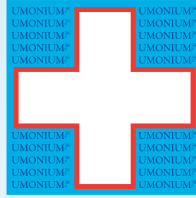


DETERGENT - DISINFECTANT
MEDICAL DEVICE
CLASS IIb



UMONIUM³⁸ NEUTRALIS



✓ FORMULA FREE FROM

- CMR** COMPONENT
- ENDOCRINE DISRUPTOR

“ Odourless, colourless detergent-disinfectant for medical devices ”



UMONIUM³⁸ NEUTRALIS is a high level odourless detergent-disinfectant, specially developed for severe risk hospital environments (neonatology, neonatal rehabilitation, IVF/AMP, general gynaecology and obstetrics, etc.). Meeting the dual challenge of performance and safety, it validates the highest performance standards while meeting reproductive and embryo-toxicity tests. It is used for the pre-disinfection and disinfection phases of all surfaces, equipment and the most sensitive invasive and non-invasive medical devices (respiratory assistance devices, instrumentation, etc.).

** Carcinogenic, Mutagenic or Reprotoxic





UMONIUM³⁸ NEUTRALIS

1L of concentrate makes up 200L of diluted solution (0.5%).



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



INDICATIONS

Colourless, odourless. Cleaning and disinfection of 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

- Compliant with ED 93/42/EEC relating to medical devices (Appendix II, excl.S4)
- Quality and traceability guaranteed by ISO 9001:2015 and EN ISO 13485:2016
- MEA (Mouse Embryo Assay) validation
- HSSA (Human Sperm Survival Assay) validation
- CE marking 1639

INSTRUCTIONS FOR USE

Cleaning/Pre-disinfection: Use a 0.5% solution (25mL/5L of water*). Soak then scrub/use the ultrasonic or a wet wipe to eliminate all dirt. Rinse thoroughly with water* or using a cloth dampened with water* if you're cleaning surfaces. **Disinfection:** Use a 2.5% solution (25mL/L of water*) on clean devices. Apply with a wet wipe or by soaking, making sure to respect a minimum contact time of 10 minutes. If you're cleaning invasive medical devices: Rinse with water*. If you're cleaning non-invasive medical device surfaces: Leave to dry or rinse with water* (or with a cloth dampened with water*) if necessary.

PROPERTIES

- Class IIb medical device
- Detergent- disinfectant with a broad spectrum of activity
- Non-toxic, no dangerous vapours
- LD₅₀ (rat): 5840 mg/kg
- Non-corrosive: pH-neutral
- Diluted product, non-irritating for the skin (no transdermal toxicity)
- Free from aldehyde, peroxide and biguanide, and other carcinogenic, mutagenic, or reprotoxic components
- Non-coagulant
- Non-flammable
- Bactericide, fungicide, mycobactericide and virucide
- 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-acting and efficient (dissolves blood)
- Effective in the presence of organic materials
- Disinfection time: 10 min.
- Residual on non-rinsed surfaces (bacteriostatic film)
- No residue after rinsing
- Stability: 36 months date of manufacture
- Colourless, fragrance-free product
- Complete safety in the environment of an embryo

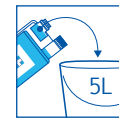


ITEM No.	NAME	BOX
PF 12510	1L dosing bottle	12 x 1L
PF 12512	5L container with pump	4 x 5L
PF 12515	125mL dosing bottle	24 x 125mL
EMB 0013	ECONOMATIC pump complete kit - 0.5% dosage	1 item
EMB 0013 - 2.5%	ECONOMATIC pump complete kit - 2.5% dosage	1 item

PROCEDURE FOR USE

STEP 1: CLEANING/PRE-DISINFECTION

→ One bath by batch



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



OR



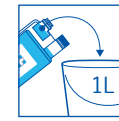
Soak then scrub/use ultrasonic OR wipe with a damp cloth to get eliminate all dirt



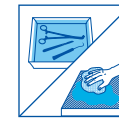
Rinse thoroughly with water* or using a cloth dampened with water* if you're cleaning surfaces

STEP 2: DISINFECTION

→ Bath use until it appears cloudy



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



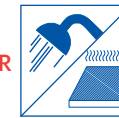
Apply by wet wiping or soaking



Minimum contact time 10 minutes



OR



If invasive medical devices: Rinse with water* OR If non-invasive medical device surfaces: Allow to dry or rinse with water* (or with a damp cloth*) if necessary

TECHNICAL DETAILS

Standards	Target organisms	Contact time (min.) 2.5%	
		Condition clean	Dirty condition
EN 13727	<i>S. aureus</i> <i>E. hirae</i> <i>P. aeruginosa</i>	1	10
EN 13697	<i>S. aureus</i> <i>E. hirae</i> <i>E. coli</i> <i>P. aeruginosa</i> <i>S. typhimurium</i> <i>E. cloacae</i> <i>L. Brevis</i>	15	15
EN 14561	<i>S. aureus</i> <i>E. hirae</i> <i>P. aeruginosa</i>	15	30
EN 13624	<i>C. albicans</i>	10	10
EN 13697	<i>C. albicans</i> <i>A. niger</i>	15	15
EN 14562	<i>C. albicans</i> <i>A. niger</i>	10	10
EN 14476	Norovirus Adenovirus Poliovirus	10	10
	Vaccinia virus	5	-
EN 14348	<i>M. avium</i> <i>M. terrae</i>	10	10
EN 14563	<i>M. avium</i> <i>M. terrae</i>	10	10

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