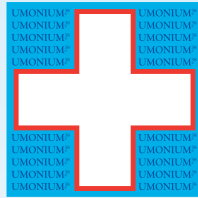


DETERGENT - DISINFECTANT
MEDICAL DEVICE
CLASS IIb



UMONIUM³⁸ NEUTRALIS



- ✓ FORMULA FREE FROM
 - CMR COMPONENT**
 - ENDOCRINE DISRUPTOR

“ Odourless and colourless
detergent - disinfectant for
medical devices ”



UMONIUM³⁸ NEUTRALIS is an odourless high-level detergent-disinfectant, specially developed for hospital environments with severe risks (zone 3 and 4). Complete safety, up to the environment of an embryo (validation Mouse Embryo Assay). It guarantees perfect disinfection of medical devices used in sensitive environments such as incubators in neonatology, surgical instruments, sterile rooms, mask for aerosol therapy, lab bench, etc.

** Carcinogenic, Mutagenic and Reprotoxic





UMONIUM³⁸ NEUTRALIS



✓ **FORMULA FREE FROM**
→ CMR COMPONENT**
→ ENDOCRINE DISRUPTOR

INDICATIONS

Odourless and colourless. Cleaning and disinfection for invasive medical devices before sterilisation. Cleaning and disinfection for non-invasive medical devices and their surfaces.

COMPOSITION

N-benzyl-N-dodecyl-N, N-dimethyl-ammonium chloride/N-benzyl-N, N-dimethyl-N-tetradecyl-ammonium chloride. 99g/L.

REGULATORY STANDARDS

- Complies with ED 93/42/EEC relating to medical devices (annexe II, excl. §4)
- Quality and traceability guaranteed by ISO 9001:2015 and EN ISO 13485:2016
- Validation MEA (Mouse Embryo Assay)
- Validation HSSA (Human Sperm Survival Assay)

INSTRUCTIONS FOR USE

Cleaning/Pre-disinfection: Use at 0.5% (25mL/5 L of water*). Soak then scrub/ use the ultrasounds or wet wipe to eliminate all dirt. Rinse thoroughly with water* or using a cloth dampened with water* if you are cleaning surfaces.

Disinfection: Use at 2.5% (25 mL/L of water*) on clean devices. Apply by wet wiping or soaking, making sure to respect a minimum contact time of 10 minutes. If you are cleaning invasive medical devices: Rinse with water*. If you are cleaning non-invasive medical device surfaces: Leave to dry or rinse with water* (or using a cloth dampened with water*) if necessary.

PROPERTIES

- Medical device Class IIb
- Detergent - disinfectant with a broad spectrum of activity
- Non-toxic, no dangerous vapours
- LD₅₀ (rats): 5840 mg/kg
- Non-corrosive: pH 7
- Diluted product not irritating to the skin (no transdermal toxicity)
- Aldehyde, peroxide and biguanide free, no other carcinogenic, mutagenic, reprotoxic components
- Non-coagulant
- Non-flammable
- Bactericide, fungicide, mycobactericide (including MRSA) and viricide
- 100% compatible on fibre optic, rubber, polycarbonate, acrylic compound, glass, Pyrex, PU, PVC, HDPE, PET, neoprene, latex, silicone, paints and stainless steel 410
- Effective, fast and efficient (dissolves blood)
- Effective in the presence of organic materials
- Disinfection time: 10 min.
- Remains on unrinsed surfaces (bacteriostatic film)
- No residue after rinsing
- Stability: 36 months date of manufacture
- Biodegradable
- Colourless, fragrance-free product
- Complete safety in the environment of an embryo



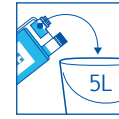
ITEM No.	NAME	BOX
PF 12510	1 litre dosing bottle	12 x 1 litre
PF 12512	5 L drum with pump	4 x 5 litres
PF 12515	125 L dosing bottle	24 x 125 mL
EMB 0013	ECONOMATIC pump complete kit - Dosage 0.5%	1 item
EMB 0013 - 2.5%	ECONOMATIC pump complete kit - Dosage 2.5%	1 item

* Clean drinking water at room temperature
** Carcinogenic, Mutagenic and Reprotoxic

PROCEDURE FOR USE

STEP 1 : CLEANING/PRE-DISINFECTION

→ Use of a bath by batch



Use at 0.5% (25mL/5 L of water*)



OR



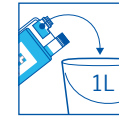
Soak then scrub/use the ultrasounds OR wet wipe to eliminate all dirt



Rinse thoroughly with water* or using a cloth dampened with water* if you are cleaning surfaces

STEP 2 : DISINFECTION

→ Bath use until it appears cloudy



Use at 2.5% (25 mL/L of water*)



Apply by wet wiping or soaking



Respect a minimum contact time of 10 minutes



OR



If you are cleaning invasive medical devices: Rinse with water* OR if you are cleaning non-invasive medical device surfaces: Leave to dry or rinse with water* (or using a cloth dampened with water*) if necessary

TECHNICAL DATA

Standards	Target organisms	Contact time (min.) 2.5%
EN 1040	<i>S. aureus</i> , <i>P. aeruginosa</i>	5
EN 13727	<i>S. aureus</i> , <i>E. hirae</i> <i>P. aeruginosa</i>	10
EN 14561	<i>S. aureus</i> , <i>P. aeruginosa</i> , <i>E. hirae</i>	30
-	MRSA, ESBL-producing <i>Klebsiella pneumoniae</i>	5
EN 1275	<i>C. albicans</i>	10
EN 13624	<i>C. albicans</i> , <i>A. niger</i>	
EN 14562		
EN 14476	Adenovirus, Poliovirus, Norovirus	1
-	HBV, HSV, HCV, H5N1	5
EN 14348	<i>M. avium</i> , <i>M. terrae</i>	10
EN 14563		

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