

“For Hygiene”
BIORAD[®]

necm
kimya

Data Sheet

RAYDOL WIPE

Containing Quaternary Ammonium Compounds (QACs) and Alcohol Disinfectant Wipe for surfaces and medical devices

- ✓ fast effective disinfection and cleaning wipes
- ✓ Surfactant suitable for healthcare
- ✓ it dries quickly after application and cleans the surfaces, leaving no stains or marks.



PRODUCT SPECIFICATIONS

It is an anticorrosive product based on alcohol and quaternary ammonium compounds, which has a pleasant smell and can be used for intermediate disinfection and cleaning of the surfaces of medical devices..

FIELD OF USE

It is used to clean and disinfect all horizontal and vertical surfaces:

- surfaces made of: PVC, glass, PP, HDPE, acrylic glass, plexiglass, epoxy floors, walls, doors, patient beds.
- surfaces in health facilities, such as: medical offices, operating rooms, intensive therapy rooms, pediatrics, neonatology departments, dental offices, ENT offices, pneumophysiology departments, endoscopy offices.
- Homes for the elderly, schools, kindergartens, buses, ambulances, the pharmaceutical and cosmetics industry and other institutional spaces
- medical devices: ultrasound probes, stethoscopes, incubators, intravenous supports, microscopes, instruments that come into contact with the patient's skin.

APPLICATION METHOD

RAYDOL WIPE is packed in a dose of 100-120-200-300 napkins and is suitable for the disinfection of small surfaces and medical devices, by wiping. An action time of 5 minutes is necessary to achieve the effectiveness according to the desired spectrum.

After surfaces disinfection with the RAYDOL WIPE product, rinsing is not necessary. The surface on which the product is intended to be used is wiped with a RAYDOL WIPE. It is waited for the duration of the effect. Minimum effective area of "RAYDOL WIPE" 25cm and 500 cm² surface area.

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ACTIVITY / TESTING METHODS / ACTION TIME

Bactericidal		Minutes / log
E. hirae, S. Aureus, P. aeruginosa, E. Coli (clean and dirty conditions)	EN 13697	5 min / 5 log
E. hirae, P. aeruginosa, S. Aureus, C. albicans (clean and dirty conditions))	EN 14561	5 min / 5 log
E. hirae, P. aeruginosa, S. Aureus (clean and dirty conditions)	EN 13727	5 min / 5 log
Fungicidal, Yeasticidal		
C. albicans, A. brasiliensis (clean and dirty conditions)	EN 13624	5 min / 4 log
C. albicans, A. brasiliensis (clean and dirty conditions)	EN 14562	5 min / 4 log
C. albicans, A. brasiliensis, (clean and dirty conditions)	EN 16615	5 min / 4 log
Mycobactericidal / Tuberculocidal		
M. terrae, M. avium (clean and dirty conditions)	EN 14348	5 min / 4 log
M. terrae, M. avium (clean and dirty conditions)	EN 14563	5 min / 4 log
Virucidal		
Adenovirus, Poliovirus, Murine norovirus, Vaccinia virus (clean and dirty conditions))	EN 14476	5 min / 4 log

MICROBIOLOGY

RAYDOL WIPE has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal and virucidal activity

CHEMICAL-PHYSICAL DATA

- Density (20o): 0,991±0,03 g/ml
- pH: 6,5 – 9

It forms a transparent solution. The solution does not release toxic vapors or unpleasant odors.

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CHEMICAL COMPOSITION reported per 100 g of product

- | | |
|--|--------------------------------------|
| ➤ Isopropyl alcohol 10% | CAS-No.: 67-63-0, EC-No.:200-661-7 |
| ➤ Didecyldimethylammonium chloride 0.25% | CAS No.: 7173-51-5 EC No.: 230-525-2 |
| ➤ Ethyl alcohol 40% | CAS-No.: 64-17-5, EC-No.: 200-578-6 |

SHELF LIFE : 2 (two) years

PERIOD OF ACTIVITY AFTER OPENING THE COVER: 75 (seventy five) days

WIPES FABRIC THICKNESS : 25-35 gsm soft but durable, high quality, non-woven blend and non-scratch design

PACKAGING METHODS:

- Dose with 300 napkins 14x20 cm
- Dose with 200 napkins 20x20 cm
- Dose with 120 napkins 14x16 cm
- Dose with 100 napkins 14x16 cm

CONDITIONS OF STORAGE AND DELIVERY OF PRODUCTS

- For the storage and preservation of products, the ambient temperature must be between 0 and 50 °C, and the humidity must be between 10% and 80% rH.
- It is sufficient to store the products above ground so that they are not exposed to direct sunlight and to prevent contact with water.
- A maximum of 7 (seven) boxes can be placed on top of each other both during storage and during loading, in order to preserve and not damage the packaging of the products.

GENERAL WARNINGS

- It is not classified as toxic, corrosive, mutagenic, irritating to the skin and does not cause respiratory tract sensitivity.
- In case of direct contact with the eyes, rinse immediately with plenty of water.
- It should not be used for cleaning hands, face and food.
- It should not be kept out of the reach of children.

SAFETY MEASURES IN THE PROCESS OF USE, TRANSPORT AND STORAGE

- application of safety measures: avoid excessive spreading. Good ventilation of the work area. It does not require special protective measures for the personnel who ensure the disinfection procedure.

- transport: in closed vehicles; does not require protective measures for the personnel providing the transport;
- storage: in closed original packaging, in a cool and well-ventilated place, away from heat and sunlight.

CLASSIFIED IN ACCORDANCE WITH REGULATION (EC) NO. 1272/2008 (CLP)

See the safety data sheet and label for labeling information according to Regulation (EC) No. 1272/2008 (CLP).



INFORMATION REGARDING THE ENVIRONMENT

According to the safety data sheet, the substances contained in the product comply with the biodegradability criterion established by Regulation (EC) No. 648/2004 on detergents. Necm Kimya manufactures its products according to advanced, safe and environmentally friendly processes, economically and in compliance with high quality standards (EN ISO 9001, GMP, ISO 13485).

CERTIFICATION

Product Class and Conformity Assessment Method:

2017/745 Medical Device Regulation Classification Rules 16, Class IIA;

Rule 16 - Specifically disinfecting, cleaning, rinsing, hydrating or sterilising devices

General explanation of the rule This rule is intended to cover various products used specifically with contact lenses such as solutions intended for storing contact lenses and solutions used to support contact lenses placed on the ocular surface.

The rule also covers substances and equipment specifically intended for the disinfection or sterilisation of devices intended by the manufacturer to be sterilised or disinfected prior to use, as referred to in MDR Article 2(1).

This rule does not apply to physical means for the cleaning of medical devices, such as ultrasound and brushes for general use. Such products will only be medical devices if they are specifically intended for the cleaning, disinfection or sterilisation of medical devices. Devices specifically intended for physical cleaning of contact lenses are covered by this rule.

This rule does not apply to products that clean medical devices by physical action, other than contact lenses.

Since our product is used for the purpose of Disinfection of invasive Medical Devices, it is designated as class IIA in accordance with this rule.