

PERALEX 9 Hecto +

PERACETIC ACID-BASED
READY-TO-USE DISINFECTANT



■ APPLICATION

- Operating room, endoscopy, optical equipment

■ PRODUCT BENEFITS

- Ready-to-use (without activator)
- High-level disinfection in 10 minutes
- Compatibility with materials used in endoscope disinfection benches, in particular corian
- Formulated without aldehydes: no fixation of proteins



Fb Franklab®
notre expertise l'Ultra-Propreté



READY
TO USE

CE
0459

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PERACETIC ACID-BASED READY-TO-USE DISINFECTANT

INSTRUCTION FOR USE

Preparation of the disinfection bath :

- Wear reusable long-sleeved gloves, goggles, apron and mask
- Pour the required quantity of the ready-to-use solution into a tray so that the equipment to be disinfected is fully immersed

Use :

- 1- Immerse the medical device to be treated
- 2- Circulate the disinfectant inside the channels for endoscopes
- 3- Contact time: 10 minutes minimum
- 4- Rinse thoroughly with microbiologically controlled water

Repeat the bath every 14 days maximum. Check the stability of the bath every morning before the first use and then every 4 hours with a PERATEST 500 strip. In France, in accordance with current French regulations, repeat the bath every 7 days maximum. Check the stability of the bath every morning before the first use with a PERATEST 500 test strip.

DISINFECTING PROPERTIES

| Activity | Standards | Contact time |
|--|---------------------|--------------|
| Bactericidal | EN 13727 | 1 minute |
| | EN 14561 | 5 minutes |
| Fungicidal | EN 13624 / EN 14562 | 5 minutes |
| Virucidal | EN 14476 | 10 minutes |
| | EN 17111 | 5 minutes |
| Mycobactericidal | EN 14348 / EN 14563 | 10 minutes |
| Sporicidal | EN 14347 | 10 minutes |
| | EN 17126 | 10 minutes |
| Sporicidal against C. difficile | EN 17126 | 10 minutes |

PRECAUTIONS OF USE

Refer to the Safety Data Sheet (SDS 010474)

FEATURES

- Aspect : **Liquid**
- Colour : **Colourless**
- Pure pH : **2,5**
- Expiration date : **1 year**

COMPOSITION

- Peracetic acid
- Hydrogen peroxide
- Acetic acid

PACKAGING

- 1 Box of 4 x 5 L cansref. **1047420**



Hazardous product - follow the precautions of use. Always read the label and product information before use. Class IIb medical device

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SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: PERALEX 9 Hecto +
Product code: 010474

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

High-level ready-to-use liquid disinfectant for manual soaking of invasive medical devices.

1.3. Details of the supplier of the safety data sheet

Registered company name: FRANKLAB
Address: 3 avenue des Frênes.78180.MONTIGNY LE BRETONNEUX.FRANCE.
Telephone: +33 1 39 44 93 40. Fax: +33 1 39 44 93 41.
contact@franklab.com
www.franklab.com

1.4. Emergency telephone number: +33 1 40 44 30 00

Association/Organization: INRS Paris.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Serious eye damage, Category 1 (Eye Dam.1, H318).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present a hazard to the environment. Ecological damages are not known or expected under normal uses.

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard Pictograms:



GHS05

Signal Word:

DANGER

Product identifiers:

008-003-00-9 HYDROGEN PEROXIDE SOLUTION

Hazard statements:

H318 Causes serious eye damages.

Precautionary statements - Prevention:

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

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2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>
The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3: COMPOSITION/INFORMATIONS ON INGREDIENTS

3.2. Mixtures

Composition:

| Identification | (EC) 1272/2008 | Note | % |
|---|---|----------|----------------------|
| INDEX: 008-003-00-9 CAS: 231-765-0 HYDROGEN PEROXIDE SOLUTION | GHS03, GHS05, GHS07 Dgr OX. Liq. 1, H271 Acute Tox. 4, H332 Acute Tox. 4, H302 Skin Corr. 1A, H314 | B [1] | $2.5 \leq x \% < 10$ |
| INDEX: 607-002-00-6 CAS: 64-19-7 EC: 200-580-7 ACETIC ACID | GHS02, GHS05 Dgr Flam. Liq. 3, H226 Skin Corr.1A, H314 | B [1] | $0 \leq x \% < 2.5$ |

Information on ingredients:

[1] Substance for which maximum workplace exposure limits are available.

SECTION 4: FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.
NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of exposure by inhalation:

Move the subject away from the exhibition site and bring it outdoors

In the event of splashes or contact with eyes:

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.
Regardless of the initial state, refer the patient to an ophthalmologist and show the label.

In the event of splashes or contact with skin:

Wash immediately with plenty of water.

In the event of swallowing:

Seek medical attention immediately, showing the label.

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

No data available.

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

No data available.

SECTION 5: FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed:

- carbon monoxide (CO)
- carbon dioxide (CO₂)

5.3. Advice for firefighters

Use self-contained breathing apparatus and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

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6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Avoid any contact with the skin and eyes.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Absorb the spill with non-combustible absorbent materials. Wash thoroughly the surface that has been contaminated.

Do NOT use textiles, sawdust, combustible materials.

6.4. Reference to other sections

No data available.

SECTION 7: HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using

Fire prevention:

Prevent access by unauthorized personnel.

Recommended equipment and procedures:

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Do not allow contact with the eyes.

Prohibited equipments and procedures:

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from combustible material and reducing agents (amines), acids, bases, heavy metal compounds (accelerators, desiccants, metallic salts).

Storage

Keep in the original container only, in a well-ventilated place, away from all sources of light. Store at temperatures between 5°C and 25°C.

Store in an upright position.

Packaging

Always keep in packaging made of an identical material to the original

Vented cap required.

7.3. Specific end use(s)

Professional use only.

Consult section 1 for the product use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits:

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010):

| CAS | TWA | STEL | Ceiling | Definition | Criteria |
|-----------|-------|-------|---------|------------|----------|
| 7722-84-1 | 1ppm | - | - | - | - |
| 64-19-7 | 10ppm | 15ppm | - | - | - |

- France (INRS-ED984 :2012):

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| CAS | VME-ppm | VME-mg/m3 | VLE-ppm | VLE-mg/m3 | Notes | TMP N° |
|-----------|---------|-----------|---------|-----------|-------|--------|
| 7722-84-1 | 1 | 1.5 | - | - | - | - |
| 64-19-7 | - | - | 10 | 25 | - | - |

- Mexico:

| CAS | TWA | STEL | Ceiling | Definition | Criteria |
|-----------|-------|-------|---------|------------|----------|
| 7722-84-1 | 1ppm | 2ppm | - | - | - |
| 64-19-7 | 10ppm | 15ppm | - | - | - |

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.
 Store personal protective equipment in a clean place, away from the work area.
 Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye/face protection

Avoid contact with eyes.
 Use eye protectors designed to protect against liquid splashes
 Before handling, wear safety goggles with protective sides accordance with standard EN166.

- Hand protection

Wear reusable gauntlet gloves (approved on the TDS 1670).

- Body protection

Work clothing worn by personnel shall be laundered regularly.
 After contact with the product, all parts of the body that have been soiled must be washed

- Respiratory protection

In case of insufficient ventilation with risk of exceeding STEL/TWA, wear suitable respiratory equipment.
 Use Type B1P1 or B2P2 filters.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information

Physical state: Fluid liquid.

Important health, safety and environmental information

pH: No data available.

Weak acid.

Flash point interval: Not relevant.

Vapour pressure (50°C) : Below 110kPa (1.10 bar).

Density: > 1

Water solubility: Soluble.

9.2. Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No dangerous reactions if handling and storage conditions are respected.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

Do not mix with other products.

10.4. Conditions to avoid

Avoid:

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- Frost
- Heat
- Exposure to the light

10.5. Incompatible materials

Keep away from:

- Wood, textiles, paper

10.6. Hazardous decomposition products

The thermal decomposition may release/form:

- carbon monoxide (CO)
- carbon dioxide (CO₂)

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

No toxicological data available for the substances.

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste:

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging:

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14: TRANSPORT INFORMATION

Exempted from Transport labeling.

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 – IMDG 2012 – ICAO/IATA 2014).

SECTION 15: REGULATION INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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- Classification and labeling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 487/2013
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013
- EU Regulation No. 1272/2008 amended by EU Regulation No. 944/2013
- EU Regulation No. 1272/2008 amended by EU Regulation No. 605/2014

- Container information:

No data available.

- Particular provisions :

No data available.

- Standardized American system for the identification of hazards presented by the product in view of emergency procedures (NFPA 704):

NFPA 704, Labeling: Health=3 Inflammability=1 Instability/Reactivity=1 Specific Risk=none



15.2. Chemical safety assessment

No data available.

SECTION 16: OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Wording of the phrases mentioned in section 3:

| | |
|------|---|
| H226 | Flammable liquid and vapour. |
| H271 | May cause fire or explosion; strong oxidizer. |
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |
| H332 | Harmful if inhaled. |

Abbreviations:

ADR: European agreement concerning the international carriage of dangerous goods by Road.

IMDG: International Maritime Dangerous Goods.

IATA: International Air Transport Association.

ICAO: International Civil Aviation Organization

RID: Regulations concerning the International carriage of Dangerous goods by rail.

GHS05: Corrosion.



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

| Nr | Denumire | Den.comerc. | Model | Nr. catalog | Tara | Producatorul | Reprezentant | Ordin | Data |
|-------------|---|-------------|-------------------------------|-------------|--------|--------------|------------------|-------------|------------|
| | | | | | | frank | sofra | | |
| DM000388409 | DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE | FRANKLAB® | VIROSPRAY, 1L | 1092911 | Franta | FRANKLAB | SOFRAGRUP S.R.L. | Rg04-000271 | 15-11-2022 |
| DM000388398 | DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE | FRANKLAB® | DDN 9, 1L | 1027101 | Franta | FRANKLAB | SOFRAGRUP S.R.L. | Rg04-000271 | 15-11-2022 |
| DM000388378 | DETERGENT | FRANKLAB® | TFD7, 5L, CAN | 1020805 | Franta | FRANKLAB | SOFRAGRUP S.R.L. | Rg04-000271 | 15-11-2022 |
| DM000388363 | DETERGENT | FRANKLAB® | ENZYMEX LD, 1L, DOSING BOTTLE | 1027101 | Franta | FRANKLAB | SOFRAGRUP S.R.L. | Rg04-000271 | 15-11-2022 |
| DM000388405 | DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE | FRANKLAB® | ENZYMEX P, 1KG | 1031789 | Franta | FRANKLAB | SOFRAGRUP S.R.L. | Rg04-000271 | 15-11-2022 |
| DM000388399 | DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE | FRANKLAB® | DDN 9, 5L | 1027105 | Franta | FRANKLAB | SOFRAGRUP S.R.L. | Rg04-000271 | 15-11-2022 |
| DM000388401 | DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE | FRANKLAB® | ECOSEPTOL FOAM, 750 ML | 1031705 | Franta | FRANKLAB | SOFRAGRUP S.R.L. | Rg04-000271 | 15-11-2022 |
| DM000388408 | DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE | FRANKLAB® | PERALEX 9 HECTO +, 5L | 1092905B | Franta | FRANKLAB | SOFRAGRUP S.R.L. | Rg04-000271 | 15-11-2022 |
| DM000388381 | DETERGENT | FRANKLAB® | TFD7, 20L, CAN | 1020821 | Franta | FRANKLAB | SOFRAGRUP S.R.L. | Rg04-000271 | 15-11-2022 |
| DM000388375 | DETERGENT | FRANKLAB® | RINCE L7, 20L, CAN | 1092921 | Franta | FRANKLAB | SOFRAGRUP S.R.L. | Rg04-000271 | 15-11-2022 |

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[Содержит\('Producatorul', 'frank'\)](#) И [Содержит\('Reprezentant', 'sofra'\)](#)

EQUIVALENCE PERALEX 9 HECTO +

| Formula code | FRANKLAB Designation | Packaging | FRANKLAB Commercial reference |
|---------------------|-----------------------------|------------------|--------------------------------------|
| F010474V1 | Peralex 9 Hecto + | 4x5L | 1047420 |

Louisa KDYEM
Regulatory Affairs Manager





A l'attention de M CHARRAT / To M CHARRAT

Conformité aux Bonnes Pratiques de Laboratoire selon les Directives 2004/9/CE et 2004/10/CE, et selon la norme ISO 17025
Compliance with Good Laboratory Practices according to Directives 2004/9/CE and 2004/10/CE, and according to the ISO 17025 standard

Société (Company) : APEX BIOSOLUTIONS – 3 rue de la terre rouge– 25220 ROCHE LEZ BEAUPRE – FRANCE

- Vu la Directive 2004/9/CE du Parlement Européen et du Conseil du 11 février 2004 relative à l'inspection et la vérification des Bonnes Pratiques de Laboratoires (BPL),
Having regard to the Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP),
- Vu la Directive 2004/10/CE du Parlement Européen et du Conseil du 11 février 2004 concernant le rapprochement des dispositions législatives, réglementaires et administratives relatives à l'application des principes de bonnes pratiques de laboratoire et au contrôle de leur application pour les essais sur les substances chimiques,
Having regard to the Directive 2004/10/EC of the European parliament and of the council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances,
- Vu la Directive 93/88/CEE du Conseil du 12 octobre 1993 modifiant la directive 90/679/CEE concernant la protection des travailleurs contre les risques liés à l'exposition à des agents biologiques au travail,
Having regard to the Council Directive 93/88/EEC of 12 October 1993 amending Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work,
- Vu la norme ISO/IEC 17025 :2017 concernant les exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais,
Having regard to the ISO/IEC 17025:2017 standard relating to general requirements for the competence of testing and calibration laboratories,

APEX BIO SOLUTIONS effectue les essais suivants conformément aux principes des BPL et de la norme ISO 17025 :

APEX BIO SOLUTIONS staff works in accordance with the principles of GLP and ISO 17025 standard in the following area:

- Etude d'efficacité biocides sur agents microbiologiques de niveau 1 et 2
- *Tests Methods and Efficacy testing of Biocides on Microbial agents Level 1 & 2*

ROCHE LEZ BEAUPRE, le 11 janvier 2024 / January, the 11th 2024

Stephanie MOROT-BIZOT

Docteur en microbiologie / PhD in microbiology

Expert member (AFNOR T72Q and CEN/TC 216/WG1 « Human Medicine », WG2 "veterinary field" and WG3 « Food Hygiene and Domestic and Institutional Use »)

A l'attention de M CHARRAT / To M CHARRAT

Conformité aux Bonnes Pratiques de Laboratoires selon les Directives 2004/9/CE et 2004/10/CE, et selon la norme ISO 17025.

Compliance with Good Laboratory Practices according to Directives 2004/9/CE and 2004/10/CE, and according to the ISO 17025 standard.

- Vu la Directive 2004/9/CE du Parlement Européen et du Conseil du 11 février 2004 relative à l'inspection et la vérification des Bonnes Pratiques de Laboratoires (BPL),
Having regard to the Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP),
- Vu la Directive 2004/10/CE du Parlement Européen et du Conseil du 11 février 2004 concernant le rapprochement des dispositions législatives, réglementaires et administratives relatives à l'application des principes de bonnes pratiques de laboratoire et au contrôle de leur application pour les essais sur les substances chimiques,
Having regard to the Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 of the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances,
- Vu la Directive 93/88/CEE du Conseil du 12 octobre 1993 modifiant la Directive 90/679/CEE concernant la protection des travailleurs contre les risques liés à l'exposition à des agents biologiques au travail,
Having regard to the Council Directive 93/88/EEC of 12 October 1993 amending Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work,
- Vu la norme ISO/IEC 17025 : 2017 concernant les exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais,
Having regard to the ISO/IEC 17025 : 2017 standard relating to general requirements for the competence of testing and calibration laboratories,

Le laboratoire d'Hygiène Hospitalière effectue les essais suivants conformément aux principes des BPL et de la norme ISO 17025 :

The hospital hygiene laboratory staff works in accordance with the principles of GLP and ISO 17025 standard in the following area :

- Etude d'efficacité biocides sur agents microbiologiques de niveau 1 et 2
- Tests Methods and Efficacy testing of Biocides on Microbial agents Level 1 and 2

Clermont-Ferrand, le 17 janvier 2024

C.H.U. de Clermont-Ferrand
Pr Ousmane TRAORE
Hygiène Hospitalière
Professeur OUSMANE TRAORE
Chef de service d'Hygiène Hospitalière

