

Reagent for NITRATE test - NIT-reagent

Creation date	13th May 2015	Version	3.0
Revision date	16th January 2024		

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- 1.1. Product identifier**
Substance / mixture Reagent for NITRATE test - NIT-reagent mixture
Number MLT00021
UFI 3EK8-AJET-QE7Q-WSSF
Other mixture names
Činidlo pro NIT - R1, Činidlo pro test NITRÁTY - NIT
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
NIT-reagent is a part of kit Reagent for NITRATE test, which is supplementary preparation for diagnostic MIKRO-LA-TEST® kits, containing a test for the demonstration of the proof of reduction of nitrate or nitrite (NIT, Nitrate, NO3 or Nitrite, NO2) and it serves for the colour expression of those tests.
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.

Skin Corr. 1B, H314
Eye Dam. 1, H318
Most serious adverse effects on human health and the environment
Causes severe skin burns and eye damage.

- 2.2. Label elements**
Hazard pictogram



Signal word
Danger

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Hazardous substances

acetic acid ... %
sulphanilic acid

Hazard statements

H314 Causes severe skin burns and eye damage.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye 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.

Supplemental information

EUH208 Contains sulphanilic acid. May produce an allergic reaction.

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: 607-002-00-6 CAS: 64-19-7 EC: 200-580-7 Registration number: 01-2119475328-30-X	acetic acid ... %	<32	Flam. Liq. 3, H226 Skin Corr. 1A, H314 Specific concentration limit: Skin Corr. 1A, H314: $C \geq 90\%$ Skin Irrit. 2, H315: $10\% \leq C < 25\%$ Skin Corr. 1B, H314: $25\% \leq C < 90\%$ Eye Irrit. 2, H319: $10\% \leq C < 25\%$	1, 2
CAS: 86-56-6 EC: 201-682-4	N,N-Dimethyl-1-naphthylamine	<1	Acute Tox. 4, H302 Aquatic Chronic 2, H411	
Index: 612-014-00-X CAS: 121-57-3 EC: 204-482-5	sulphanilic acid	<0,5	Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319	

Notes

- Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.
- A substance for which exposure limits are set.

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

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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. Beware of the contaminated clothes. Depending on the situation, call the emergency service or provide medical treatment.

If on skin

Remove contaminated clothes. Rinse the affected parts of the body with a stream of lukewarm water for 10-30 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.

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. Irritation, nausea.

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.

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 aerosols. Prevent contact with skin and eyes. Observe the principles of work safety in chemical laboratories.

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6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

6.4. Reference to other sections

See the Section 7, 8 and 13.

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

Observe the normal operating procedures for handling chemical substances and mixtures. Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Do not inhale aerosols. Prevent contact with skin and eyes. 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. Store locked up.

Storage temperature

min 2 °C, max 8 °C

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
acetic acid ... % (CAS: 64-19-7)	PEL	25 mg/m ³	irritating to mucous membranes (eyes, respiratory system) and skin
	PEL	10 ppm	
	NPK-P	50 mg/m ³	
	NPK-P	20 ppm	

European Union**Commission Directive (EU) 2017/164**

Substance name (component)	Type	Value	Note
acetic acid ... % (CAS: 64-19-7)	OEL 8 hours	25 mg/m ³	
	OEL 8 hours	10 ppm	
	OEL 15 minutes	50 mg/m ³	
	OEL 15 minutes	20 ppm	

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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.

Skin protection

Hand protection: Protective gloves resistant to the product. Other protection: protective workwear.

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	liquid
Colour	colourless
Odour	acetic
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	1.5 (undiluted)
Kinematic viscosity	data not available
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

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

not available

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. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Unknown.

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.

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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

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

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	113300 mg/kg				Calculation of value

acetic acid ... %						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	3310 mg/kg		Rat (Rattus norvegicus)		
Dermal	LD ₅₀	1060 mg/kg		Rabbit		
Inhalation	LC ₅₀	0.04 mg/m ³		Rat (Rattus norvegicus)		

N,N-Dimethyl-1-naphthylamine						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	680 mg/kg		Rat		

Skin corrosion/irritation

Causes severe skin burns and eye damage. Data for the components of the mixture are not available.

Serious eye damage/irritation

Causes severe skin burns and eye damage. Causes serious eye damage. Data for the components of the mixture are not available.

Respiratory or skin sensitisation

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

Germ cell mutagenicity

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

Carcinogenicity

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

Reproductive toxicity

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

Toxicity for specific target organ - single exposure

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.

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Toxicity for specific target organ - repeated exposure

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

Aspiration hazard

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

11.2. Information on other hazards

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

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

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

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

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

12.4. Mobility in soil

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

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

Not available.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

Waste type code

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**

UN 3265

14.2. UN proper shipping name

CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Acetic acid/ Dimethyl(1-naphthyl)amine/ Sulphanilic acid mixture)

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14.3. Transport hazard class(es)

8 Corrosive substances

14.4. Packing group

II

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

not available

14.7. Maritime transport in bulk according to IMO instruments

not relevant

Additional information

Hazard identification No.

80

UN number

3265

Classification code

C3

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

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

A chemical safety assessment has not been carried out.

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

H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.

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Guidelines for safe handling used in the safety data sheet

P280	Wear protective gloves/protective clothing/eye 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.

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

EUH208	Contains sulphanilic acid. May produce an allergic reaction.
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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
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log K _{ow}	Octanol-water partition coefficient
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible Exposure Limit
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative
Acute Tox.	Acute toxicity
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
Eye Dam.	Serious eye damage
Flam. Liq.	Flammable liquid
Skin Corr.	Skin corrosion

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Skin Sens.

Skin sensitization

Training guidelines

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

Recommended restrictions of use

For in vitro diagnostic use only.

Information about data sources used to compile the Safety Data Sheet

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

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

The version 3.0 replaces the SDS version from 04 March 2019. 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.