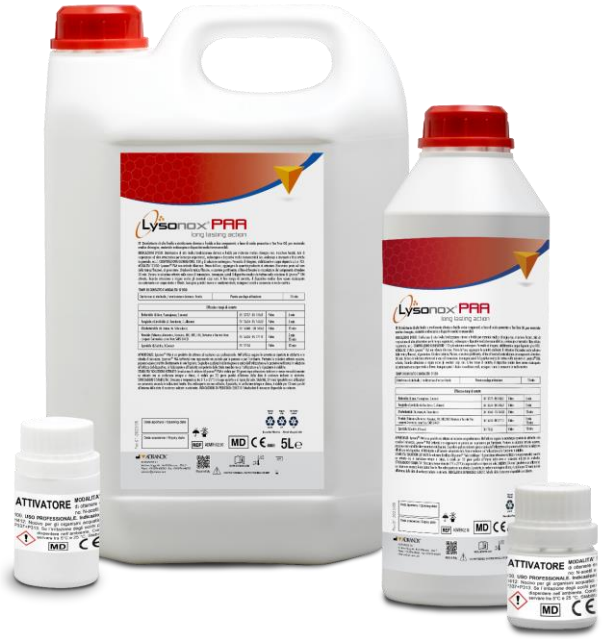
Lysonox® PAA
long lasting action

High-level disinfectant and two-component cold chemical sterilizer, based on peracetic acid and Tea Tree Oil, for medical surgical devices, endoscopy equipments and thermolabile medical devices.



PATENT PENDING N°. 102022000023985

FIELD OF USE

Lysonox® PAA is recommended for the following fields of use:

- High level disinfection and cold chemical sterilization of medical devices (e.g. face masks, breathing tubes and other equipment for respiratory therapy), endoscopy equipments and thermolabile medical devices (e.g. endoscopes and optical-fibre devices in general)

FEATURES

Lysonox® PAA is a liquid product which, after activation, has a composition based on **peracetic acid** and **Tea Tree Oil**, for the high-level disinfection/cold chemical sterilization of thermolabile medical devices in general. It consists of a generator and an activator that exploits the presence of stabilized Tee Tree Oil: once the activator is mixed with the generator, a slow release epoxy system is created. The resulting solution develops peracetic acid slowly but constantly, allowing for very high compatibility with materials, including the most delicate ones (e.g. optics). Its particular and unique formulation, compared to all the other products on the market, allows to have a stability of the activated solution up to **18 days,** with consequent advantages of use and economy for all customers who use the product.

SPECIAL PROPERTIES AND CLINICAL BENEFIT

- Liquid peracetic acid, easy and quick to activate
- Presence of stabilized **Tea Tree Oil**, for the generation of the **Long Lasting Action system**
- Active after 30 min max from mixing the components (activator + generator)
- Non-activated product stability: 2 years
- Full spectrum of activity
- High compatibility with materials
- For manual use
- Designed for every type of operational requirement
- Stability of the activated solution in an open bath: **18 days**
- Stability of the activated solution when not in use and in a closed container: 23 days
- **Fast:** contact time from 5 min to 15 min (max)
- Suitable for use with other products of the Lysonox® line

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CONTACT TIME, APPLICATION AND USE*

High Level disinfection/ Cold Chemical Sterilization	**Ready to use (after activation)**	**15 min**

Lysonox® PAA does not need to be diluted. Before use, add the premeasured activator amount (located on the back of tank/bottle) to the generator. Close tank/bottle and shake gently in order to promote components mixing. Wait for maximum 30 minutes. Pour the activated solution into the dip bath

Soak the medical device to be treated in the activated Lysonox® PAA solution, ensuring that internal lumen parts are wetted by the solution. After contact time, rinse carefully the medical device using filtered or sterile water.
Dry the device in sterile conditions, dry channels and store aseptically.

Before using Lysonox® PAA, we recommend the use of Lysonox® VIKING for the pre-cleaning phase and, if a cleansing and decontamination phase is needed, the use of Lysonox® INSTRUMENTS DR.

MECHANISM OF ACTION

The biocidal system of Lysonox® PAA offers a broad spectrum of action thanks to the extemporaneous development of peracetic acid associated with Tea Tree Oil. In particular:

Tea Tree Oil (TTO)

This compound, present in the activator, is used for two fundamental functions: an epoxy function that allows a prolonged release of peracetic acid over time (once the generator and activator are mixed together) and a natural antibacterial, antifungal and antiviral function, to the ability of the terpene compounds present in this phytocomplex to denature the cell wall of pathogens, preventing their replication.

Peracetic Acid:

is the active ingredient of the product prepared extemporaneously by the reaction between activator and generator. Peracetic acid acts with an oxidative reaction on lipid membranes, DNA and other essential elements for the life of cells. Sulphidrilic bonds –SH, -S-S- and double bonds in proteins, enzymes and other metabolites are the main action sites for peracetic acid. Attacking these important groups, the chemiosmotic function of the cytoplasmic membrane is interrupted, thus causing protein denaturation and the death of the microorganism.
The synergy between the peracetic acid formed and the Tee Tree Oil makes Lysonox® PAA a unique product with very high performance for the high-level disinfection of the most critical and thermolabile medical devices.

ANTIMICROBIAL ACTIVITY

The biocidal activity tests of Lysonox® PAA were performed at the minimum effective concentration (equal to 500 ppm of Peracetic acid) according to the standards in force published by the European Committee for Standardization (CEN TC 216) by Test Centers Certified as operating according to the GLP standards (Good Laboratory Practices) and ISO 17025 certificates. Lysonox® PAA has the following activity:

Biocidal Activity:	**EN Tests**	**Contact Time**
Bactericide (S.Aureus, P.Aeruginosa, E.Hirae)	EN 13727, EN 14561	5 min
Fungicide and Levuricide (C.Albicans, A.Brasiliensis)	EN 13624, EN 14562	5 min
Mycobactericide (M.Terrae, M.Avium)	EN 14348, EN 14563	15 min
Virucide (Poliovirus,Adenovirus, Norovirus, HIV, HBV, HCV, Rotavirus e Vaccinia Virus such as Virus SARS CoV-2)	EN 14476, EN 17111	5 min /15 min
Sporicide (B.Subtilis, B.Cereus)	EN17126	10 min

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STABILITY OF ACTIVATED SOLUTIONS

Stability tests of the activated solution made it possible to verify that the Lysonox® PAA solution is stable for **18 days** (use in a manual bath), while if activated but in an unopened and closed package, it is stable for 23 days as long as the within the expiration date indicated on the label. These values are to be understood as certain data. In any case, however, external variables can influence these values. For this it is possible to use systems known as reactive strips (**test strips**), which allow to verify the concentration % m/v of peracetic acid.
The test strips are characterized by specificity towards peracetic acid itself.

HOW TO USE THE TEST STRIPS:

- ✓ Dip the strip for 1 sec
- ✓ Take it out and briefly shake it
- ✓ Read it within 10 sec

Colour: **blue-grey-black**
Activated solution

No colour
Non-activated

MATERIAL COMPATIBILITY

Lysonox® PAA, if used according to the indications for use, is compatible with:

- Stainless steel
- Aluminum
- Polyethylene
- PVC
- Polystyrene
- Teflon (PTFE)
- Polycarbonates

Not recommended for use with materials such as copper and zinc. In any case, for confirmation, and in case of materials not present in this list, you can contact ADRANOX directly.

CHEMICAL-PHYSICAL DATA

The following parameters refer to the activated solution (generator + activator):

- ➢ Appearance: clear liquid
- ➢ Density: 1.005 – 1.015
- ➢ pH: neutral – acid

COMPOSITION

100 g of solution contains:

Generator:
Hydrogen peroxide, stabilizer and purified water to taste at 100
Activator:
N-Acetyl and O-Acetyl donors, TTO, new generation chelator and technological excipients q.s. at 100

STORAGE INFORMATION

Store at a temperature between 5°C and 25°C in a dry place and away from the sun. Stability: 24 months (unused product) if stored according to the indications provided. Once opened but not activated, the product, in unopened and closed package, is stable for 12 months as long as it is within the expiry date indicated on the label.

WARNINGS

Lysonox® PAA is a product to be activated for professional use only.
When using, follow the warnings on the label and in the safety data sheet.

Report any serious accident involving the user and/or patient that has occurred in connection with the use of the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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CE MARKING: CE 0051 MD

Lysonox® PAA is a class IIb medical device and meets the legal requirements for medical devices according to the Regulation 2017/745 (MDR).

- **PACKAGING AVAILABLE**

  • Pack*. 12 bottles X 1L Code ADMR102.10
  • Pack*. 4 tanks X 5L Code ADMR102.50

  *each bottle/tank is supplied with an activator

INFORMAZIONI ADDIZIONALI

Lysonox® PAA (activated) does not pose a danger to people or the environment. Therefore the exhausted activated solutions can be disposed of directly into the sewer system (ref. section 13 of the safety data sheet). For handling use suitable protective gloves.

ADRANOX is a certified company and operates according to the UNI EN ISO 13485:2016 standard

Contact ADRANOX directly for any information on the use of Lysonox® PAA, according to your needs.

ADRANOX favors production and packaging systems that respect the environment and aim at limiting the use of plastic and derivatives
.

Manufacturer

ADRANOX srl
Registered office: Via Imre Nagy 46, 46100 Mantova
Headquarters: Via Primo Maggio n° 29, 46051
San Giorgio Bigarello (MN), Italy.
Company with a single shareholder
Phone. +39 0376405362 Fax. +39 0376446392
adranox@adranox.com - www.adranox.com

The information contained is based on our knowledge as of the date indicated below. It refers to the product indicated and is not a specific guarantee of particular characteristics of the product.

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