

The Q-Net™ Monthly

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What's News

Infection control and instrument reprocessing are dynamic fields, always in a state of flux. Many questions arise in day-to-day practice, from event-related sterility to the ethical questions surrounding the reuse of single-use items. Rapid dissemination of information via published papers and the internet is necessary to keep abreast with these topics. If you have any questions that you would like to see addressed in this newsletter, please send it to the attention of this newsletter's publisher. All correspondence are considered confidential.

'Q-Net 99'

'Q-Net-99,' a bound collection of all of 1999's newsletters, will be published in January 2000.



What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

Q-Net addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

FDA clears 3 more liquid germicides

Cidex OPA®, *Endo-Spor Plus™* and *Sporocidin®* were cleared recently by the FDA for reprocessing medical instruments, including endoscopes.

Health care facilities routinely use glutaraldehyde to reprocess *semi-critical* items. A recent survey published in this newsletter (April-May, 1999) indicated that 80% of the respondents used glutaraldehyde (all formulations) to reprocess flexible endoscopes.

Health care facilities looking for alternatives to glutaraldehyde now have 3 new choices: **Cidex OPA®** (*Advanced Sterilization Products, 33 Technology Drive, Irvine CA 92618; 949-789-3885*); **Endo-Spor Plus™/Hyprocide™** (*Metrex, 1717 West Collins, Orange, CA 92867; 800-841-1428*); and **Sporocidin®** (*Sporocidin International, 5901 Montrose Road, Rockville, MD 20852; 301-231-7700*). Each of these liquid chemical germicides (LCGs) was recently cleared by the FDA (see Table 1, next page) for reprocessing medical instruments, including flexible endoscopes.

The ideal LCG for reprocessing endoscopes destroys mycobacteria and bacterial spores, is rapid-acting and inexpensive, does not cause instrument damage, and is both environmentally safe and easy to use. While these 3 LCGs (and any other) are unlikely to satisfy all of these criteria, each may have a suitable application for both automated and manual instrument reprocessing.

Are these three LCGs labeled as 'sterilants' or 'high-level disinfectants'?

Before answering this question, it is necessary to provide some background information.

What is a sterilant? A LCG labeled as a sterilant destroys high numbers of resistant bacterial spores, usually within 20 hours of exposure (FDA. "Guidance on the content and format of premarket notification [510(k)] submissions for liquid chemical sterilants and high-level disinfectants," 1997). Several formidable tests may be used to demonstrate that a LCG is a sterilant, including the AOAC's (Association of Official Analytical Chemists) Sporicidal Test.

Although processes labeled for sterilization have traditionally been required to demonstrate a *sterility assurance level* (or, SAL) of 10^{-6} , the FDA appears to have revised its standard, currently requiring LCGs labeled as sterilants to demonstrate a lower (and less rigorous) SAL of 10^{-3} (FDA, 1997).

And what is a high-level disinfectant? A LCG labeled for high-level disinfection achieves at least a 6 log reduction of mycobacteria (*Muscarella LF. Gastro-intest Endosc 50[2]:301-3*). In addition, high-level disinfectants have traditionally been required by the FDA to be sporicidal - that is, destroy high numbers of bacterial spores usually within 20 hours. While it may take several hours for a high-level disinfectant to destroy bacterial spores, less than one hour is usually sufficient for it to destroy mycobacteria. In general, mycobacteria are less resistant to LCGs than bacterial spores (see this newsletter's December 1997 issue).

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Name of liquid germicide	Active chemical ingredient(s)	Immersion time for high-level disinfection	Sterilant claim	Maximum reuse life	Minimum concentration	Activation required?
Cidex OPA	0.55 ortho-phthalaldehyde	12 minutes at 20 C	Not applicable*	14 days	0.30%	No
Endo-Spor Plus/ Hyprocide	7.35% hydrogen peroxide, 0.23% peracetic acid	15 minutes at 20 C	3 hours at 20 C	14 days	Not available**	No
Sporicidin	0.95% glutaraldehyde, 1.64% phenol/phenate	20 minutes at 25 C	12 hours at 25 C	7 days	0.6% glutaraldehyde 1.3% phenol	Yes

TABLE 1: Characteristics of 3 liquid chemical germicides.

Table 1's LEGEND:

* *The sporicidal properties of this product may be limited.*

** *Chemical test strips may not be available.*

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Also, in order for a LCG to be labeled for high-level disinfection, data must be provided that demonstrate its effectiveness during challenging simulated in-use tests. These tests, designed to provide a wide margin of safety, reveal whether the LCG, subjected to a set of *worst-case* conditions (eg, diluted to its minimum effective concentration and in the presence of an organic soil, such as 5% calf serum), destroys mycobacteria on the internal surfaces of complex devices, such as flexible endoscopes.

What are the advantages and disadvantages of these 3 LCGs? Unlike Cidex,™ whose label claims that an exposure time of 45 minutes is necessary to achieve high-level disinfection of "unclean" instruments (or, 20 minutes for pre-cleaned items), each of the LCGs in Table 1 achieves high-level disinfection within 20 minutes. Only Sporicidin requires an elevated temperature of 25° C, and may therefore require the use of an immersion heater. But because the temperature of many reprocessing rooms is at or near 25° C, heating this LCG to satisfy its label claim may not be necessary.

Also, of the three LCGs listed in Table 1, only Sporicidin requires the addition of a chemical activator prior to the solution's use. Chemical indicators to monitor the reuse concentration of Endo-Spor Plus may not be available. And Cidex OPA may not be a sterilant (as previously defined and required by the FDA to be labeled as a high-level disinfectant

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[FDA, 1997]); the significance of this limitation is unclear. Both Cidex OPA and Sporicidin contain chemical aldehydes and therefore may, but do not necessarily, require air ventilation and/or other engineering measures designed to maintain their airborne concentrations within permissible levels. Endo-Spor Plus contains oxidizing agents whose compatibility with the immersed instrument will likely depend on the materials used in the instrument's constructions.

Deja Vu ... all over again and again?

At the time this newsletter went to press, a report of several patient injuries at a medical facility in southern California surfaced. Details are limited. Bronchoscopes were apparently reprocessed inadequately using an automated endoscope system. Initial information indicates that as many as 13 patients might have been infected with *Pseudomonas aeruginosa*, a waterborne microorganism. Similar incidents of patient infection, and methods for their prevention, were reported in this newsletter's June 1999 issue. To be continued ...

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD.* Please direct all correspondence to:

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