Standard and Guidelines for the use of High-Level Disinfectants

Dr. Reza Sadeghi

High Level Disinfection

High-Level Disinfection
This procedure kills vegetative microorganisms and inactivates viruses, but not necessarily high numbers of bacterial spores. Such disinfectants are capable of sterilization when the contact time is relatively long (e.g., 6 to 10 hours). As high-level disinfectants, they are used for relatively short periods of time (e.g., 10 to 30 minutes). These chemical germicides are potent sporicides and, in the United States, are classified by the FDA as sterilant/disinfectants. They are formulated for use on medical devices, but not on environmental surfaces such as laboratory benches or floors.

Intermediate-Level Disinfection
This procedure kills vegetative microorganisms, including *Mycobacterium tuberculosis*, all fungi, and inactivates most viruses. Chemical germicides used in this procedure often correspond to Environmental Protection Agency (EPA)-approved "hospital disinfectants" that are also "tuberculocidal." They are used commonly in laboratories for disinfection of laboratory benches and as part of detergent germicides used for housekeeping purposes.

Low-Level Disinfection
This procedure kills most vegetative bacteria except *M. tuberculosis*, some fungi, and inactivates some viruses. The EPA approves chemical germicides used in this procedure in the US as "hospital disinfectants" or "sanitizers."

Sporicides

Often referred to as high level disinfectants, they are used to destroy all forms of microbial life including viruses, fungi, bacteria and also low levels of their spores. A high level disinfectant can only be classed as a sterilant if it is capable of destroying all microorganisms present including high levels of spores.

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High Level Disinfection

Noncritical devices:
Contact intact skin only
May be cleaned with low-level disinfection
Examples: Blood pressure cuffs, tables

Semi-critical devices:
Contact intact mucous membranes, do not penetrate body surfaces
Require high-level disinfection or sterilization
Rationale – Intact mucous membranes resist common bacterial spores but are susceptible to other organisms
Examples: cystoscopes, respiratory therapy equipment, anesthesia equipment, bronchoscopes, GI endoscopes

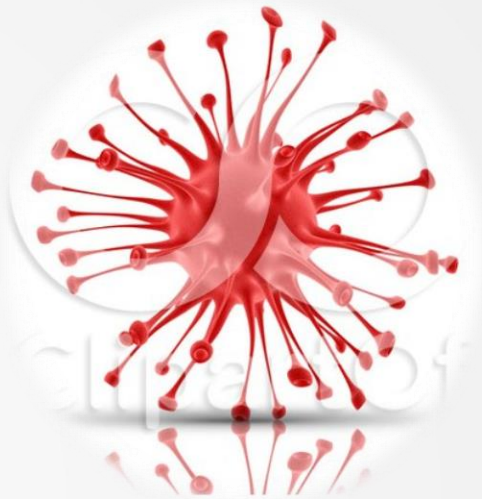
Critical devices:
Introduced into bloodstream or other normally sterile areas
Risk of infection is high
Sterilization is required
Examples: surgical instruments, biopsy forceps, laparoscopes, cardiac and urinary catheters

High Level Disinfection

- Refers to a chemical germicide as capable of destroying all viruses, vegetative bacteria, fungi, mycobacteria and some but not all bacterial spore.

- Is a sterilante used for a shorter contact time to achieve a 6-log reduction of a species of mycobacterium. Such as M.Bovis or M.Terrae, that has resistance characterizes similar to human strain of M.Tuberculosis.

High Level Disinfection



Germicide	Concentration
Glutaraldehyde	> 2.0%
Ortho-phethalaldehyde	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%- 7.5% / 0.23%
Peracetic acid	0.2% - 0.35%
Chlorine compounds (chlorine dioxide, hypochlorus Acid)	650-675 active free cl-

*May cause cosmetic and functional damage; **efficacy not verified

High Level Disinfection

EUROPEAN NORM EN

Table 3d — Food, industrial, domestic and institutional area – Test conditions and requirements of standard test methods to be used to substantiate claims for sporicidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
EN 13704 2,1	Obligatory test conditions				
	Spores of *Bacillus subtilis* ATCC 6633	20	60	Clean conditions: 0,3 g/l bovine albumin	≥ 3,0
	The following additional test conditions are permitted:				
	Spores of *Bacillus cereus* ATCC 12826 Spores of *Clostridium sporogenes 51* CIP 7 939	4 or 10 or 40 75	5 or 15 or 30		≥ 3,0
	Obligatory test conditions				
EN 14347 1	*Bacillus subtilis* ATCC 6633 *Bacillus cereus* ATCC 12826	20	30, 60 or 120	None	≥ 4,0

High Level Disinfection

EUROPEAN NORM EN

Table 1d — Medical area – Test conditions and requirements of standard test methods to be used to substantiate claims for mycobactericidal and tuberculocidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
	Obligatory test conditions				
EN 14348 2,1	*Mycobacterium avium* ATCC 15769 (mycobactericidal) and *Mycobacterium terrae* ATCC 15755 (mycobactericidal) or *Mycobacterium terrae* ATCC 15755 (tuberculocidal)	20	60	Clean conditions: bovine albumin 0,3 g/l Dirty conditions: bovine albumin 3,0 g/l + sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C-steps	5, 15, 30		
	Obligatory test conditions				
EN 14563 2,2	*Mycobacterium avium* ATCC 15769 (mycobactericidal) and *Mycobacterium terrae* ATCC 15755 (mycobactericidal) or *Mycobacterium terrae* ATCC 15755 (tuberculocidal)	20	60	Clean conditions: bovine albumin 0,3 g/l Dirty conditions: bovine albumin 3,0 g/l + sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C-steps (max. 60 °C)	5, 15, 30		

High Level Disinfection

NFT 72230 or NFT 72231

– Determines the fungicidal activity on the 4 strains:

1 – Bacillus cereus: CIP

7,803. 2 – Bacillus subtilis var.niger: CIP 7,718.

3 – Clostridium sporogenes 51: CIP 7,939 .

4 – Penicillium verrucosum var.cyclopium: IP 1231 80.

Complies with any product capable of reducing this microbial population by 5 log (105) in 1 hour at 20°C or in 5 minutes at 75°C.

NFT 72300 or NFT 72301

– Determination of the efficacy of products on various microorganisms (bacterial reduction 105, fungal reduction 104 and spore reduction 103) under practical conditions of use for non-fixed contact times and temperatures.

– Interfering substances vary according to the conditions of use or hard water 30°HF.

High Level Disinfection

MICROBIOLOGICAL PROPERTIES

Active against	Standards	Contact time
Bacteria	EN 1040, EN 13727, NF T 72-171 EN 14561	5 minutes
	Helicobacter pylori	10 minutes
Mycobacteria	Mycobacterium tuberculosis (TB)	5 minutes
	EN 14348 (M. terrae, M. avium) pr EN 14563 (M. terrae)	10 minutes
Yeasts / Moulds	EN 1275,	10 minutes
	EN 13624, EN 14562	10 minutes
Viruses	HIV-1, HBV, Herpesvirus, BVDV (surrogate of HCV)	5 minutes
	EN 14476	10 minutes
Spores of bacteria	T 72-301 (C. difficile)	30 minutes
	NF T 72-230	1 hour
	Urogenital mycoplasma	5 minutes

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High Level Disinfection

deconex® 54 SPORCIDE

Efficacy

Spectrum of activity	Method	Concentration (%)	Contact time
Bactericidal activity (S. aureus)	NF T 72 301 EN 1040	undiluted	10 min
Levurocidal activity (C. albicans)	NF T 72 301 EN 1275	undiluted	10 min
Tuberculocidal activity (M. tuberculosis)	NF T 72 301	undiluted	10 min
Sporicidal activity (B. subtilis)	NF T 72 231	undiluted	60 min
Efficacy against viruses:			
Poliovirus	NF T 72 180	undiluted	10 min

Safety information

Please refer to deconex® 54 SPORCIDE safety data sheet for information about industrial safety and proper disposal.

Storage

Store the product at temperatures between 5 and 25 °C.

High Level Disinfection

Proven efficacy

Bacteria and Fungi

EN		3 min.	5 min.	10 min.	45 min.	2 hrs.
Phase 1 / Basic test Appraised efficacy according to EN Phase 1 (Basic tests / suspension tests) without contamination does not define the applicability of a product for a specific purpose	Bactericidal (EN 1040)		conc.			
	Yeasticidal (EN 1275)		conc.			
	Fungicidal (EN 1275)		conc.			
Appraised efficacy according to **French Norms**	Tuberculocidal (tested with *M.tuberculosis*)		conc.			

Bacterial spores

Efficacy against bacterial spores			3 min.	5 min.	10 min.	45 min.	2 hrs.
	Sporicidal (NF T 72 230)	3 log				conc.	
		5 log					conc.

Viruses

Efficacy against viruses (acc. to German Society for the Control of Viral Diseases - **DVV**)		3 min.	5 min.	10 min.	45 min.	2 hrs.
	Virucidal against enveloped viruses (incl. HBV, HIV, HCV)	conc.				
Appraised efficacy against non-enveloped viruses	Virucidal (NF T 72 180)			conc.		

Supported by comprehensive proofs of efficacy and scientific-based research and development, our hygiene and disinfection products ensure best possible quality.
Research for infection protection. www.bode-science-center.com

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High Level Disinfection

Glutaraldehyde

- **Glutaraldehyde is used most commonly as a HLD for medial equipment such as endoscopes, transducers, anesthesia and respiratory therapy equipment.**
- **Glutaraldehyde, a saturated dialdehyde, has been the most widely used chemical for the HLD.**
- **Most aqueous solutions of GA are acidic and must be activated (made Alkaline to PH 7.5-8.5) to become sporicidal.**

High Level Disinfection

Glutaraldehyde

- Once activated, these solutions have a shelf-life of minimally 14 days, because of the polymerization of the GA molecules at Alkaline PH levels, this polymerization block the active site (aldehyde groups) that are responsible for its biocidal activity.

- Mechanism of action:

Alkylation of sulfidryl, hydroxyl, carboxyl and amino group,

which alters RNA, DNA and protein synthesis.

High Level Disinfection

Table 1. GA-based HLDs Cleared by FDA as of March 2015[a].

GA-based HLD	% of GA as Active Ingredient
Aldahol III HLD	3.4%
Aldahol V HLD	3.4%
Extended Use Aldahol HLD	3.4%
Sporicidin Sterilizing and Disinfecting Solution	1.12%
Rapicide HLD and Sterilant	2.5%
TD-5 HLD	2.65%
Banicide Advanced for Sterilization and HLD	3.5%
Cetylcide-G Concentrate and Diluent Concentrate	3.2%
MedSci	3.0%
Procide 14 N.S.	2.4%
Omnicide Long Life Activated Dialdehyde Solution	2.4%
Omnicide Plus	3.4%
Metricide Plus 30 Long-life Activated Dialdehyde Solution	3.4%
Metricide 28 Long-life Activated Dialdehyde Solution	2.5%.
Metricide Activated Dialdehyde Solution	2.6%
Cidex Activated Dialdehyde Solution	2.4%
Cidex Formula 7 Long-life Activated Dialdehyde Solution	2.5%
Cidex Plus 28 Day Solution	3.4%
Wavicide-01	2.5%
Cidex Activated Dialdehyde Solution	2.4%

Table 2. Percentage of GA-based HLDs Approved by Five Ultrasound Manufacturers.

Company	# HLDs	# GA-based HLDs	% GA-based HLDS
Philips[7]	68	Total of 23	34%
FUJIFILM SonoSite[8]	28	Minimum of 6	21%
Siemens[9]	63	Minimum of 15	24%
Canon[10]	24/14[a]	Total of 7	29%/50%[b]
GE Healthcare[11]	21[c]	Minimum of 8	38%

High Level Disinfection

FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices

Metrex Research, Inc.	3.4% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only. FDA accepted Metricide Plus as identical to Cidex Plus.	90 min at 25°C 28 days Maximum Reuse FDA accepted Metricide Plus as identical to Cidex Plus.
K931052 Metricide 28 Long-Life Activated Dialdehyde Solution			
Metrex Research, Inc.	2.5% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only. FDA accepted Metricide 28 as identical to Cidex Formula 7.	90 min at 25°C 28 days Maximum Reuse FDA accepted Metricide 28 as identical to Cidex Formula 7.
K930284 Metricide Activated Dialdehyde Solution			
Metrex Research, Inc.	2.6% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 25°C 14 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only. FDA accepted Metricide as identical to Cidex.	45 min at 25°C 14 days Maximum Reuse FDA accepted Metricide as identical to Cidex.
K924434 Cidex™ Activated Dialdehyde Solution			
Johnson & Johnson Medical Products	2.4% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 25°C 14 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 25°C 14 days Maximum Reuse Contact conditions based on literature references.
K924334 Cidex Formula 7™ Long-Life Activated Dialdehyde Solution			
Johnson & Johnson Medical Products	2.5% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 20-25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	90 min at 25°C 28 days Maximum Reuse Contact conditions based on literature references.

7/9/22, 12:57 AM FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices | FDA

MediVators, Inc.	2.5% glutaraldehyde	**Indication for device sterilization.** 7 hrs 40 min at 35°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes and additional supporting information.	**Automated Endoscope Reprocessor** 5.0 min at 35°C 28 days Maximum Reuse (For processing in an AER only with FDA-cleared capability to maintain the solution temperature at 35°C.) Contact conditions established by simulated use testing with endoscopes.
K991487 °Cidex®OPA Solution High Level Disinfectant			
Advanced Sterilization Products	0.55% *ortho*-phthaldehyde	**No indication for device sterilization.** Passes the AOAC Sporicidal Activity Test in 32 hrs at 20°C.	12 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K974188 °Cetylcide-G Concentrate and Diluent Concentrate			
Cetylite Industries, Inc.	3.2% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 20°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	40 min at 20°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K974062 MedSci 3% Glutaraldehyde			
MedSci, Inc.	3% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	25 min at 25°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K972708 EndoSpor Plus Sterilizing and Disinfecting Solution *Note: Due to the lack of test strips for monitoring the concentrations of the active ingredients, the reuse period is limited to 14 days.*			
Cottrell Limited	7.35% hydrogen peroxide 0.23% peracetic acid	**Indication for device sterilization.** 180 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.	15 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.

High Level Disinfection

FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices

Reckitt & Colman Inc.	7.5% hydrogen peroxide	**Indication for device sterilization.** 6 hrs at 20°C 21 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	30 min at 20°C 21 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K960513 Peract™ 20 Liquid Sterilant/Disinfectant			
Minntech Corporation	1.0% hydrogen peroxide 0.08% peracetic acid	**Indication for device sterilization.** 8 hrs at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.	25 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K932922 Procide 14 N.S.			
Cottrell Limited	2.4% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 20°C 14 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K932922 Omnicide™ Long Life Activated Dialdehyde Solution			
Cottrell Limited	2.4% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 20°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 20°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K932922 Omnicide™ Plus			
Cottrell Limited	3.4% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 20°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 20°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.

7/9/22, 12:57 AM FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices | FDA

MediVators, Inc.	2.5% glutaraldehyde	**Indication for device sterilization.** 7 hrs 40 min at 35°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes and additional supporting information.	**Automated Endoscope Reprocessor** 5.0 min at 35°C 28 days Maximum Reuse (For processing in an AER only with FDA-cleared capability to maintain the solution temperature at 35°C.) Contact conditions established by simulated use testing with endoscopes.
K991487 °Cidex®OPA Solution High Level Disinfectant			
Advanced Sterilization Products	0.55% *ortho*-phthaldehyde	**No indication for device sterilization.** Passes the AOAC Sporicidal Activity Test in 32 hrs at 20°C.	12 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K974188 °Cetylcide-G Concentrate and Diluent Concentrate			
Cetylite Industries, Inc.	3.2% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 20°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	40 min at 20°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K974062 MedSci 3% Glutaraldehyde			
MedSci, Inc.	3% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	25 min at 25°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K972708 EndoSpor Plus Sterilizing and Disinfecting Solution *Note: Due to the lack of test strips for monitoring the concentrations of the active ingredients, the reuse period is limited to 14 days.*			
Cottrell Limited	7.35% hydrogen peroxide 0.23% peracetic acid	**Indication for device sterilization.** 180 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.	15 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.

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Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes

SGNA™

Society of Gastroenterology Nurses and Associates, Inc.

2. Soak time exception

The Society of Gastroenterology Nurses and Associates, Inc., in collaboration with the American Society for Gastrointestinal Endoscopy (ASGE), the American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG), and the Association for Professionals in Infection Control and Epidemiology (APIC) adopted the *Multi-society Guideline on Reprocessing Flexible Gastrointestinal Endoscopes* (American Society for Gastrointestinal Endoscopy Quality Assurance in Endoscopy Committee et al., 2011). This guideline, based on scientific data, supports the position that after meticulous manual cleaning, high-level disinfection is achievable with a 20-minute exposure at 20°C (room temperature) in a greater than 2% glutaraldehyde solution which tests above its minimum effective concentration (Petersen et al., 2011; AAMI, 2010; United States Food and Drug Administration 2009). These conditions may not be extended to other glutaraldehyde solutions. This recommendation differs from the label claims on a greater than 2% glutaraldehyde stating a 20-90 minute exposure at 25°C for HLD because the current federal labeling regulation assumes no cleaning of the medical device prior to chemical exposure.

Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

Users should always refer to FDA labeling and manufacturers' instructions for device-specific reprocessing guidance. Accrediting bodies will typically survey for performance in accordance with this guidance. In rare cases, FDA labeling claims and/or manufacturers' guidance may lag behind evolving data or rely on extreme assumptions or thresholds of safety that are not pertinent to safe, yet efficient, healthcare. If alternative practices are demonstrated to be optimal by several well-designed scientific studies and they are endorsed by multiple professional societies, they can be considered for use by an organization.[11] For instance, the FDA cleared labels for HLD with greater than 2% glutaraldehyde at 25°C advised contact times ranging from 20 to 90 minutes depending on the product. Multiple scientific studies and professional organizations support the efficacy of greater than 2% glutaraldehyde at 20 minutes at 20°C.[38]

High Level Disinfection

Glutaraldehyde Concentration:

The concentration of active GA decrease over time, because:

1. **Evaporation:**

   The solution conversion to a gaseous state and release to air.

2. **Dilution:**

   Reduction the concentration of GA, because the presence of droplets of water adhering to instruments.

3. **Carry Cover:**

   Gradual loss due to adherence of the solution to the surfaces of instrument.

4. **Challenging loads of microbes and organic matter.**
5. **Aging**

High Level Disinfection

End Point:

- Type of instruments
- Number of instruments
- Number of days that have been used.
- Presence of droplets of water.
- Evaporation
- Carry cover.
- Chemical formulations.
- High level Disinfection must be changed when the solutions fail to meet MEC or exceed the HLD reuse life , whichever comes first (AORN 2015, AAMI 2015, ASGE 2008)
- If additional HLD is added to an AER or basin, the reuse life should be determined by the first use activation of the original solution-Topping off. (Multi society guidelines 2016).

High Level Disinfection

Monitoring GA Concentration:

Minimum effective Concentration of GA is 1.5% .

- **Test strips for GA 2.4% show failure when the Concentration drops below 1.5% .**
- **The MEC may never be used to extend the reuse life claim of the product. (AAMI . 2019)**

The Frequency of Testing: (CDC-2019)

✓ **Should be based on how frequently the solutions are used**

Used daily	**Test daily , before use**
Used weekly	**Test weekly , before use**
Used 30 time per day	**Test each 10 times**

High Level Disinfection

ADVANTAGES:

- ✓ Excellent **biocidal** activity
- ✓ Effectiveness is supported by numerous studies.
- ✓ **Inexpensive**
- ✓ **Non corrosive** to metals, rubbers and plastics.
- ✓ Can be use for manual or AER.
- ✓ **Activity** in the presence of organic matter.

High Level Disinfection

Disadvantages:

- Respiratory irritant (coughing, sneezing)
- Allergic contact dermatitis.
- Develop acute sensitives (display as itching, slight redness, swelling)
- Irritation of eyes , and nasal membranes(rhinitis , epistaxis)
- Asthma like syndrome
- Remaining on equipment: colitis , keratopathy
- Fixation of blood and tissue on surface
- GA can be absorbed by inhalation , ingestion and skin
- Irritation odor.
- GA can be absorbed by inhalation, ingestion and skin.
- It has detectable odor at 0.04 ppmv , and is irritating to skin and mucous membrenes at 0.3 ppmv.
- Vapors are released whenever solutions are distributed and the surface tension is broken (Mixing, adding and removing equipment or disposing of a GA solutions)

High Level Disinfection

Reprocessing Room Standards:

Reprocessing of contaminated patient equipment should be done in an area designated and dedicated for this function.

There should be negative air pressure in the reprocessing room. (FGI,2014) Keeping processing room temperature as low as possible.

Minimum of 10 air exchanges per hour in the reprocessing area. (FGI,2014)

The vapor concentration of the chemical disinfectant being used should not exceed allowable limits (0.05 ppm for glutaraldehyde).

The minimum capture velocity at least 100 feet per minute.

Local exhaust ventilation also be installed at the point of release. Exhaust to fume cabinets with activated charcoal.

Exhaust should be vented directly outside. Air must not be recirculate.

Reducing the release of GA vapor during transfer and pouring GA to soaking basin.

Specific containers (Basin) for HLD Solution. Use appropriately- sizes soaking basins.

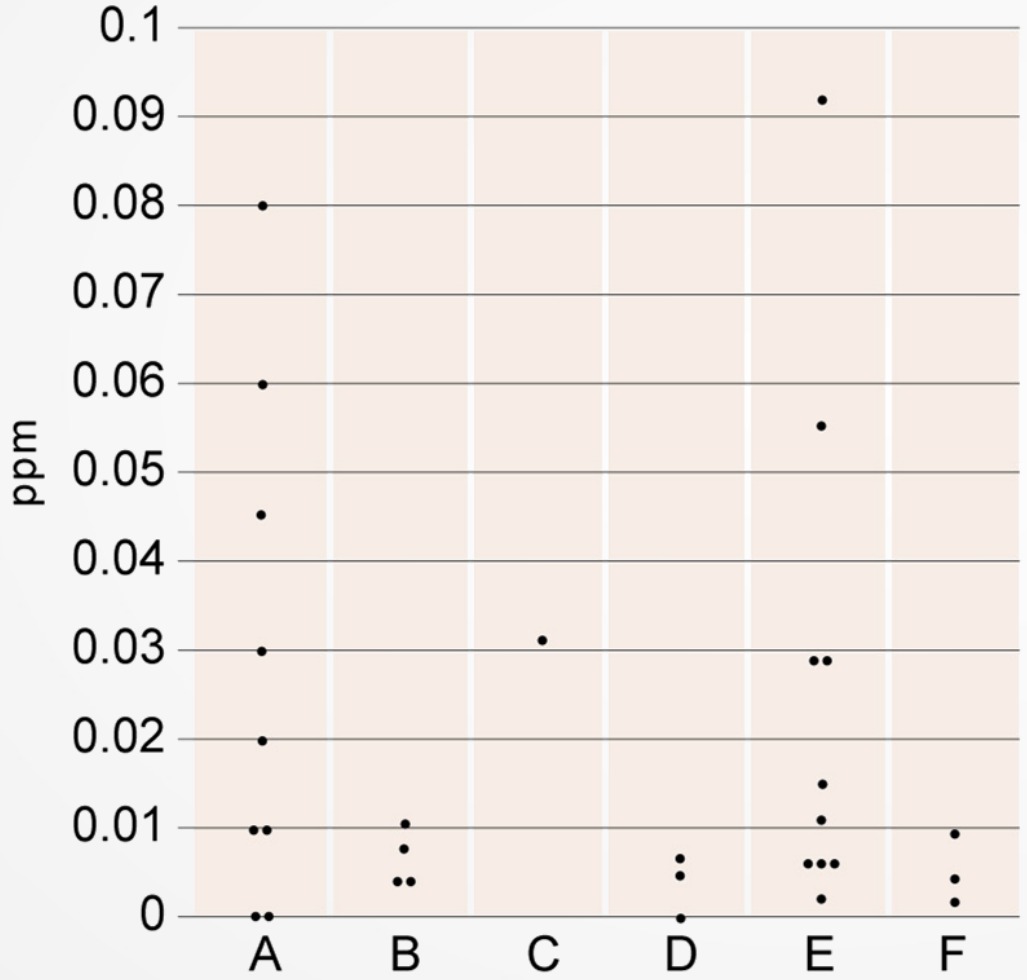
The agent should be used in closed containers with tight- fitting lids.

Eye wash stations

The room must have more than one sink and separate hand washing facilities sink should be deep enough to allow complete immersion of the endoscope.

High Level Disinfection

Glutaraldehyde Exposures with and without Local Exhaust Ventilation



A. Manual Sterilization, Poor Ventilation and Work Practices

B. Manual Sterilization Under Local Exhaust Ventilation

C. Automatic Sterilization, Poor Ventilation

D. Automatic Sterilization, Proper Ventilation

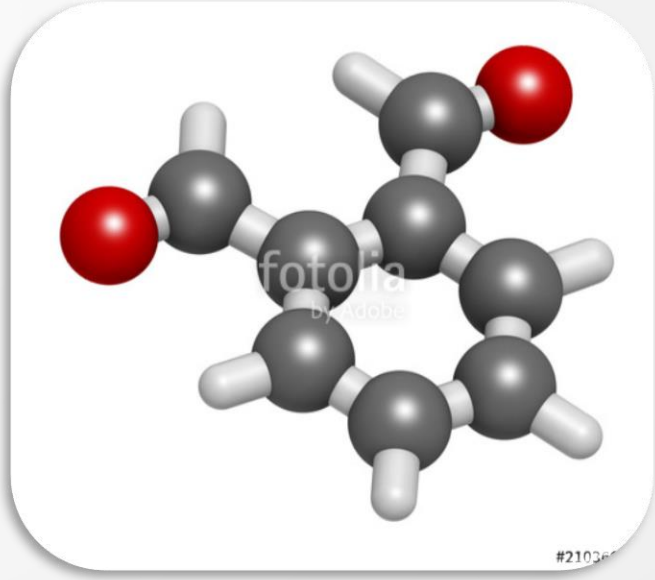
E. Solution Handling, No Local Exhaust Ventilation

F. Solution Handling, Local Exhaust Ventilation

High Level Disinfection

Ortho-phthalaldehyde (OPA):

- Is an alkylating agent which contains 0.55% benzenedicarboxaldehyde
- OPA Solution is a clear, pla-blue with a pH 7.5
- The minimum effective concentration (MEC): 0.3%
- The solution may be reused for a maximum of 14 days.
- Should be monitored during using solution. (Test strips fot OPA)
- No activation
- Shelf life: 75 days.
- Manual-AER
- The HLD claim of OPA : 10-12 min at 20℃



High Level Disinfection

Advantages:

- Fast acting
- Good microbiocidal activity
- No activation required.
- Odor not significant
- Good material compatibility
- Stable in wide range PH
- Does not coagulate blood or fix Proteins.

High Level Disinfection

Disadvantages:

- **Stain skins, mucous membranes, clothing and environmental surfaces (Gray)**
- **(Test : Stain patient mouth)**
- **More expensive than GA.**
- **Irritates eyes and damage when it contacts**
- **Can aggravate bronchitis or asthma**
- **Slow sporicidal activity**
- **Potential irritant to eyes, skin, nose and other tissues**
- **Require neutralization prior to disposal.**
- **Repeated exposure: hypersensitivity in patients with bladder cancer.**

In conclusion, 0·5% (w/v) OPA is considered to be a viable alternative to glutaraldehyde for high level disinfection where, by definition, the compound need not have a lethal action against high levels of bacterial spores (Russell 1994; Rutala & Weber 1995). OPA should not be used in situations where sterilization is required, but it might be particularly useful in washer systems where glutaraldehyde-resistant organisms have developed.

High Level Disinfection

Anderson-SE; Umbright-C; Sellamuthu-R; Fluharty-K; Franko-J; Jackson-L; Kashon-M; Johnson-V; Joseph-P

Toxicologist 2010 Mar; 114(1):66

https://www.toxicology.org/pubs/docs/Tox/2010Tox.pdf

20036564

Although ortho-phthalaldehyde (OPA) has been recommended as an alternative to glutaraldehyde for the sterilization and disinfection of heat-sensitive medical equipment, its toxicity has not been thoroughly investigated. The present study was designed to evaluate the dermal irritation and sensitization potential of OPA. Results of the Epiderm Skin Irritation Test identified OPA as a dermal irritant and furthermore, demonstrated that OPA is a more potent skin irritant than glutaraldehyde. Consistent with the in vitro results, exposure to 0.75% OPA induced irritancy when evaluated in a combined irritancy local lymph node assay (LLNA) exposed to 0.75% OPA. A concentration-dependant increase in lymphocyte proliferation was observed after OPA exposure with a calculated EC3 value of 0.051%, classifying this chemical as an extreme sensitizer. IgE-inducing potential was evaluated by phenotypic analysis of draining lymph node cells and measurement of total and OPAspecific serum IgE levels in the mice. The 0.1% and 0.75% exposed groups yielded significant increases in the IgE+B220+ cell population in the lymph nodes while only the 0.75% exposed group demonstrated significant increases in IL-4 mRNA in the draining lymph nodes and total and OPA specific serum IgE levels. A significant elevation in OPA-specific IgG1 was also observed after exposure to 0.75% OPA. These results demonstrated the dermal irritation and sensitization potential of OPA in an animal model raising concern about the skin irritation and sensitization potential of OPA among healthcare workers who are potentially exposed to the chemical.

High Level Disinfection

Reviewing the Use of Glutaraldehyde for High-level Disinfection by Sonographers

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A guideline for high-level disinfectants for endoscopes also reviewed the advantages and disadvantages of OPA.[27] The advantages of using OPA were that the disinfection time is low, it has high efficacy, no activation is needed, it is not carcinogenic, and it can be used manually or in an automated system. The disadvantages were the irritant potential for eyes/skin/nose, aggravation of lung conditions, high cost, and the fact that it stains easily.

High Level Disinfection

Fact Sheet

Safe use of *ortho*-phthalaldehyde (OPA)

Infection Control Service
Telephone: 1300 232 272
Workforce Health
Telephone: 8226 4394
11 Hindmarsh Square, Adelaide SA 5000
www.sahealth.sa.gov.au/infectionprevention

Official
Version 1.2 (Sep2020)

Personal Protective Equipment is required to prevent OPA from contacting the skin and eyes. A full-face visor should be worn throughout the disinfection process. Note: Contact lenses may pose a special hazard and may absorb or concentrate irritants. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation

Gloves must be of appropriate length and should be made from a compatible material.

OPA solution must be used in a well-ventilated area in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air conditioning system, use under local exhaust hood, or under ductless fume hood or portable ventilation device. These should contain filter media that absorbs OPA from the air.

High Level Disinfection

Peracetic Acid (PPA):

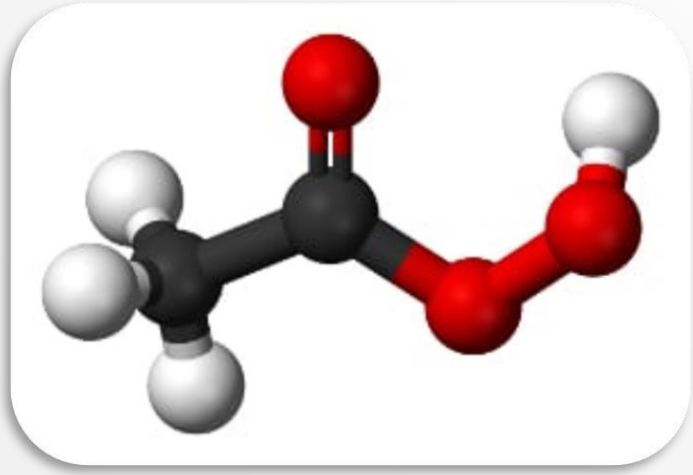
Oxidising agent.

Mechanism of action:

Denaturating Protein

Disrupting cell-wall permeability

Oxidising sulphydryl and Sulphur bounds in protein.



Advantages:

- **Rapid sterilization time (30-45 min)**
- **Low-temperature (50-53℃) liquid immersion sterile.**
- **Significant efficacy at higher temperatures.**

  (6 log reduction of spores at 50℃＜2 min)
- **Rapidly sporicidal.**
- **Environmentally friendly (acetic acid, O2, H2O).**
- **No adverse health effects when used under normal conditions.**
- **Does not coagulate Blood or fix tissues to Protein.**
- **Does not allow biofilm creation.**
- **Removed GA hardened bioburden from biopsy channels.**
- **Has not cause resistant organisms.**

High Level Disinfection

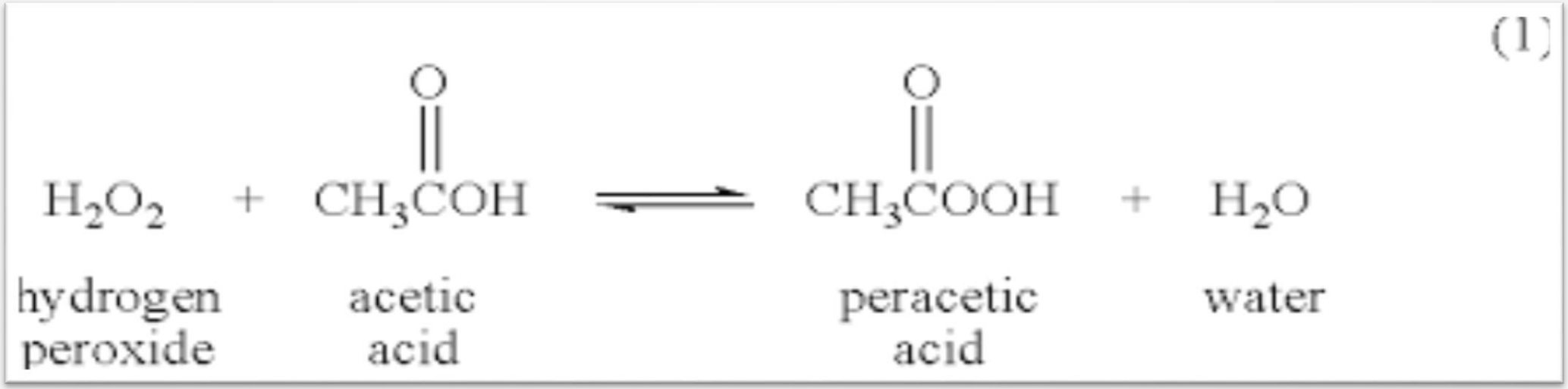
Disadvantages:

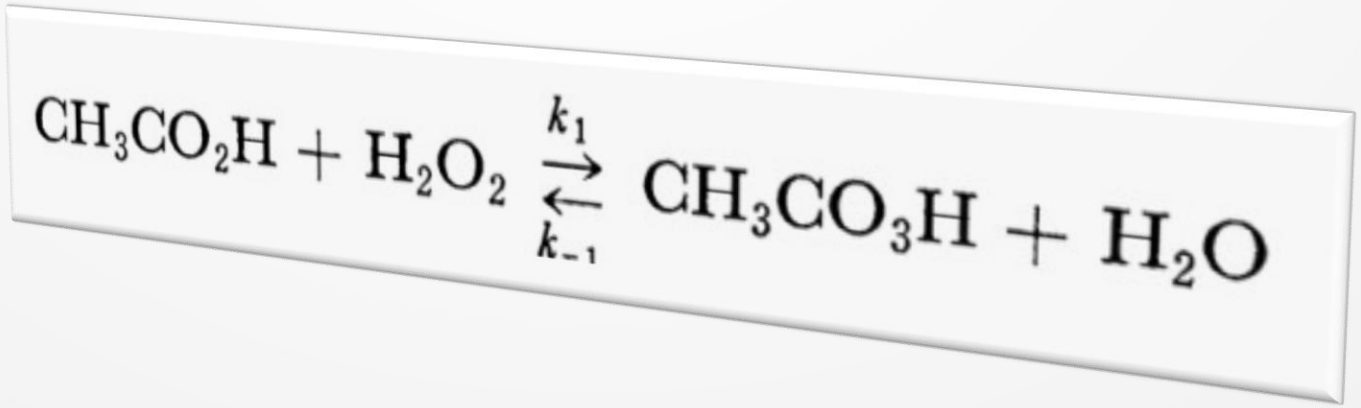
- Potential material incompatibility (Aluminium anodized)
- Can corrode copper, brass, bronze, plain steel and galvanized Iron.
- Oxidizing ability may expose the leaks in internal channels of scopes previously disinfected with GA.
- Unstable, when diluted.
- More expensive.
- Serious eye and skin damage with contact.
- Concentrates are used only in specific AER.
- This biocide is used in a number of AER (steris 1)
  - The sterilant: 35% PPA , is dilated to 0.2% at 50℃ temp.
- Exposure.Time: 12 min /cycle: 25-30 min
- Instruments are processed in an unwrapped condition and are wet.
- They can not be stored in a sterile state.

High Level Disinfection

Preparation of Peracetic Acid from Acetic Acid

And Hydrogen Peroxide





Dr. Reza sadeghi

High Level Disinfection

Disinfecting properties

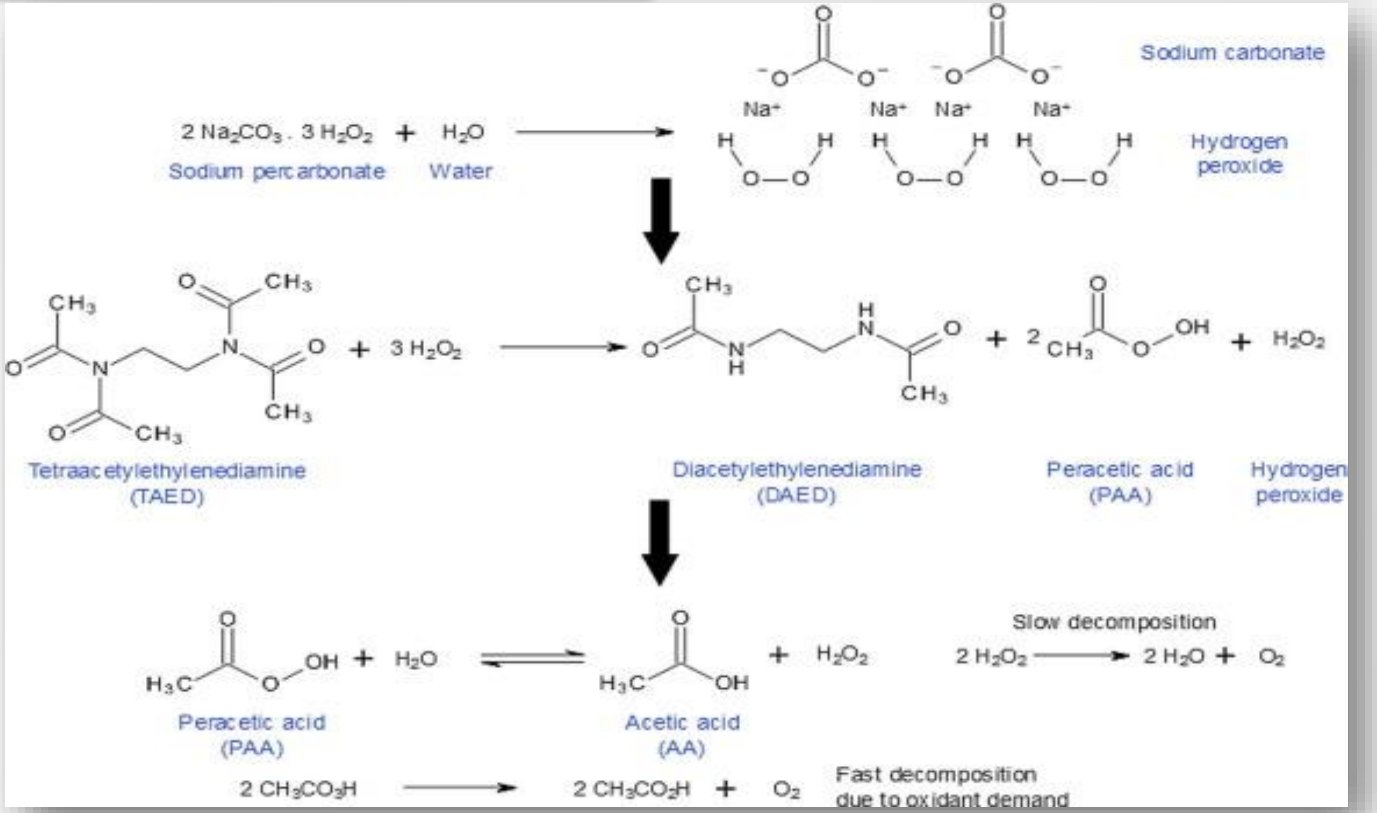
ACTIVITY SPECTRUM	STANDARD	STRAINS	CONTACT TIME
BACTERICIDAL* (Clean conditions)	EN 13727:2012 + A2:2015 (phase 2 / step 1)	Pseudomonas aeruginosa Staphylococcus aureus Enterococcus hirae	5 Min.
FUNGICIDAL (Clean conditions)	EN 13624:2013 (phase 2 / step 1)	Candida Albicans Aspergillus Brasiliensis	5 Min.
VIRUCIDAL** (Clean conditions)	EN 14476:2013 + A2:2019 (phase 2 / step 1)	Adenovirus, Norovirus Polyovirus	5 Min.
TUBERCULOCIDAL (Clean conditions)	EN 14348:2005 (phase 2 / step 1)	Mycobacterium Terrae (Surrogate M. tuberculosis)	5 Min.
MYCOBACTERICIDAL (Clean conditions)	EN 14348:2005 (phase 2 / step 1)	Mycobacterium Terrae Mycobacterium Avium	5 Min.
SPORICIDAL*** (Clean conditions)	EN 17126:2019 (phase 2 / step 1)	Bacillus subtilis Clostridioides difficille	5 Min. 5 Min.
		Bacillus cereus	5 Min.

Physical properties

- Appearance: Transparent solution
- Density: 1,02 g/cm^3 at 20˚C
- pH: 4.5-6.0 (neutral) at 20˚C
- Odour: Mild (acetic acid)
- Storage: 5˚C - 35˚C
- Stability: 24 months
- Biodegradability: According to OCDE 301D

High Level Disinfection

Preparation of Peracetic Acid from sodium Percarbonate and TAED



The active substance peracetic acid is formed when the solid biocidal product containing the precursors TAED and sodium percarbonate is diluted with water (e.g. in mixing of the disinfection solution). Sodium percarbonate dissociates to sodium carbonate and hydrogen peroxide. In the presence of hydrogen peroxide, TAED rapidly undergoes perhydrolysis to form DAED (diacetylethylenediamine) and the active substance peracetic acid.

High Level Disinfection

ANIOS OXY'FLOOR

Detergent disinfectant
Floors and surfaces

- Powder without odour
- Twin action : cleaning and disinfection in a simultaneous operation
- Active against Clostridium difficile in 15 minutes
- Alternative to Chlorine
- Unique dose : no overdosing

INDICATIONS

Cleaning and disinfection with broad spectrum for floors and surfaces, during epidemic period.
High level activity against Clostridium difficile, Norovirus, Rotavirus, Mycobacterium terrae and avium…

CHARACTERISTICS

- Powder releasing peracetic acid
- White powder with low granulometry
- Hygroscopic powder (keep away from humidity)
- pH of diluted product (0.5%) : approx. 9.3
- Density : 0.91
- Formulation without perborate
- Without characterisitic odour after dilution
- Blue coloured solution after dilution
- Use duration : 8 hours

PRODUCT
TO BE DILUTED
25 g › 5 L

MICROBIOLOGICAL PROPERTIES

ANIOS OXY'FLOOR diluted at 0.5% has the following antimicrobial effectiveness (dirty conditions) :

Active against	Standards	Contact time
Bacteria	EN 13697, EN 13727, EN 14561 Activity against MdRB	5 minutes
Yeasts/ Moulds	EN 13697 : Candida albicans, EN 14562	5 minutes
	EN 13697 : Aspergillus niger, EN 14562	15 minutes
Mycobacteria	EN 14563, EN 14348, EN 13697	15 minutes
Spores of bacteria	Clostridium difficile : EN 13697 EN 13704 (5 log)	15 minutes
Viruses	According to EN 14476+A1 : • Vaccinia virus, • PRV (surrogate of HBV), • Norovirus	5 minutes
	• BVDV (surrogate of HCV),	10 minutes
	• Rotavirus	15 minutes

Other activities available in the product dossier

COMPOSITION

Powder based on sodium percarbonate, tetraacetylethylenediamine and N-alkyl(C12-14)-N-benzyl-N,N-dimethylammonium chloride.
Extemporaneous production of peracetic acid diluted in water.
Composition in active substances for 100g of a 0.5% solution:
-Peracetic acid (generated in situ) (N° CAS 79-21-0) : approx. 750 ppm (0,75 mg/g),
-N-alkyl(C12-14)-N-benzyl-N,N-dimethylammonium chloride (N°CAS : 85409-22-9) : 0.012 % (0,12 mg/g).

High Level Disinfection

ANIOSEPT ACTIV

2 in 1: Cleaning disinfectant
High level disinfectant/
Cold sterilization
of medical devices

- 2 in 1 powder: cleaning disinfection + high level disinfection/cold sterilization
- Wide antimicrobial spectrum in 15 minutes (sporicidal at 2%)
- Shelf-life: 2 years
- Perborate free formulation
- Dilution control with specific test strips

INDICATIONS

Cleaning disinfection and high level disinfection/cold sterilization of instruments and endoscopes, thermosensitive equipment.

CHARACTERISTICS

- Powder liberating of peracetic acid
- White powder with thin granulometry
- Hygroscopic powder (keep in a dry place)
- Ensure that the seal is fully closed between each use
- Slightly perfumed
- pH of diluted product (1%): approx. 8.5

TO BE DILUTED

MICROBIOLOGICAL PROPERTIES

Results described in the table here-below correspond to tests realised **in dirty conditions: Cleaning disinfectant**

Required disinfection level	Contact time according to the concentration in ANIOSEPT ACTIV		
LOW bactericide, yeasticide	0,5 %	1 %	2 %
	5 minutes	5 minutes	-
INTERMEDIATE bactericide, fungicide, virucide, tuberculocide	60 minutes	30 minutes	15 minutes

Results described in the table here-below correspond to tests realised **in clean conditions: High level disinfectant/Cold sterilization**

Required disinfection level	Contact time according to the concentration in ANIOSEPT ACTIV		
HIGH bactericide, fungicide, virucide, mycobactericide, sporicide	0,5 %	1 %	2 %
	90 minutes	60 minutes	15 minutes

COMPOSITION

Powder based on sodium percarbonate, tetraacetyl-ethylenediamine and N-alkyl(C12-14)-N-benzyl-N, N-dimethylammonium chloride. Extemporaneous production of peracetic acid when diluted in water.

Dr. Reza sadeghi

Thank you

Dr. Reza sadeghi