

Reagent for PHENYLALANINE test

Creation date	13th May 2015	Version	3.0
Revision date	09th January 2024		

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

- 1.1. Product identifier**
Substance / mixture Reagent for PHENYLALANINE test
Number substance
Chemical name MLT00017
CAS number ferric chloride hexahydrate
EC (EINECS) number 10025-77-1
Registration number 231-729-4
Other substance name 01-2119497998-05-x

Činidlo pro test FENYLALANIN; Реактив для теста ФЕНИЛАЛАНИН

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

The kit of the Reagent for PHENYLALANINE test is a supplementary reagent for MIKROLATEST® diagnostic kits containing test for the detection of phenylalanine deaminase (Phenylalanine test, PHE) and serves for colour expression of this test.

The use descriptors

PC 21 Laboratory chemicals

Substance uses advised against

The product should not be used in ways other than those referred in Section 1.

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 substance in accordance with Regulation (EC) No 1272/2008**

The substance is classified as dangerous.

Skin Irrit. 2, H315

Eye Dam. 1, H318

Most serious adverse effects on human health and the environment

Causes serious eye damage. Causes skin irritation.

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

Danger

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Dangerous substance

ferric chloride hexahydrate
(EC: 231-729-4; CAS: 10025-77-1)

Hazard statements

H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards

The substance does not have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Substance does not 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**3.1. Substances****Chemical characterization**

The substance specified below.

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 10025-77-1 EC: 231-729-4 Registration number: 01-2119497998-05-x	substance main component ferric chloride hexahydrate	10	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318	

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

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. No neutralization should be performed in any case! Rinsing should be continued for 10-30 minutes from the inner to the outer eye corner to make sure that the other eye is not involved. Depending on the situation, call medical rescue service or ensure medical treatment as promptly as possible. Everyone must be referred for treatment even if affected only a little.

If swallowed

DO NOT INDUCE VOMITING! Rinse out the mouth with water and provide 2-5 dL of water. Provide medical treatment if the person has any health problems.

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

Inhaling vapours can cause corrosion of the breathing system.

If on skin

Causes skin irritation.

If in eyes

Causes serious eye damage.

If swallowed

Corrosion of the digestion system can occur. 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**

Accommodate according to the location of the fire.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

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. Observe the principles of work safety in chemical laboratories.

6.2. Environmental precautions

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

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 contact with skin and eyes. Wash hands and exposed parts of the body thoroughly after handling. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Observe the normal operating procedures for handling chemical substances and mixtures. Observe the principles of safety work in chemical laboratories.

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.

Storage temperature

min 2 °C, max 25 °C

7.3. Specific end use(s)

For in vitro diagnostic devices.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

none

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8.2. Exposure controls

Take off contaminated clothing and wash before reuse. Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. 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

Protective goggles or face shield (based on the nature of the work performed).

Skin protection

Hand protection: Protective gloves resistant to the product. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. Observe other recommendations of the manufacturer. Other protection: protective workwear. Contaminated skin should be washed thoroughly.

Respiratory protection

If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.

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	yellow-orange
Odour	without fragrance
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available
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 20 °C)
Kinematic viscosity	data not available
Solubility in water	data not available
Solubility in fats	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	data not available
Relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

Evaporation rate	data not available
Appearance	clear
Explosive properties	data not available
Vapour density	data not available

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

The substance is non-flammable.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Explosion hazard with alkali metals and ethylene oxide.

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10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost. Protect from heat.

10.5. Incompatible materials

Metals (steel, copper).

10.6. Hazardous decomposition products

Not developed under normal uses.

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 substance.

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	3160 mg/kg				Calculation of value

ferric chloride hexahydrate						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	316 mg/kg		Rat		

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye damage.

Respiratory or skin sensitisation

No data available for the substance. Based on available data the classification criteria are not met.

Germ cell mutagenicity

No data available for the substance. Based on available data the classification criteria are not met.

Carcinogenicity

No data available for the substance. Based on available data the classification criteria are not met.

Reproductive toxicity

No data available for the substance. Based on available data the classification criteria are not met.

Toxicity for specific target organ - single exposure

No data available for the substance. Based on available data the classification criteria are not met.

Toxicity for specific target organ - repeated exposure

No data available for the substance. Based on available data the classification criteria are not met.

Aspiration hazard

No data available for the substance. Based on available data the classification criteria are not met.

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11.2. Information on other hazards

The substance does not have 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**

Based on available data the classification criteria are not met.

Acute toxicity

ferric chloride hexahydrate				
Parameter	Value	Exposure time	Species	Environment
LD ₅₀	20.3 mg/l	96 hours	Fish (Lepomis macrochirus)	

12.2. Persistence and degradability

No data available for the substance.

12.3. Bioaccumulative potential

No data available for the substance.

12.4. Mobility in soil

No data available for the substance.

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

This substance does not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.

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

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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

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. 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

not available

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

H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.

Guidelines for safe handling used in the safety data sheet

P280	Wear protective gloves/protective clothing/eye protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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
EuPCS	European Product Categorisation System
IATA	International Air Transport Association

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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
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
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
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
Eye Dam.	Serious eye damage
Skin Irrit.	Skin irritation

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

not available

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 3.0 replaces the SDS version from 04 January 2019. Changes were made in sections 1, 2, 11, 12, 13, 15 and 16.

More information

Classification procedure - calculation method.

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.