

Reagent for ACETOIN test (solvent)

Creation date	13th March 2015	Version	4.0
Revision date	05th January 2024		

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

Substance / mixture

mixture

Number

MLT00016

UFI

KSCS-DWAR-EJ5N-U6DX

Other mixture names

Činidlo pro test ACETOIN (rozpouštědlo), VPT I

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

Main intended use

PC-MED-OTH

Other medical devices

Secondary uses

PC-TEC-19

Reagents and laboratory chemicals

The use descriptors

PC 21

Laboratory chemicals

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

The mixture is classified as dangerous.

Flam. Liq. 2, H225

Acute Tox. 4, H302

Eye Irrit. 2, H319

STOT SE 2, H371

Most serious adverse physico-chemical effects

Highly flammable liquid and vapor.

Most serious adverse effects on human health and the environment

Causes serious eye irritation. May cause damage to organs. Harmful if swallowed.

Reagent for ACETOIN test (solvent)

Creation date

13th March 2015

Revision date

05th January 2024

Version

4.0

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

Danger

Hazardous substances

methanol

Hazard statements

H225

Highly flammable liquid and vapour.

H302

Harmful if swallowed.

H319

Causes serious eye irritation.

H371

May cause damage to organs.

Precautionary statements

P210

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P261

Avoid breathing vapours.

P280

Wear protective gloves/protective clothing/eye protection.

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.

P370+P378

In case of fire: Use powder extinguisher/sand/carbon dioxide to extinguish.

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: 603-002-00-5 CAS: 64-17-5 EC: 200-578-6	ethanol	95	Flam. Liq. 2, H225 Eye Irrit. 2, H319	1
Index: 603-001-00-X CAS: 67-56-1 EC: 200-659-6	methanol	5	Flam. Liq. 2, H225 Acute Tox. 3, H301+H311+H331 STOT SE 1 (**), H370 Specific concentration limit: STOT SE 1, H370: C ≥ 10 % STOT SE 2, H371: 3 % ≤ C < 10 %	1, 2, 3

Notes

** another exposure route cannot be ruled out

1 A substance for which exposure limits are set.

2 Substance for which biological limit values exist.

3 The use of the substance is restricted by Annex XVII of REACH Regulation

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

Reagent for ACETOIN test (solvent)

Creation date	13th March 2015	Version	4.0
Revision date	05th January 2024		

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

Discontinue the exposure, remove casualty to fresh air, keep at rest and seek medical advice.

If on skin

Remove contaminated clothes. After contact with skin, wash immediately with soap and water.

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 be continued for 10-30 minutes from the inner to the outer eye corner to make sure that the other eye is not involved. Transport victim to the doctor.

If swallowed

Rinse the mouth with water, let the victim drink 1/2 liter of lukewarm water, induce vomiting. Get immediate medical treatment.

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

Irritant effects, respiratory paralysis, narcosis, intoxication, euphoria.

If on skin

Dermatitis.

If in eyes

Causes serious eye damage.

If swallowed

Irritation, nausea. Disorder of digestive system, stomach pain, vomiting, diarrhoea.

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

Symptoms of poisoning may manifest after many hours, medical supervision is necessary for 48 hours after the accident.

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

Water spray jet, water mist, powder, inert gases, carbon dioxide, Alcohol-resistant 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. 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.

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

Highly flammable liquid and vapor. Remove all ignition sources; provide sufficient ventilation. Avoid further leakage, mark the affected area. In case of major accidents, evacuate all persons from the danger area. Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale aerosols.

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

Absorb spillage with a suitable (non-flammable) absorbent material (sand, earth, vapex) and store contaminated material in hazardous waste collection containers and dispose of according to the instructions in 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.

Reagent for ACETOIN test (solvent)

Creation date	13th March 2015	Version	4.0
Revision date	05th January 2024		

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 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. Do not store together with alkali metals and oxidizing agents.

Storage class 3A - Flammable liquids (flash point below 55 °C)

Storage temperature min 2 °C, max 25 °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
ethanol (CAS: 64-17-5)	PEL	1000 mg/m ³	
	PEL	522 ppm	
	NPK-P	3000 mg/m ³	
	NPK-P	1566 ppm	
methanol (CAS: 67-56-1)	PEL	250 mg/m ³	skin penetration is significantly involved during exposure
	PEL	188 ppm	
	NPK-P	1000 mg/m ³	
	NPK-P	751 ppm	

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

Substance name (component)	Type	Value	Note
methanol (CAS: 67-56-1)	OEL 8 hours	260 mg/m ³	Skin
	OEL 8 hours	200 ppm	

Biological limit values**Czech Republic****Decree No. 107/2017 Coll.**

Name	Parameter	Value	Tested material	Time of sampling
methanol (CAS: 67-56-1)	methanol	15 mg/l	Urine	End of shift
		0,47 mmol/l		

Reagent for ACETOIN test (solvent)

Creation date	13th March 2015	Version	4.0
Revision date	05th January 2024		

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. 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. For close/long-term contact: rubber gloves (butyl rubber, thickness 0.7 mm, penetration time >480 min.), for short-term contact: rubber gloves (nitrile, thickness 0.4 mm, penetration time >120 min.).

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

Avoid heat sources and open flames.

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	alcohol
Melting point/freezing point	-114 °C
Boiling point or initial boiling point and boiling range	78 °C
Flammability	highly flammable
Lower and upper explosion limit	
bottom	3.3 %
upper	19 %
Flash point	12.9 °C
Auto-ignition temperature	363 °C
Decomposition temperature	data not available
pH	7 (10 g/l% solution at 20 °C)
Kinematic viscosity	data not available
Viscosity	1.2 mPa,s
Solubility in water	789 000 mg/l
Partition coefficient n-octanol/water (log value)	-0.35
Vapour pressure	57.26 hPa at 19.65 °C
Density and/or relative density	
Density	0.7844 g/cm ³ at 25 °C
Relative vapour density	data not available
Particle characteristics	data not available
Form	clear

9.2. Other information

Explosive properties	The product does not have explosive properties.
Vapour density	1.6
Temperature group: T2 Explosive group: II. B	

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

Vapors may form an explosive mixture with air.

10.2. Chemical stability

The product is stable under normal conditions (room temperature).

Reagent for ACETOIN test (solvent)

Creation date	13th March 2015	Version	4.0
Revision date	05th January 2024		

10.3. Possibility of hazardous reactions

Risk of ignition or formation of flammable gases with chromium oxide, hydrogen peroxide, nitrogen dioxide, nitric acid, phosphorus oxides, manganese acid, perchloric acid, sulfuric acid, potassium permanganate, perchlorates, fluorine, strong oxidizing agents, alkali oxides and alkali metals.

10.4. Conditions to avoid

Heating to 15 ° C below flash point.

10.5. Incompatible materials

Rubber, various plastics.

10.6. Hazardous decomposition products

No decomposition products known.

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.

Acute toxicity

May cause damage to organs. Harmful if swallowed.

Reagent for ACETOIN test (solvent)						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	2000 mg/kg				Calculation of value
Dermal	ATE	6000 mg/kg				Calculation of value
Inhalation (vapor)	ATE	60 mg/l				Calculation of value

ethanol						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	10470 mg/kg		Rat		
Dermal	LD ₅₀	15800 mg/kg		Rat		
Inhalation	LC ₅₀	30000 mg/m ³		Rat		

Skin corrosion/irritation

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.

Serious eye damage/irritation

Causes serious eye irritation. 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.

Reagent for ACETOIN test (solvent)

Creation date	13th March 2015	Version	4.0
Revision date	05th January 2024		

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 damage to organs.

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

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

11.2. Information on other hazards

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

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

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

Acute toxicity

ethanol				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	11200 mg/l	96 hours	Fish	Fresh water
EC ₅₀ /LC ₅₀	5012 mg/l		Invertebrates	Fresh water
EC ₅₀ /LC ₅₀	857 mg/l		Invertebrates	Salt water
EC ₅₀ /LC ₅₀	275 mg/l		Algae	Fresh water
EC ₅₀ /LC ₅₀	1970 mg/l		Algae	Salt water
EC ₅₀ /LC ₅₀	4432 mg/l		Higher plants	Fresh water
LC ₅₀	633 mg/kg of dry substance of soil		Higher plants	
EC ₅₀ /LC ₅₀	5800 mg/l		Aquatic microorganisms	

Chronic toxicity

ethanol				
Parameter	Value	Exposure time	Species	Environment
NOEC	115 mg/l		Algae	Fresh water
NOEC	1580 mg/l		Algae (Selenastrum capricornutum)	Salt water
NOEC	280 mg/l		Higher plants	Salt water

12.2. Persistence and degradability

The mixture is biodegradable.

12.3. Bioaccumulative potential

LogKow <4.5, no bioaccumulation potential.

12.4. Mobility in soil

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

12.5. Results of PBT and vPvB assessment

Reagent for ACETOIN test (solvent)

Creation date	13th March 2015	Version	4.0
Revision date	05th January 2024		

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

At higher concentration, harmful effect on aquatic organisms.

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

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 1170

14.2. UN proper shipping name

ETHANOL

14.3. Transport hazard class(es)

3 Flammable liquids

14.4. Packing group

II

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

Hazard identification No.

33

UN number

1170

Classification code

F1

Safety signs

3



Tunnel restriction code

(D/E)

Reagent for ACETOIN test (solvent)

Creation date	13th March 2015	Version	4.0
Revision date	05th January 2024		

Air transport - ICAO/IATA

Packaging instructions passenger	353
Cargo packaging instructions	364

Marine transport - IMDG

EmS (emergency plan)	F-E, S-D
MFAG	305

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).

Restrictions pursuant to Annex XVII of Regulation (EC) No. 1907/2006 (REACH), as amended

methanol

Restriction	Conditions of restriction
69	Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight.

15.2. Chemical safety assessment

not available

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

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H370	Causes damage to organs.
H371	May cause damage to organs.
H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.

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 vapours.
P280	Wear protective gloves/protective clothing/eye protection.
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.
P370+P378	In case of fire: Use powder extinguisher/sand/carbon dioxide to extinguish.

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

Reagent for ACETOIN test (solvent)

Creation date	13th March 2015	Version	4.0
Revision date	05th January 2024		

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
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log Kow	Octanol-water partition coefficient
NOEC	No observed effect concentration
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 Irrit.	Eye irritation
Flam. Liq.	Flammable liquid
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 4.0 replaces the SDS version from 02 February 2023. Changes were made in sections 2, 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.