

INDOLtest

| | | | |
|---------------|--------------------|---------|-----|
| Creation date | 16th January 2015 | Version | 3.0 |
| Revision date | 09th November 2023 | | |

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

- 1.1. Product identifier**
Substance / mixture INDOLtest
Number mixture
UFI MLT00028
NS5U-9JRE-8E77-P788
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**

Mixture's intended use

INDOLtest is designed for rapid determination of Indole, degradation product of bacterial metabolism of tryptophane. It is designed for a quick presumptive determination of E. coli, screening differentiation of indole positive and indole negative bacterial genera and as a necessary additional test for some identification 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.

Skin Irrit. 2, H315
Eye Irrit. 2, H319
STOT SE 3, H335

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

Most serious adverse effects on human health and the environment

Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.

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

Warning

Hazardous substances

Hydrochloric acid 35%

Hazard statements

| | |
|------|-----------------------------------|
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory irritation. |

Precautionary statements

| | |
|----------------|--|
| P280 | Wear protective gloves/protective clothing/eye protection. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |

2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

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: 017-002-01-X CAS: 7647-01-0 EC: 231-595-7 | Hydrochloric acid 35% | 15 | Met. Corr. 1, H290 Skin Corr. 1B, H314 STOT SE 3, H335 Specific concentration limit: Skin Corr. 1B, H314: C ≥ 25 % Skin Irrit. 2, H315; Eye Irrit. 2, H319: 10 % ≤ C < 25 % STOT SE 3, H335: C ≥ 10 % | 1 |
| CAS: 6203-18-5 EC: 228-267-0 | 4-dimethylaminocinnamaldehyde | 1 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 | |

Notes

1 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. Protect the person against growing cold. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. Rinsing should continue at least for 10 minutes. Provide medical treatment, specialized if possible.

If swallowed

DO NOT INDUCE VOMITING! Rinse out the mouth with water and provide 2-5 dL of water. Provide medical treatment if the person has any health problems.

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

It can cause irritation of the respiratory tract, coughing, shortness of breath.

If on skin

Causes skin irritation.

If in eyes

Causes serious eye irritation.

If swallowed

Irritation, nausea.

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

Symptomatic treatment.

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

Accommodate extinguishing components to the location of fire. Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

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.

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 mist/vapours/spray. 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.

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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**

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes. Wash hands and exposed parts of the body thoroughly after handling. Use only outdoors or in a well-ventilated area. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Observe the principles of safety work in chemical laboratories.

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. Keep container tightly closed.

Storage temperature

min 2 °C, max 8 °C

7.3. Specific end use(s)

For professional use only.

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 195/2021 Coll.**

| Substance name (component) | Type | Value | Conversion for ppm | Note |
|--|-------|----------------------|--------------------|--|
| Hydrochloric acid 35% (CAS: 7647-01-0) | PEL | 8 mg/m ³ | 0,660 | irritating to mucous membranes (eyes, respiratory system) and skin |
| | NPK-P | 15 mg/m ³ | 0,660 | |

European Union**Commission Directive 2000/39/EC**

| Substance name (component) | Type | Value |
|--|----------------|----------------------|
| Hydrochloric acid 35% (CAS: 7647-01-0) | OEL 8 hours | 8 mg/m ³ |
| | OEL 8 hours | 5 ppm |
| | OEL 15 minutes | 15 mg/m ³ |
| | OEL 15 minutes | 10 ppm |

DNEL**Hydrochloric acid 35%**

| Workers / consumers | Route of exposure | Value | Effect | Value determination | Source |
|---------------------|-------------------|------------------------|-----------------------|---------------------|--------|
| Workers | Inhalation | 15.0 mg/m ³ | Acute effects local | | |
| Workers | Inhalation | 8.0 mg/m ³ | Chronic effects local | | |
| Consumers | Inhalation | 8.0 mg/m ³ | Chronic effects local | | |

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| Hydrochloric acid 35% | | | | | |
|-----------------------|-------------------|----------------------|---------------------|---------------------|--------|
| Workers / consumers | Route of exposure | Value | Effect | Value determination | Source |
| Consumers | Inhalation | 15 mg/m ³ | Acute effects local | | |

8.2. Exposure controls

Take off contaminated clothing and wash before reuse. Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. If exposure limits cannot be observed in this mode, suitable protection of airways must be used. Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

Protective goggles.

Skin protection

Hand protection: Protective gloves resistant to the product. 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.

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 | yellow |
| Odour | acid |
| 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 |
| 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 |
|------------|-------|

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

not available

10.2. Chemical stability

The product is stable under normal conditions.

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10.3. Possibility of hazardous reactions

Risk of explosion with alkali metals, concentrated sulfuric acid. Forms dangerous gases in contact with aluminum, hydrides, formaldehyde, metals, strong alkalis and sulphides.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Avoid exposure to heat and sunlight.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents. Metals.

10.6. Hazardous decomposition products

Not developed under normal uses. When reacting with metals, hydrogen is produced.

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

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.

Skin corrosion/irritation

Causes skin irritation. Data for the components of the mixture are not available.

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.

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 respiratory irritation. Data for the components of the mixture are not available.

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.

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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

| Hydrochloric acid 35% | | | | |
|-----------------------|-----------|---------------|---------|-------------|
| Parameter | Value | Exposure time | Species | Environment |
| LC50 | 20.5 mg/l | 96 hours | Fish | |

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**

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

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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

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

| | |
|------|--|
| H290 | May be corrosive to metals. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory irritation. |

Guidelines for safe handling used in the safety data sheet

| | |
|----------------|--|
| P280 | Wear protective gloves/protective clothing/eye protection. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

| | |
|--------|---|
| ADR | European agreement concerning the international carriage of dangerous goods by road |
| BCF | Bioconcentration Factor |
| CAS | Chemical Abstracts Service |
| CLP | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures |
| EC | Identification code for each substance listed in EINECS |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| EmS | Emergency plan |
| EU | European Union |
| EuPCS | European Product Categorisation System |
| IATA | International Air Transport Association |
| IBC | International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals |
| ICAO | International Civil Aviation Organization |
| IMDG | International Maritime Dangerous Goods |

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| 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 |
| Met. Corr. | Corrosive to metals |
| Skin Corr. | Skin corrosion |
| 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 3.0 replaces the SDS version from 31 January 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.