SCIENTIFIC EFFICACY TESTING

These tests were also performed by the Biotech-Germande laboratory. Studies show that Aperlan has a powerful biocidal action combined with a detergent property capable of lifting a bacterial biofilm within 3 minutes of contact for both the biofilm types tested.

TESTS	MICROORGANISMS	CONDITION TO REACH THE REQUIRED ACTIVITIES	
		Contact time /Temperature	Concentration (ppm)
BACTERICIDAL ACTIVITY			
NF EN 1040	Pseudomonas aeruginosa ATCC 15442	5 min/37°C	< 358
	Staphylococcus aureus ATCC 6538	5 min/37°C	< 358
NF EN 13727 Hard water 300 mg/L $CaCO_3$ 0.3 g/L bovine albumin	Pseudomonas aeruginosa CIP 103467	5 min/37°C	27[a]
	Staphylococcus aureus CIP 4.83	5 min/37°C	27[a]
	Enterococcus hirae CPI 5855	5 min/37°C	81[a]
Pr EN 14562 Hard water 300 mg/L $CaCO_3$ 0.3 g/L bovine albumin	Pseudomonas aeruginosa ATCC 15442	5 min/37°C	< 302
	Staphylococcus aureus ATCC 6538	5 min/37°C	< 302
	Enterococcus hirae ATCC 10541	5 min/37°C	< 302
FUNGICIDAL ACTIVITY			
NF EN 1275	Candida albicans ATCC 10231	5 min/37°C	< 358
	Aspergillus niger ATCC 16404	5 min/37°C	640
NF EN 136240 Hard water 300 mg/L $CaCO_3$ 0.3 g/L bovine albumin	Candida albicans ATCC 10231	5 min/37°C	< 302
	Aspergillus niger ATCC 16404	5 min/37°C	640
Pr EN 14562 Hard water 300 mg/L $CaCO_3$ 0.3 g/L bovine albumin	Candida albicans ATCC 10231	5 min/37°C	< 358
	Aspergillus niger ATCC 16404	5 min/37°C	640
MYCOBACTERICIDAL ACTIVITY			
BS EN 14348 Hard water 300 mg/L $CaCO_3$ 0.3 g/L bovine albumin	Mycobacterium terrae CIP 104321	5 min/37°C	325[a]
	Mycobacterium avium ATCC 15769	5 min/37°C	604
Pr EN 14563 Hard water 300 mg/L $CaCO_3$ 0.3 g/L bovine albumin	Mycobacterium terrae CIP 104321	5 min/37°C	< 302
	Mycobacterium avium ATCC 15769	5 min/37°C	< 302
VIRUCIDAL ACTIVITY			
NF T 72-180	Adenovirus type 5	5 min/37°C	407[a]
	Enterovirus polio 1	5 min/37°C	407[a]
	Orthopoxvirus de la vaccine	5 min/37°C	407[a]
SPORICIDAL ACTIVITY			
Pr EN 14347	Bacillus subtilis CIP 52.62	5 min/37°C	< 640
	Bacillus cereus CIP 105151	5 min/37°C	2560
	Bacillus cereus CIP 105151	15 min/37°C	1280

Results of the evaluation of the biocidal activities of Aperlan Poka-Yoke disinfectant solution in use conditions (5 minutes, 37°C) in accordance with European and French standards in force. (a) : Value obtained from a concentrated solution containing 4.84 % (w/w) of peracetic acid.

Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.

GETINGE

Getinge Infection Control
PO Box 69, SE-310 44 Getinge, Sweden
Phone: +46 35 15 55 00
Fax: +46 35 549 52
info@getinge.com www.getinge.com

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GETINGE

POKA-YOKE CHEMICALS
A SAFER WAY TO REPROCESS FLEXIBLE ENDOSCOPES

NEEDS TO BE CHANGED TO THE RETUSCHED PHOTO

APERLAN - POWERFUL DISINFECTANT

Aperlan Poka-Yoke achieves within 5 minutes at 37°C all the required levels of disinfection of flexible endoscopes, i.e: bactericidal, fungicidal, virucidal, sporicidal and tuberculocidal. This enables you to improve the safety of patients and the working conditions of the nursing staff. Moreover, it ensures a longer active life of your flexible endoscopes. Aperlan Poka-Yoke, a safer product for users than glutaraldehyde, is active on biofilms and biodegradable. Its essential properties comprise a broad anti-microbial spectrum and rapid action.

The disinfecting capacity of Aperlan Poka-Yoke has been demonstrated and verified by independent hygiene institutes* as well as validated in hospital environments.

User safety comes first

The high-level disinfectant is peracetic acid-based and comes in two separate bottles – Agent A and Agent B. The two agents are mixed inside the machine and last for about 80 cycles. The Aperlan Poka-Yoke is used as single shot, i.e. it is not recycled/ reused.

* See the results from the evaluation from Biotech-Germande laboratory.

CHEMICAL PROPERTIES

Aperlan is principally composed of peracetic acid, hydrogen peroxide and acetic acid. The peracetic acid liberates a particularly active form of oxygen that acts on the functional groups of the living tissue and inhibits the vital processes of microorganisms. The hydrogen peroxide helps removes tough stains while contributing to the stability of the peracetic acid.

The acetic acid prevents the formation of mineral deposits.

The principal components of Aperlan Poka-Yoke are:

AGENT A	AGENT B
Acetic Acid (CH_3CO_2H)	Potassium hydroxide (KOH)
Peracetic Acid (CH_3CO_3H)	
Hydrogen Peroxide (H_2O_2)	

The concentration of the Aperlan Poka-Yoke in use conditions is 810 ppm at a temperature of 37°C. This ensures that the endoscopes are treated gently but efficiently.

Bio-compatibility

Dilution of Aperlan Poka-Yoke with water renders it harmless to the environment: it breaks down into water, oxygen and acetate groups and the dilution pushes the pH of the environment towards neutrality.

Agent B acts as a buffer on the peracetic acid, neutralizing the pH to some extent.

Compatibility of materials

Non-exhaustive studies of compatibility with common materials indicate the following:

- Completely compatible with stainless steel, polyethylene, polypropylene, PVC, Viton, polymethylpentene, Teflon …
- Compatible under normal conditions of use* with polycarbonate, polyurethane, silicone, polysulphone, polyamide, polyester, polystyrene …
- Not compatible with brass, copper, iron, platinum, aluminum …

*** contact time not exceeding the time needed for disinfection followed by thorough rinsing.**

Storage conditions

Under normal storage conditions (unopened original packaging, temperature between 0 and 30°C, shielded from daylight) Aperlan Poka-Yoke retains all its properties for over one year.

Stability: 1 year (in original sealed packaging) at 20°C.

Expiry date appears on the packaging.

Regulations

Aperlan Poka-Yoke is a Class IIa medical device which complies with the essential requirements of European Directive 93/42/EEC.

CE marking certificate No 0120.

Aperlan must not be used manually as a disinfectant.

HIGH-EFFICIENCY DETERGENTS

Getinge Poka-Yoke DLC is an alkaline type detergent with well-documented efficiency for protein and biofilm removal. The powerful logarithmic reduction of microorganisms found on endoscopes during tests carried out after the washing phase proves that DLC complements the disinfecting power of Aperlan Poka-Yoke and gives superb cleaning and disinfection results.

The 3-liter bottles last for 30-60 cycles, allowing about one week of operation without the need to change the detergent bottle.

The efficacy of the cleaning stage of the standard cycle of the Getinge Poka-Yoke is consistent with the requirements of ISO (FD13 15883-4:2006 clauses 4.3.5 and 6.11 when the test soil is the one described in the ISO/DTS 15883/5:2005 ANNEX A.