

Reagent for ACETOIN test_R2

Creation date	22nd March 2019	Version	3.0
Revision date	05th January 2024		

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

Substance / mixture	Reagent for ACETOIN test_R2
Number	substance
Chemical name	MLT00016
CAS number	potassium hydroxide
Index number	1310-58-3
EC (EINECS) number	019-002-00-8
Registration number	215-181-3
Other substance name	01-2119487136-33-

Činidlo pro test ACETOIN; VPT II

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

The Reagent for ACETOIN test is supplementary colour forming reagent for the test for the formation of acetoin (the Voges-Proskauer reaction) included in some of MIKROLATEST ® kits.

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.

Met. Corr. 1, H290
Acute Tox. 4, H302
Skin Corr. 1A, H314
Eye Dam. 1, H318

Most serious adverse physico-chemical effects

May be corrosive to metals.

Most serious adverse effects on human health and the environment

Causes severe skin burns and eye damage. Harmful if swallowed.

Reagent for ACETOIN test_R2

Creation date	22nd March 2019	Version	3.0
Revision date	05th January 2024		

2.2. Label elements

Hazard pictogram



Signal word

Danger

Dangerous substance

potassium hydroxide

(Index: 019-002-00-8; CAS: 1310-58-3)

Hazard statements

H290

May be corrosive to metals.

H302

Harmful if swallowed.

H314

Causes severe skin burns and eye damage.

Precautionary statements

P280

Wear protective gloves/eye protection/face protection.

P301+P330+P331

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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+P313

IF exposed or concerned: Get medical advice/attention.

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

Mixture of substances and additives specified below.

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 019-002-00-8 CAS: 1310-58-3 EC: 215-181-3 Registration number: 01-2119487136-33-	substance main component potassium hydroxide	31	Met. Corr. 1, H290 Acute Tox. 4, H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 Specific concentration limit: Skin Irrit. 2, H315: 0.5 % ≤ C < 2 % Skin Corr. 1A, H314: C ≥ 5 % Skin Corr. 1B, H314: 2 % ≤ C < 5 % Eye Irrit. 2, H319: 0.5 % ≤ C < 2 %	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.

Reagent for ACETOIN test_R2

Creation date	22nd March 2019		
Revision date	05th January 2024	Version	3.0

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

Take care of your own safety, do not let the affected person walk! Terminate the exposure immediately; move the affected person to fresh air. Beware of the contaminated clothes. Depending on the situation, call the medical rescue service and ensure medical treatment considering the frequent need of further observation for at least 24 hours.

If on skin

Remove contaminated clothes. Take off any rings, watches, bracelets before or during washing if worn in the contaminated areas of the skin. Depending on the situation, call the medical rescue service and always ensure medical treatment. Rinse contaminated areas with a flow of water, lukewarm at best, for 10-30 minutes; do not use any brush, soap or neutralizers. Rinse skin with water/shower. Rinse cautiously with water for several minutes.

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 - there is danger of further damage to the gastrointestinal tract!!! Danger of esophageal and gastric perforation! RINSE THE MOUTH WITH WATER IMMEDIATELY AND LET THE PERSON DRINK 2-5 dl of cold water to reduce the heating effect of the corrosive substance. Consuming larger amounts of liquid is not advisable as it may induce vomiting and potential inhaling of the corrosive substances in the lungs. The affected person must not be forced to drink, particularly if already feeling pain in the mouth or throat. In this case let the affected person only rinse the mouth with water. DO NOT PROVIDE ACTIVATED CARBON! Depending on the situation, call medical rescue service or ensure medical treatment as promptly as possible.

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 severe skin burns.

If in eyes

Causes serious eye damage.

If swallowed

Corrosion of the digestion system can occur.

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. No unsuitable extinguishing media are known, use the extinguishing media adapted to burning substances in the surrounding area.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

Reacts with metals to form hydrogen.

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.

Reagent for ACETOIN test_R2

Creation date	22nd March 2019		
Revision date	05th January 2024	Version	3.0

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

May be corrosive to metals. Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale aerosols. 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. Absorb spillage to prevent material damage.

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. Do not inhale aerosols. Prevent contact with skin and eyes. Do not eat, drink or smoke when using this product. 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.

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. Store locked up. Store only in the original package. Unsuitable materials for containers: aluminum, zinc, lead, tin, copper.

Storage temperature

min 2 °C, max 25 °C

7.3. Specific end use(s)

The solution is designed 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
potassium hydroxide (CAS: 1310-58-3)	PEL	1 mg/m ³	irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	2 mg/m ³	

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. 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.

Reagent for ACETOIN test_R2

Creation date	22nd March 2019	Version	3.0
Revision date	05th January 2024		

Respiratory protection

If all workplace limits are observed and good ventilation is ensured, no special precautions necessary. 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	data not available
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	data not available
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	data not available
Relative vapour density	data not available
Particle characteristics	data not available
Form	liquid, Colorless liquid

9.2. Other information

Evaporation rate	data not available
------------------	--------------------

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

Reacts with acids and water to produce heat. Reacts with metals to form hydrogen.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Reactions with acids. Reaction with light metals to form hydrogen. Heavy heat always to form occurs when diluted with water or dissolved in water.

10.4. Conditions to avoid

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

10.5. Incompatible materials

Protect from strong acids, oxidizing agents, water, aluminum, zinc, magnesium and ammonium compounds. May be corrosive to metals.

10.6. Hazardous decomposition products

Not developed under normal uses. Hydrogen. Other information: Hygroscopic: absorbs moisture or water from the air.

Reagent for ACETOIN test_R2

Creation date	22nd March 2019		
Revision date	05th January 2024	Version	3.0

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. 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.

Acute toxicity

Harmful if swallowed.

Reagent for ACETOIN test_R2						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	1613 mg/kg				Calculation of value

Skin corrosion/irritation

Causes severe skin burns and eye damage.

Serious eye damage/irritation

Causes severe skin burns and 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

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 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.

Reagent for ACETOIN test_R2

Creation date	22nd March 2019	Version	3.0
Revision date	05th January 2024		

Acute toxicity

potassium hydroxide				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	270 mg/l		Daphnia (Daphnia magna)	
LC ₅₀	100 mg/l	96 hours	Fish (Oncorhynchus mykiss)	

12.2. Persistence and degradability

Inorganic substance.

12.3. Bioaccumulative potential

Bioaccumulation is unlikely.

12.4. Mobility in soil

It is mobile in the aquatic environment. Ion exchange may occur when the product penetrates the soil.

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

Water hazard class 1 (on the list): slightly hazardous for water. Harmful effect due to pH change. Do not allow undiluted product or large quantities diluted product of it to reach ground water, water course or sewage system. Do not allow undiluted or non-neutralized to enter sewage or wells.

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

06 02 04* sodium and potassium hydroxide

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

UN 1814

14.2. UN proper shipping name

POTASSIUM HYDROXIDE SOLUTION

14.3. Transport hazard class(es)

8 Corrosive substances

14.4. Packing group

II

Reagent for ACETOIN test_R2

Creation date	22nd March 2019	Version	3.0
Revision date	05th January 2024		

14.5. Environmental hazards

The mixture is not hazardous to the environment during transport.

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

Hazard identification No.

80

UN number

1814

Classification code

C5

Safety signs

8



Tunnel restriction code

(E)

Air transport - ICAO/IATA

Packaging instructions passenger

851

Cargo packaging instructions

855

Marine transport - IMDG

EmS (emergency plan)

F-A, S-B

MFAG

705

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**

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.

Guidelines for safe handling used in the safety data sheet

P280	Wear protective gloves/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.

Reagent for ACETOIN test_R2

Creation date	22nd March 2019	Version	3.0
Revision date	05th January 2024		

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+P313 IF exposed or concerned: 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
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
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
Met. Corr.	Corrosive to metals
Skin Corr.	Skin corrosion

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.

Reagent for ACETOIN test_R2

Creation date	22nd March 2019		
Revision date	05th January 2024	Version	3.0

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

The version 3.0 replaces the SDS version from 02 February 2023. Changes were made in sections 2, 12, 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.