

BIOWIPES ACTIVE



Ready-to-use disinfectant and cleaning wipes for the simultaneous disinfection and cleansing of all non-invasive medical devices surfaces.



FEATURES

Lysonox® BIOWIPES ACTIVE are wipes, ready to use, for the simultaneous cleansing and disinfection of all surfaces of medical devices and furnishings (e.g. scialytics, operating tables, electromedical devices, touch screens, monitors, PCs, etc.). The biocidal complex together with a low concentration of alcohol make Lysonox® BIOWIPES ACTIVE compatible with practically all materials present in the medical field. The absence of CMR substances (carcinogens, mutagens and teratogens), allows to have the maximum degree of safety for the operator and the patient. The dispensing takes place directly through the practical pop-up cap, which avoids unnecessary product losses and allows for greater economy of use. Finally, the broad spectrum of action makes Lysonox® BIOWIPES ACTIVE the ideal product for all operational needs in the field of environmental disinfection.

FIELDS OF USE

Lysonox® BIOWIPES ACTIVE is indicated for the following fields of use:

- Disinfection and simultaneous cleaning of all non-invasive medical devices surfaces such as:
 - Scialytics
 - Operating beds
 - Trolleys
 - Monitors and touch screens
 - Medical equipments
 - Work plans
 - Incubators and thermal cradles in general
 - Hemodialysis equipments
 - o Surfaces in general of hospital wards

SPECIAL PROPERTIES AND CLINICAL BENEFIT

- Ready-to-use product in high quality wipes with a broad spectrum of action
- · Without aldehydes and derivatives
- Without chlorinated agents or polyhexanide, without phenolic compounds
- Fragrance free
- Without CMR substances
- No need to rinse
- Dries quickly
- Does not leave any kind of residue
- · Pop-up cap for practical and effective opening
- · High compatibility with materials
- Product stability (unused): 36 months
- Fast: contact time from 5 min to 30 min







BIOWIPES ACTIVE



CONTACT TIME AND USE

Intermediate level disinfection (bactericidal, yeasticidal, mycobactericidal and virucidal activity)	Ready To Use	5 - 30 min
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Lysonox® BIOWIPES ACTIVE are pre-soaked and ready-to-use wipes, in flow pack packaging. Open the pop-up cap and take out a wipe. Apply and use the product directly on the surface to be treated. Do not rinse. Close the package carefully after application.

Since the Lysonox® BIOWIPES ACTIVE do not have to be rinsed, the contact times indicated in the table above will potentially always be respected.

MECHANISM OF ACTION

The biocidal system of Lysonox® BIOWIPES ACTIVE allows for a broad spectrum of action. In particular:

Didecyldimethylammonium chloride:

4th generation quaternary ammonium salt, with precipitating, complexing and denaturing effects of bacterial proteins, which causes damage to the cytoplasmic membrane of cells. The natural surfactant effect increases the effectiveness of removing organic residues.

Chlorhexidine

Causes numerous physiological and cytological changes in the bacterial cell, some of which are reversible, in 6 stages that ultimately result in bacterial cell death: (1) rapid attraction to the bacterial cell, (2) adsorption of some phosphoric compounds on the bacterial surface, (3) cell wall exclusion reaction, (4) attraction to the cytoplasmic membrane, (5) loss of low molecular weight cytoplasmic compounds and inhibition of some enzymes, (6) cytoplasmic precipitation.

Alcohol

Ethanol acts by denaturation and coagulation of proteins at the level of the wall, the cytoplasmic membrane and the cytoplasm. The different phenomena observed constitute upheavals of cytoplasmic integrity, with cell lysis and interference on cellular metabolism. This process is optimized in the presence of water, which facilitates the penetration inside the bacterial cell.

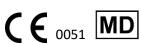
The synergy between the active ingredients and the excipients present in the product allow Lysonox® BIOWIPES ACTIVE to be used easily in various situations, where high compatibility with materials and a broad spectrum of action are required.

ANTIMICROBIAL ACTIVITY

The biocidal activity tests of Lysonox® BIOWIPES ACTIVE were performed according to the current standards published by the European Committee for Standardization (CEN TC 216) by Test Centers Certified as operating according to GLP standards (Good Laboratory Practices) and ISO 17025 certified. Lysonox® BIOWIPES ACTIVE has a biocidal activity as follow:

Biocidal Activity	EN Tests	Contact Time
Battericide (S.Aureus, P.Aeruginosa, E.Hirae)	EN 13727* EN 16615* (with mechanical action)	5 min
Yeasticide Candida Albicans	EN 13624* EN 16615* (with mechanical action)	15 min
Mycobactericide (M.Terrae, M.Avium)	EN 14348	15 min
Virucide (Norovirus, Adenovirus, HIV, HBV, HCV, Vaccinia Virus, Coronavirus included as SARS CoV-2 virus, Rotavirus)	EN 14476 EN 16777	15 min /30 min (Adeno e Norovirus)

^{*}Tests in dirty conditions







BIOWIPES ACTIVE



MATERIALS COMPATIBILITY

In vitro tests carried out in the laboratory have allowed us to verify the compatibility of the product with various surfaces. The long-term effect was simulated by immersing the various materials in Lysonox® BIOWIPES ACTIVE. In fact, it has been verified that static exposure is a predictive factor of long-term effects.

The samples of the various materials were immersed in the solution as they were for periods of different lengths. At established intervals (from 15 min up to 100 hours), the samples were dried and individually examined under a digital microscope, to ascertain the possible presence of corrosion and/or degradation. They were then reimmersed and exposure to the product continued. All the materials listed on the following page have been tested and found to be free from corrosion, degradation and morphological and visual alteration after immersion for prolonged periods of exposure.

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

- Stainless steel
- Aluminum
- Polypropylenes (PPE)
- PVC
- Polystyrene
- Teflon (PTFE)
- Polycarbonates

The product is not compatible with 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

Appareance: clear liquid (imbibition liquid of the

wipes)

Density: 0,965 - 0,985

pH: 8,5 - 9,5

COMPOSITION

100 g of ready-to-use solution contains:

Didecyldimethylammonium chloride, chlorhexidine digluconate, alcohol, non-ionic surfactant and purified water qs to 100

STORAGE INFORMATION

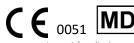
Store tightly closed. Storage temperature: between 5°C and 35°C. Keep out of reach of children.

Stability: 36 months (product not used) if stored according to the indications provided. Once opened for the first time, the product, in unopened packaging, is stable for 12 months as long as it is within the expiry date indicated on the label.

WARNINGS

Lysonox® BIOWIPES ACTIVE is a ready-to-use product for professional use only. When using, follow the warnings on the label and in the safety data sheet. Dispose of used wipes and empty flow packs according to local regulations.

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









CE MARKING: C € 0051 MD



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

PACKAGING AVAILABLE

Pack. 100 wipes X 6 Flow pack Cod. ADMR204.100

ADDITIONAL INFORMATION

Lysonox® BIOWIPES ACTIVE is a product that meets the requirements imposed by the regulation on detergents N° 648/2004. Biodegradability > 90%.

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® BIOWIPES ACTIVE, 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

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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.





