

Reagent for HIPPURATE test

Creation date	13th March 2015	Version	3.0
Revision date	17th January 2024		

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

Substance / mixture	mixture
Number	MLT00019

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

The set of the Reagent for HIPPURATE test is an auxiliary colour-producing reagent for the diagnostic strips HIPPURATE test and for kit STREPTO test 16, intended for a test, detecting the sodium hippurate (HIP) hydrolysis. The directions for use of the reagent are included in the operating instructions for the corresponding preparation of the MIKROLATEST.

Main intended use

PC-MED-OTH	Other medical devices
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Secondary uses

PC-TEC-19	Reagents and laboratory chemicals
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The use descriptors

PC 21	Laboratory chemicals
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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.

Flam. Liq. 2, H225
Acute Tox. 4, H302
Skin Irrit. 2, H315
Eye Dam. 1, H318
STOT SE 3, H336, H335

Most serious adverse physico-chemical effects

Highly flammable liquid and vapour.

Most serious adverse effects on human health and the environment

May cause drowsiness or dizziness. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. Harmful if swallowed.

Reagent for HIPPURATE test

Creation date 13th March 2015
Revision date 17th January 2024 Version 3.0

2.2. Label elements

Hazard pictogram



Signal word

Danger

Hazardous substances

acetone
butan-1-ol
ninhydrine

Hazard statements

H225 Highly flammable liquid and vapour.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261 Avoid breathing mist/vapours/spray.
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.
P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.

Supplemental information

EUH066 Repeated exposure may cause skin dryness or cracking.

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 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: 606-001-00-8 CAS: 67-64-1 EC: 200-662-2 Registration number: 01-2119471330-49-x	acetone	47	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 EUH066	1
Index: 603-004-00-6 CAS: 71-36-3 EC: 200-751-6 Registration number: 01-211484630-38-x	butan-1-ol	47	Flam. Liq. 3, H226 Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335, H336	1

Reagent for HIPPURATE test

Creation date 13th March 2015
Revision date 17th January 2024 Version 3.0

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 485-47-2 EC: 207-618-1	ninhydrine	6	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319	

Notes

1 A substance for which exposure limits are set.

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. Protect the person against growing cold. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

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! Provide medical treatment.

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

May cause respiratory irritation, cough, shortness of breath, headache. May cause drowsiness or dizziness. Inhaling vapours can cause corrosion of the breathing system, narcosis, inebriation.

If on skin

Causes skin irritation.

If in eyes

Causes serious eye damage.

If swallowed

Corrosion of the digestion system can occur. Irritation, nausea, stomach and intestinal disorder, salivation, coma.

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**

Dry powder, carbon dioxide, foam.

Unsuitable extinguishing media

water - full jet

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Vapours are heavier than air and may spread along floors. Form explosive mixtures with air at elevated temperatures.

Reagent for HIPPURATE test

Creation date	13th March 2015	Version	3.0
Revision date	17th January 2024		

5.3. Advice for firefighters

Use a self-contained breathing apparatus and full-body protective clothing. Closed containers with the product near the fire should be cooled with water. 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**

Highly flammable liquid and vapour. Risk of explosion. Remove all ignition sources; provide sufficient ventilation. Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale aerosols. 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**

Observe the principles of safety work in chemical laboratories. Prevent formation of gases and vapours in flammable or explosive concentrations and concentrations exceeding the occupational exposure limits. The product should be used only in the areas where it is not in contact with open fire and other ignition sources. Use non-sparking tools. Use of antistatic clothes and footwear is recommended. Do not inhale aerosols. Prevent contact with skin and eyes. No smoking. 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. Do not expose to sunlight.

Storage temperature

min 2 °C, max 8 °C

The specific requirements or rules relating to the substance/mixture

Solvent vapours are heavier than air and accumulate especially near the floor where they may form an explosive mixture with the air.

7.3. Specific end use(s)

For in vitro diagnostic devices.

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

The mixture contains substances for which occupational exposure limits are set.

Czech Republic**Government Regulation 330/2023 Coll.**

Substance name (component)	Type	Value	Note
acetone (CAS: 67-64-1)	PEL	800 mg/m ³	irritating to mucous membranes (eyes, respiratory system) and skin
	PEL	331,4 ppm	
	NPK-P	1500 mg/m ³	
	NPK-P	621,4 ppm	

Reagent for HIPPURATE test

Creation date

13th March 2015

Revision date

17th January 2024

Version

3.0

Czech Republic

Government Regulation 330/2023 Coll.

Substance name (component)	Type	Value	Note
butan-1-ol (CAS: 71-36-3)	PEL	300 mg/m ³	irritating to mucous membranes (eyes, respiratory system) and skin
	PEL	97 ppm	
	NPK-P	600 mg/m ³	
	NPK-P	194 ppm	

European Union

Commission Directive 2000/39/EC

Substance name (component)	Type	Value	Note
acetone (CAS: 67-64-1)	OEL 8 hours	1210 mg/m ³	
	OEL 8 hours	500 ppm	

United Kingdom

EH40/2005 Workplace exposure limits (Fourth Edition 2020)

Substance name (component)	Type	Value	Note
acetone (CAS: 67-64-1)	WEL 8h	1210 mg/m ³	
	WEL 8h	500 ppm	
	WEL 15min	3620 mg/m ³	
	WEL 15min	1500 ppm	
butan-1-ol (CAS: 71-36-3)	WEL 15min	154 mg/m ³	Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.
	WEL 15min	50 ppm	

8.2. Exposure controls

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. If exposure limits cannot be observed in this mode, suitable protection of airways must be used. 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.

Other protection: protective workwear. Contaminated skin should be washed thoroughly.

Reagent for HIPPURATE test

Creation date	13th March 2015		
Revision date	17th January 2024	Version	3.0

Respiratory protection

Halfmask with a filter against organic vapours or a self-contained breathing apparatus as appropriate if exposure limit values of substances are exceeded or in a poorly ventilated environment.

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
Odour	alcoholic
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	highly flammable
Lower and upper explosion limit	data not available
Flash point	22 °C
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	data not available
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	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

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

Vapour/air mixtures are explosive at intense warming.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Risk of ignition or formation of inflammable gases with chromium (VI) oxide, strong oxidizing agents, strong reducing agents, chromosulphuric acid, fluorine and nitric acid.

10.4. Conditions to avoid

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

10.5. Incompatible materials

Rubber, various plastics.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

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

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. No toxicological data is available for the mixture.

Reagent for HIPPURATE test

Creation date

13th March 2015

Revision date

17th January 2024

Version

3.0

Acute toxicity

Harmful if swallowed.

Reagent for HIPPURATE test

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	1439 mg/kg				Calculation of value

acetone

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	5800 mg/kg		Rat (Rattus norvegicus)		
Dermal		20000 mg/kg		Rabbit		
Inhalation		76 mg/l				

butan-1-ol

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	790 mg/kg		Rat (Rattus norvegicus)		
Dermal	LD ₅₀	3400 mg/kg		Rabbit		
Inhalation	LD ₅₀	18 mg/kg		Rat (Rattus norvegicus)		

ninhydrine

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	600 mg/kg		Rat (Rattus norvegicus)		

Skin corrosion/irritation

Causes skin irritation. Data for the components of the mixture are not available.

Serious eye damage/irritation

Causes serious eye damage. Data for the components of the mixture are not available.

Respiratory or skin sensitisation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Germ cell mutagenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Carcinogenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Reproductive toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - single exposure

May cause drowsiness or dizziness. May cause respiratory irritation. Data for the components of the mixture are not available.

Reagent for HIPPURATE test

Creation date	13th March 2015		
Revision date	17th January 2024	Version	3.0

Toxicity for specific target organ - repeated exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Aspiration hazard

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture 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**

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

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

07 04 04* other organic solvents, washing liquids and mother liquors

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

Reagent for HIPPURATE test

Creation date	13th March 2015		
Revision date	17th January 2024	Version	3.0

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

Additional information

It is not transported.

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 reportable explosives precursors: Reporting of suspicious transactions, disappearances and thefts according to Regulation (EU) 2019/1148, Article 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

Assessment was not carried out.

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

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.

Guidelines for safe handling used in the safety data sheet

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261	Avoid breathing mist/vapours/spray.
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.
P308+P311	IF exposed or concerned: Call a POISON CENTER or doctor.

A list of additional standard phrases used in the safety data sheet

EUH066	Repeated exposure may cause skin dryness or cracking.
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Other important information about human health protection

Reagent for HIPPURATE test

Creation date	13th March 2015	Version	3.0
Revision date	17th January 2024		

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
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
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
Eye Dam.	Serious eye damage
Flam. Liq.	Flammable liquid
Skin Irrit.	Skin irritation
STOT SE	Specific target organ toxicity - single 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 3.0 replaces the SDS version from 04 October 2018. Changes were made in sections 1, 2, 11, 12, 13, 15 and 16.

Reagent for HIPPURATE test

Creation date	13th March 2015		
Revision date	17th January 2024	Version	3.0

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.