

PARAFFIN OIL

Creation date	24th April 2019	Version	3.0
Revision date	03rd June 2024		

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

Substance / mixture	PARAFFIN OIL
Number	substance
Chemical name	MLT00042
CAS number	White mineral oil
EC (EINECS) number	8042-47-5
Registration number	232-455-8
Other substance name	01-2119487078-27

PARAFINOVÝ OLEJ STERILIZOVANÝ

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

Paraffin oil is supplementary preparation for diagnostic MIKROLATEST® kits, containing tests requiring incubation with prevention of oxygen access. The method of using Paraffin oil is included in the working instruction of the respective diagnostic MIKROLATEST® kit.

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 not classified as dangerous according to Regulation (EC) No 1272/2008.

Most serious adverse physico-chemical effects

Contaminated surfaces will be very slippery.

Most serious adverse effects on human health and the environment

Do not discharge into the environment.

2.2. Label elements

none

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.

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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: 8042-47-5 EC: 232-455-8 Registration number: 01-2119487078-27	substance main component White mineral oil	100	not classified as dangerous	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.

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. In case of ingestion and risk of aspiration bronchopneumonia, observation by a doctor for 48 hours is recommended.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

If on skin

Remove contaminated clothes. Wash with plenty of soap and water. Get medical attention if symptoms occur.

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. Seek (professional) medical attention, especially if pain or redness of eyes persists.

If swallowed

Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed

If inhaled

Inhalation may cause irritation of the respiratory mucosa. Depending on the amount of exposure may occur headache, drowsiness, nausea, dizziness, and, in extreme cases, loss of consciousness. Seek medical attention if breathing is difficult.

If on skin

Adverse symptoms may include the following: irritation, dryness, cracking

If in eyes

Not expected.

If swallowed

May cause gastrointestinal irritation accompanied by abdominal pain and nausea; vomiting and diarrhea may also 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

Accommodate extinguishing components to the location of fire. Foam, extinguishing powder, carbon dioxide (CO₂), water spray or mist.

Unsuitable extinguishing media

Water stream; it can only be used to cool product packaging near fire.

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5.2. Special hazards arising from the substance or mixture

Fire produces smoke which can be form carbon monoxide and carbon dioxide, soot and various hydrocarbons and aldehydes formed by incomplete combustion and thermolysis of the substance. Do not breathe fumes of fire. Vapors may form explosive mixtures in contact with air. Vapors are heavier than air and may be dispersed in the ground to sources of ignition. Fire residues and contaminated extinguishing liquid are disposed of according to local regulations. If possible, remove the closed product containers from the vicinity of the fire or cool with water.

5.3. Advice for firefighters

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

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

Avoid contact with eyes and skin. Do not breathe gas / aerosol. Wear suitable personal protective equipment. Evacuate personnel. Ensure adequate ventilation, especially in confined areas. Remove all possible sources of ignition. Do not touch or step on spilled material.

6.2. Environmental precautions

Prevent product spillage (eg universal or chemical sorption pads), especially contamination of soil and leakage to surface or groundwater and to sewerage. In case of large quantities of product leakage and especially if such material enters drains or waterways, inform firefighters, police or other competent local authority (s) like Environmental Department of the Regional Authority.

6.3. Methods and material for containment and cleaning up

It is recommended to cover the product a suitable non-combustible oil-absorbing material (depending on the amount of product leaked, eg universal bulk chemical sorbent or universal chemical cloth, sand, diatomaceous earth, earth and other suitable absorbent materials). Collect the collected material in well sealed containers and dispose of according to local regulations.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Use only in well-ventilated areas. Do not breathe vapor or spray mist. Avoid contact with skin, eyes, avoid minor skin injuries and contact with dirty clothing. Wear personal protective equipment. Ensure regular cleaning of equipment, work surfaces and clothing. Do not rub your hands into rags contaminated with the product. Do not put dirty rags in pockets of work clothes. Do not use abrasives, solvents or fuels. Wash your hands before each break and at the end of the working day. Avoid static electricity by grounding. Ground the containers, tanks, and lifting facilities.

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 facilities should be designed to avoid possible soil contamination or contamination water in case of leakage. Keep away from heat and direct sunlight, frost and moisture.

7.3. Specific end use(s)

The reagent of the kit is designed for in vitro diagnostic use.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Czech Republic****Government Regulation 330/2023 Coll.**

Substance name (component)	Type	Value
White mineral oil (CAS: 8042-47-5)	PEL	5 mg/m ³
	NPK-P	10 mg/m ³

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DNEL

White mineral oil					
Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Dermal	220 mg/kg	Chronic effects systemic		
Workers	Inhalation	160 mg/m ³	Chronic effects systemic		
Consumers	Inhalation	2600 mg/m ³	Acute effects systemic		
Consumers	Dermal	92 mg/kg	Chronic effects systemic		
Consumers	Inhalation	35 mg/m ³	Chronic effects systemic		
Consumers	Oral	40 mg/kg	Chronic effects systemic		

8.2. Exposure controls

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. Observe the usual basic occupational hygiene measures. Ensure good ventilation at permanent workplaces so that PELs are not exceeded.

Eye/face protection

When working where can be form spraying or heating the product: goggles with sides / closed glasses or face shield.

Skin protection

Hydrocarbon-resistant protective gloves, fluorinated rubber, nitrile rubber. Follow the permeability and breakthrough time guidelines provided by the glove supplier. Long sleeved working (protective) clothing, protective gloves, protective boots. Do not eat, drink and smoke during work. Take off soiled and stained clothing. Wash contaminated clothing before reuse. After work wash your hands with warm water and soap and treat your skin with suitable repair cream.

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. Do not allow to enter surface waterways or drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless
Odour	after oil
Melting point/freezing point	-6 °C
Boiling point or initial boiling point and boiling range	>300 °C
Flammability	data not available
Lower and upper explosion limit	
bottom	0.9 %
upper	7 %
Flash point	>185 °C
Auto-ignition temperature	>209 °C
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Viscosity	20.7 – 25.3
Viscosity - flow time	mm ² /s
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	> 3.5
Vapour pressure	data not available
Density and/or relative density	
Density	0.862 g/cm ³ at 15 °C

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Relative vapour density	data not available
Particle characteristics	data not available
9.2. Other information	
Appearance	clear colourless liquid
Oxidising properties	The product has no oxidizing properties.
Explosive properties	The product does not have explosive properties.

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

Not known. Unknown.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Keep away from flames, sparks, temperatures above flash point and frost.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

None under normal use conditions. Fire produces smoke which can be form carbon monoxide and carbon dioxide, soot and various hydrocarbons and aldehydes formed by incomplete combustion and thermolysis of the substance.

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

Based on available data the classification criteria are not met.

White mineral oil					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD ₅₀	>5000 mg/kg bw			
Dermal	LD ₅₀	>2000 mg/kg bw	24 hours	Rabbit	
Inhalation (aerosols)	LC ₅₀	>5000 mg/m ³	48 hours	Rat	

Skin corrosion/irritation

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

Serious eye damage/irritation

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

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.

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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.

More information

Characteristic skin lesions (pimples) may develop after prolonged or repeated exposure (contact with contaminated clothing).

11.2. Information on other hazards

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

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

Based on available data the classification criteria are not met.

Acute toxicity

White mineral oil				
Parameter	Value	Exposure time	Species	Environment
EL ₅₀	>100 mg/l	48 hours	Algae (Pseudokirchnerella subcapitata)	
EL ₅₀	>100 mg/l	48 hours	Daphnia (Daphnia magna)	
LL ₅₀	>100 mg/l	96 hours	Fish (Oncorhynchus mykiss)	

Chronic toxicity

White mineral oil				
Parameter	Value	Exposure time	Species	Environment
NOEL	10 mg/l	214 days	Daphnia (Daphnia magna)	
NOEL	1000 mg/l	14/21 days	Fish (Oncorhynchus mykiss)	

12.2. Persistence and degradability

No data available for the substance.

12.3. Bioaccumulative potential

log pow: 3,5

12.4. Mobility in soil

Soil: Based on physical and chemical properties, the product has a low potential to penetrate the soil. Air: The evaporation the loss is limited. Water: Insoluble. He floats on the surface.

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

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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

Prevent contamination of the soil and entering surface or ground water. Do not allow to enter drains.

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

13 02 05* mineral-based non-chlorinated engine, gear and lubricating oils

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

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

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SECTION 16: Other information

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
EL ₅₀	Effective Loading for 50% of the tested organisms
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
LL ₅₀	Lethal Loading for 50% of tested organisms
log K _{ow}	Octanol-water partition coefficient
NOEL	No observed effect level
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

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.
REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

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

The version 3.0 replaces the SDS version from 05 February 2024.

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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.