DETERGENT- DISINFECTANT
MEDICAL DEVICE
CLASS IIb

EVALUATION 99,4% BIODEGRADABILITY*

PACKAGING* VEGETAL PLASTIC

# UMONIUM 38®

## NEUTRALIS

ECO FRIENDLY

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

“ Odourless, colourless detergent-disinfectant for medical devices ”






UMONIUM 38® **NEUTRALIS** is a high level odourless detergent-disinfectant, specially developed for severe risk hospital environments (neonatology, neonatal rehabilitation, IVF/MAP, 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.).

laboratoire HUCKERT'S INTERNATIONAL
SINCE 1957

MADE IN BELGIUM

* 5 L container packaging only
** Carcinogenic, Mutagenic or Reprotoxic

www.huckerts.net

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# NEUTRALIS

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



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VALIDATION MOUSE EMBRYO ASSAY

VALIDATION HUMAN SPERM SURVIVAL ASSAY

## INDICATIONS
A colourless, odourless concentrated solution for the cleaning and disinfection of non-invasive medical devices and the surfaces of non-invasive medical devices.

## 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.§4)
- Quality and traceability guaranteed by ISO 9001 and EN ISO 13485
- 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
- $LD_{50}$ (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
- No VOC release




| ITEM No. | NAME | BOX |
|---|---|---|
| PF 12510 | 1L dosing bottle | 12 x 1L |
| PF 12512 | 5L container with pump | 4 x 5L |
| EMB 0013 - 0,5% | 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 ❶ : CLEANING/PRE-DISINFECTION
➥ One bath by batch




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



OR

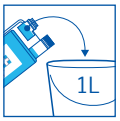


Soak then scrub/use ultrasonic OR wipe with a damp cloth to get eliminate all dirt



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

### STEP ❷ : 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 | 2.5% Dirty condition | 5 % Condition clean |
|---|---|---|---|---|---|
| EN 13727 | BACTERIA | *S. aureus* *E. hirae* *P. aeruginosa* | 1 | 10 | - |
| EN 13697 | BACTERIA | *S. aureus* *E. hirae* *E. coli* *P. aeruginosa* *S. typhimurium* *E. cloacae* *L. Brevis* | 15 | 15 | - |
| EN 14561 | BACTERIA | *S. aureus* *E. hirae* *P. aeruginosa* | 15 | 30 | - |
| EN 17387 | BACTERIA | *S. aureus* *E. hirae* | - | - | 5 |
| EN 13624 | FUNGI | *C. albicans* | 10 | 10 | - |
| EN 13697 | FUNGI | *C. albicans* *A. niger* | 15 | 15 | - |
| EN 14562 | FUNGI | *C. albicans* *A. niger* | 10 | 10 | - |
| EN 14476 | VIRUSES | Norovirus Adenovirus Poliovirus | 10 | 10 | - |
| | VIRUSES | Vaccinia virus | 5 | - | - |
| EN 17111 | VIRUSES | Vaccinia virus | 60 | - | - |
| EN 14348 | MYCOBACT. | *M. avium* *M. terrae* | 10 | 10 | - |
| EN 14563 | MYCOBACT. | *M. avium* *M. terrae* | 10 | 10 | - |

*tests carried out at a concentration of 2%

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

FP00012 EN - Ed. 3.9 - 03/2026 - *Product photos are non-binding.*

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