

IRON_R3

Creation date	27th May 2015	Version	3.1
Revision date	09th October 2023		

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Substance / mixture	IRON_R3
Number	mixture
UFI	XSYS0049
Other mixture names	USJS-S9VF-UM7A-TRHT
	FE 125, IRON

1.2. Relevant identified uses of the substance or mixture and uses advised against**Mixture's intended use**

Reagent 3 is part of the IRON kit for the quantitative in vitro determination of iron in serum and plasma.

Main intended use

PC-MED-OTH Other medical devices

Secondary uses

PC-TEC-19 Reagents and laboratory chemicals

Mixture uses advised against

not available

1.3. Details of the supplier of the safety data sheet**Manufacturer**

Name or trade name	Erba Lachema s.r.o.
Address	Karásek 2219/1d , Brno, 62100
	Czech Republic
Identification number (CRN)	26918846
VAT Reg No	CZ26918846
Phone	+420 517 077 111
E-mail	msds@erba.com
Web address	www.erbalachema.com

Competent person responsible for the safety data sheet

Name	Erba Lachema s.r.o.
E-mail	msds@erba.com

1.4. Emergency telephone number

European emergency number: 112 112

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification of the mixture in accordance with Regulation (EC) No 1272/2008**

The mixture is classified as dangerous.

Skin Sens. 1, H317

Carc. 2, H351

Full text of all classifications and hazard statements is given in the section 16.

Most serious adverse effects on human health and the environment

May cause an allergic skin reaction. Suspected of causing cancer.

2.2. Label elements**Hazard pictogram****Signal word**

Warning

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Hazardous substances

hydroxylammonium chloride

Hazard statements

H317 May cause an allergic skin reaction.
H351 Suspected of causing cancer.

Precautionary statements

P261 Avoid breathing vapour/aerosol..
P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

Mixture of substances and additives specified below.

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 612-123-00-2 CAS: 5470-11-1 EC: 226-798-2	hydroxylammonium chloride	1,5	Met. Corr. 1, H290 Acute Tox. 4, H302, H312 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319 Carc. 2, H351 STOT RE 2, H373 Aquatic Acute 1, H400 (M=1)	
Index: 007-004-00-1 CAS: 7697-37-2 EC: 231-714-2 Registration number: 01-2119487297-23-xxxx	Nitric acid	0,02	Ox. Liq. 2, H272 Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Acute Tox. 3, H331 Specific concentration limit: Skin Corr. 1A, H314: C ≥ 20 % Skin Corr. 1B, H314: 5 % ≤ C < 20 % Ox. Liq. 3, H272: 65 % ≤ C < 99 % Ox. Liq. 2, H272: C ≥ 99 % Eye Irrit. 2, H319: 1 % ≤ C < 3 % Eye Dam. 1, H318: 3 % ≤ C < 5 % Met. Corr. 1, H290: C ≥ 1 % Skin Irrit. 2, H315: 1 % ≤ C < 5 % Acute Tox. 3, H331: C ≤ 70 % Acute Tox. 1, H330: C > 70 %	1

Notes

1 A substance for which exposure limits are set.

Full text of all classifications and hazard statements is given in the section 16.

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SECTION 4: First aid measures**4.1. Description of first aid measures**

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet. If unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. Rinsing should continue at least for 10 minutes. Transfer to a specialist.

If swallowed

Rinse mouth with water, drink small amount of lukewarm water. Provide medical treatment. For persons with no symptoms, call the Toxicological Information Centre to decide about the need of medical treatment; provide information about the substances or composition of the product from the original packaging or the Safety Data Sheet of the product.

4.2. Most important symptoms and effects, both acute and delayed**If inhaled**

Irritation of breathing apparatus. Mucous membranes may be irritated.

If on skin

May cause an allergic skin reaction.

If in eyes

Mild irritation of eye conjunctiva.

If swallowed

Irritation, nausea.

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

Symptomatic treatment.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist. Accommodate according to the location of the fire.

Unsuitable extinguishing media

Unknown.

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide, HCl or nitrogen oxides and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Prevent contact with skin and eyes.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

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6.3. Methods and material for containment and cleaning up

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Prevent contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose. Store locked up.

Storage temperature min 2 °C, max 25 °C

The specific requirements or rules relating to the substance/mixture

Avoid contact with oxidizing agents.

7.3. Specific end use(s)

For in vitro diagnostic devices.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Czech Republic****Government Regulation 195/2021 Coll.**

Substance name (component)	Type	Value	Conversion for ppm	Note
Nitric acid (CAS: 7697-37-2)	PEL	1 mg/m ³	0,382	irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	2,5 mg/m ³	0,382	

European Union**Commission Directive 2006/15/EC**

Substance name (component)	Type	Value
Nitric acid (CAS: 7697-37-2)	OEL 15 minutes	2,6 mg/m ³
	OEL 15 minutes	1 ppm

8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

It is not needed.

Skin protection

Hand protection: Protective gloves, impermeable and resistant to the product. Protective clothing.

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Respiratory protection

Under good ventilation/ exhaustion at the workplace, the use of these products should not require respiratory protection.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	liquid
Colour	colourless, Clear colourless liquid
Odour	data not available
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	The product is non-flammable.
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	4.5 (undiluted at 25 °C)
Kinematic viscosity	data not available
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	1.0065 g/cm ³
Relative vapour density	data not available
Particle characteristics	data not available
Form	clear

9.2. Other information

Oxidising properties	The product has no oxidizing properties.
Explosive properties	The product does not have explosive properties.

SECTION 10: Stability and reactivity**10.1. Reactivity**

not available

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Avoid exposure to heat.

10.5. Incompatible materials

Protect against strong bases and oxidizing agents.

10.6. Hazardous decomposition products

Not developed under normal uses. Hazardous decomposition products such as carbon monoxide and carbon dioxide, hydrogen chloride and nitrogen oxides are formed at high temperature and in a fire.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

No toxicological data is available for the mixture.

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Acute toxicity

Based on available data the classification criteria are not met.

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	32680 mg/kg				Calculation of value
Dermal	ATE	71900 mg/kg				Calculation of value
Inhalation (vapor)	ATE	20600 mg/l				Calculation of value

hydroxylammonium chloride						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	141 mg/kg		Rat (Rattus norvegicus)		

Skin corrosion/irritation

Based on available data the classification criteria are not met.

Serious eye damage/irritation

Based on available data the classification criteria are not met.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Carcinogenicity

Suspected of causing cancer. Based on available data the classification criteria are not met.

Reproductive toxicity

Based on available data the classification criteria are not met.

Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

Aspiration hazard

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. Based on available data the classification criteria are not met.

11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information**12.1. Toxicity**

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

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Acute toxicity

hydroxylammonium chloride				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	1-10 mg/l	48 hours	Fish (Leuciscus idus)	

12.2. Persistence and degradability

No data are available for either the mixture or the components.

12.3. Bioaccumulative potential

No data are available for either the mixture or the components.

12.4. Mobility in soil

No data are available for either the mixture or the components.

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

Not available.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

Waste type code

16 05 06 laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals *

Packaging waste type code

15 01 10 packaging containing residues of or contaminated by hazardous substances *

(*) - Hazardous waste according to Directive 2008/98/EC on hazardous waste

SECTION 14: Transport information**14.1. UN number or ID number**

not subject to transport regulations

14.2. UN proper shipping name

not relevant

14.3. Transport hazard class(es)

not relevant

14.4. Packing group

not relevant

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

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SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006, as amended. Product contains regulated explosives precursor: Making available, introduction, possession and use of those precursors by member of the general public according to Regulation (EU) 2019/1148, Article 5 to 9. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: Other information**A list of standard risk phrases used in the safety data sheet**

H272	May intensify fire; oxidiser.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H351	Suspected of causing cancer.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.

Guidelines for safe handling used in the safety data sheet

P261	Avoid breathing vapour/aerosol..
P280	Wear protective gloves/protective clothing/eye protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union

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EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log K _{ow}	Octanol-water partition coefficient
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible Exposure Limit
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative
Acute Tox.	Acute toxicity
Aquatic Acute	Hazardous to the aquatic environment
Carc.	Carcinogenicity
Eye Dam.	Serious eye damage
Met. Corr.	Corrosive to metals
Ox. Liq.	Oxidising liquid
Skin Corr.	Skin corrosion
Skin Sens.	Skin sensitization
STOT RE	Specific target organ toxicity - repeated exposure

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

For in vitro diagnostic use only.

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

The version 3.1 replaces the SDS version from 17 August 2023. Changes were made in sections 1, 3 and 16.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.