

**Reagent for HIPPURATE test - weight**

Creation date	21st May 2015	Version	4.0
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 - weight

Substance / mixture	substance
Number	MLT00019
Chemical name	ninhydrine
CAS number	485-47-2
EC (EINECS) number	207-618-1

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

The weight is a part of 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.

**The use descriptors**

PC 21 Laboratory chemicals

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

The substance is classified as dangerous.

Acute Tox. 4, H302

Skin Irrit. 2, H315

Eye Irrit. 2, H319

**Most serious adverse effects on human health and the environment**

Harmful if swallowed. Causes skin irritation. Causes serious eye irritation.

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

Warning

**Hazard statements**

H302	Harmful if swallowed.
H315	Causes skin irritation.

**Reagent for HIPPURATE test - weight**

Creation date	21st May 2015	Version	4.0
Revision date	17th January 2024		

H319 Causes serious eye irritation.

**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 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. Dust may form explosive mixture with air.

**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: 485-47-2 EC: 207-618-1	<b>substance main component</b> ninhydrine	100	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319	

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. Rinsing should continue at least for 10 minutes. Provide medical treatment, specialized if possible.

**If swallowed**

Rinse mouth with water, drink 1/2 l of lukewarm water. Provide medical treatment.

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

Not expected.

**If on skin**

Causes skin irritation.

**If in eyes**

Causes serious eye irritation.

**If swallowed**

Irritation, nausea.

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

Symptomatic treatment.

**Reagent for HIPPURATE test - weight**

Creation date

21st May 2015

Revision date

17th January 2024

Version

4.0

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

Accommodate according to the location of the fire. In case of fire, use water spray/ fog, carbon dioxide or dry chemical powder.

**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. 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. Do not inhale dust. Prevent contact with the substance. Provide sufficient ventilation. 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**

Place the product mechanically in an appropriate manner. Dispose of the collected material according to the instructions in the section 13.

**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. Do not inhale dust. Prevent contact with skin and eyes. 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.

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

**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.

**Skin protection**

Hand protection: Protective gloves resistant to the product.

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

**Reagent for HIPPURATE test - weight**

Creation date	21st May 2015	Version	4.0
Revision date	17th January 2024		

**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	solid
Colour	light yellow
Odour	data not available
Melting point/freezing point	250 °C
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	5 (undiluted)
Kinematic viscosity	data not available
Solubility in water	20 g/l at 20°C
Partition coefficient n-octanol/water (log value)	log POW: 0.67
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	crystalline
------------	-------------

**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**

Unknown.

**10.4. Conditions to avoid**

The product is stable and no degradation occurs under normal use.

**10.5. Incompatible materials**

Protect against strong oxidizing agents and strong acids.

**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**

No toxicological data is available for the substance.

**Reagent for HIPPURATE test - weight**

Creation date

21st May 2015

Revision date

17th January 2024

Version

4.0

**Acute toxicity**

Harmful if swallowed.

**Reagent for HIPPURATE test - weight**

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

**ninhydrine**

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

**Skin corrosion/irritation**

Causes skin irritation.

**Serious eye damage/irritation**

Causes serious eye irritation.

**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.

**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**

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

**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.

**Reagent for HIPPURATE test - weight**

Creation date	21st May 2015	Version	4.0
Revision date	17th January 2024		

**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

**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

**Reagent for HIPPURATE test - weight**

Creation date	21st May 2015		
Revision date	17th January 2024	Version	4.0

**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**

Assessment was not carried out.

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

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

**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
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 <sub>50</sub>	Lethal dose of a substance in which it can be expected death of 50% of the population
log K <sub>ow</sub>	Octanol-water partition coefficient
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic

**Reagent for HIPPURATE test - weight**

Creation date	21st May 2015	Version	4.0
Revision date	17th January 2024		

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 Irrit.	Eye irritation
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**

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 4.0 replaces the SDS version from 04 October 2018. Changes were made in sections 1, 2, 11, 12, 13, 15 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.