; Irritating to eyes and skin

• **Safety phrases**

S26; In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36; Wear suitable protective clothing.

3 COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient chemical name	CAS N.	Conc.	Classification: indications of danger and R phrases	EINECS/ELINCS N.
Guanidine Hydrochloride	50-01-1	43% (w/v)	Xn; R22; R36/38	200-002-3
Guanidine Hydrochloride	50-01-1	38% (w/v)	Xn; R22; R36/38	200-002-3

For indications of danger and R-phrases see heading 16.

4 FIRST AID MEASURES

Immediate medical attention: call an internal First Aider where available or else contact a physician immediately

Description of symptoms and effects; information on first aid:

• **Inhalation**

Symptoms: N.A.
Delayed effects expected: N.A.
First Aid Information: If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

• **Skin Contact**

Symptoms: N.A.
Delayed effects expected: N.A.
First Aid Information: In case of skin contact immediately wash skin with soap and copious quantities of water

• **Eye Contact**

Symptoms: N.A.
Delayed effects expected: N.A.
First Aid Information: Flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Call a physician.

• **Ingestion**

Symptoms: N.A.
Delayed effects expected: N.A.
First Aid Information: If swallowed wash out mouth with water provided person is conscious, call a physician.

Special first aid means that must be available at the workplace: N.A.

5 FIRE-FIGHTING MEASURES

The product is not flammable.

Suitable extinguishing media: N.A.

Not suitable extinguishing media: N.A.

Special exposure hazard arising from the substance or preparation itself, combustion products, resulting gases: May emit toxic fumes under fire conditions.

Special protective equipment for fire-fighters: Wear self contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6 ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTION:

- **Removal of ignition sources:** Use appropriate spill absorbent kit as instructed by the manufacturer. Alternatively, mop up with an absorbent material and hold for waste disposal.
- **Provision for sufficient ventilation / respiratory protection:** Ventilate area and wash spill site after material pick up is complete.
- **Control of dust:** N.P.
- **Prevention of skin and eye contact:** wear appropriate personal protective equipment as specified in section 8, keep unprotected persons away.

ENVIRONMENTAL PRECAUTIONS:

- **Keeping away from drains, surface and ground water and soil:** do not discharge into drains, water courses or onto the ground. Collect and dispose of spillage as indicated in section 13.
- **Alert the neighbourhood:** not required

METHODS FOR CLEANING UP

- **Use of absorbent material:** No restriction.
- **Reduction of gases / fumes:** N.A.

7 HANDLING AND STORAGE

7.1 Handling

Safety precautions

- **Containment, local and general ventilation:** N.A.
- **Measures to prevent aerosol and dust generation and fire:** N.A.
- **Measures required to protect the environment:** N.A.

Specific requirements or rules (procedures or equipment recommended): Wash thoroughly after handling. Do not use if skin is cut or scratched. Avoid contact with eyes, skin and clothing.

7.2 Storage

Safety conditions

- **Specific design for storage rooms or vessels:** N.A.

Incompatible materials: N.A.

- **Conditions of storage:** Store at temperatures and conditions as indicated on the product label.
- **Special electrical equipment:** N.A.
- **Prevention of static electricity:** N.A.
- **Quantity limits:** N.A.
- **Type of materials used in packing / containers of substance:** N.A.

7.3 Specific use(s)

Recommendations: in vitro diagnostic medical device (IVD).

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limits values

A) Occupational

- Italy:
 - OEL 8 hours: N.A.
 - OEL Short Time: N.A.
- European community:
 - OEL 8 hours: N.A.
 - OEL Short Time: N.A.
- ACGIH:
- Note:
Currently recommended monitoring procedures: N.A.

B) Biological

- Italy : N.A.
- European Community : N.A.
- ACGIH : N.A.
- Note:
Currently recommended monitoring procedures: N.A.

8.2 Exposure controls

8.2.1 Occupational exposure controls

Personal protection equipment:

8.2.1.1 Respiratory protection

Not required.

8.2.1.2 Hand protection

Standard laboratory rubber or latex gloves.

8.2.1.3 Eye protection

Protective glasses.

8.2.1.4 Skin protection

A laboratory coat or apron is recommended.

Specific hygiene measures: Not required.

8.2.2 Environmental exposure controls

No data yet available.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

• Appearance

Physical state: liquid

Colour: Colourless (Buffer)

Pale Green (Chromogen)

• Odour

Odourless

9.2 Important health, safety and environmental information

pH at 25°C:	N.A.
Boiling point:	N.A.
Flash point:	N.A.
Explosive properties:	N.A.
Oxidising properties:	N.A.
Vapour pressure at 20°C:	N.A.
Relative density at 20°C:	N.A.
Solubility in water:	Soluble
Partition coefficient n-octanol / water:	N.A.
Viscosity:	N.A.
Vapour density (air = 1):	N.A.
Evaporation rate:	N.A.

9.3 Other information

Autoignition temperature:	N.A.
Melting point / melting range:	N.A.
Decomposition temperature:	N.A.
Apparent density:	N.A.
Miscibility with other solvent:	N.A.
Conductivity:	N.A.

10 STABILITY AND REACTIVITY

10.1 **Stability:** stable

10.2 **Conditions to avoid:** N.A.

10.3 **Materials to avoid:** Strong oxidising agents, also acids.

10.4 **Hazardous decomposition products:** N.A.

11 TOXICOLOGICAL INFORMATION

Dangerous-to-health effects from exposure to the preparation: N.A.

Target organ: N.A.

Symptoms: N.A.

Information on the different routes of exposure

- **Inhalation:** N.A.
- **Ingestion:** N.A.
- **Eye and skin contact:** N.A.

Delayed, immediate and chronic effects from short- and long-term exposure

- **Sensitisation:** N.A.
- **Carcinogenicity:** N.A.
- **Mutagenicity:** N.A.
- **Reproductive toxicity:** N.A.

12 ECOLOGICAL INFORMATION

12.1 Ecotoxicity

- **Aquatic:** N.A.
- **Soil:** N.A.
- **Other organisms:** N.A.
- **Inhibitory effects on micro-organisms, possible impact on sewage treatment plants:** N.A.

12.2 Mobility

- **Known or predicted distribution to environmental compartments:** N.A.
- **Surface tension:** N.A.
- **Absorption / desorption:** N.A.

12.3 Persistence and degradability

- **Biodegradation:** N.A.
- **Degradation half lives (oxidation / hydrolysis):** N.A.

12.4 Bioaccumulative potential

- **Kow:** N.A.
- **BCF:** N.A.

12.5 Other adverse effects

- **Ozone depletion potential:** N.A.
- **Photochemical ozone creation potential and / or global warming potential:** N.A.

13 DISPOSAL CONSIDERATIONS

Description and information on safe handling of surplus or wasting resulting from the foreseeable use: chemical waste must not be disposed together with household garbage.

Appropriate methods of disposal:

Waste is classified as special waste.

Observe all governmental environmental regulations for waste disposal. Contact a licensed professional waste disposal service for disposal of waste material and of unused product.

- **Incineration:** N.A.
- **Recycling:** N.A.
- **Landfilling:** N.A.

Appropriate methods of disposal of the combined packing: N.A.

14 TRANSPORT INFORMATION

This product is not subject to transport regulation.

15 REGULATORY INFORMATION

Information shown on the label

Trade name of the preparation: REF 37478 Iron - REF 37478 Iron - REF 40034 Iron

• **Responsible for placing on the market:**

A. Menarini Diagnostics S.r.l.

Via Sette Santi, 3 – 50131 Firenze – Italy

Chemical name of the substance contained in the preparation: Guanidine Hydrochloride

- **Symbol of danger:** Xn
- **Indications of danger:** not required
- **Risk phrases (R):** R22; Harmful if swallowed
R36/38; Irritating to eyes and skin

- **Safety phrases (S):** S26; In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36; Wear suitable protective clothing.

Directives: 1999/45/EC, 67/548/EEC, 2001/58/EC directives and following amendments and modifications.

Specific provision in relation to protection of man or the environment at community level

- **Restrictions on marketing:** N.A.
- **Occupational exposure limit values:** see heading 8

16 OTHER INFORMATION

The information herein contained is based on current knowledge and we disclaim any responsibility for the final use of the product. The receiver is the only responsible for the compliance to applicable local regulations.

Indications of danger and R phrases listed in heading 2:

Xn	Harmful
R22	Harmful if swallowed
R36/38	Irritating to eyes and skin

Decoding:

N.P. = Not Pertinent

N.A. = Not Available

ACGIH = American Conference Governmental Industrial Hygienist

OEL = Occupational Exposure Limit value

IFCC = International Federation of Clinical Chemistry and Laboratory Medicine