

The Q-Net™ Monthly

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What's News

This is a time to celebrate. It's the Holiday Season, the ending of one year and the beginning of the next. A time to reflect and prepare a list of new year resolutions. *And early next year two new liquid chemical germicides will be available for reprocessing medical instruments.*

Not since 2% glutaraldehyde has a germicide been cleared by the FDA for the processing of medical instruments, including endoscopes. If you don't like one germicide, now you can choose another. *Happy Holidays and Best Wishes from Q-Net!*

'Q-Net 97'



'Q-Net-97,' a bound collection of all of 1997's newsletters, will be published in January 1998. Order your copy today.

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 2 new liquid germicides

Sporox® and Peract™ 20 were recently cleared by the FDA for reprocessing medical instruments, including endoscopes.

Health care facilities routinely use glutaraldehyde to reprocess their endoscopes. Several different glutaraldehyde formulations are available, including 2% and 3.4% concentrations.

Early next year two new liquid chemical germicides (LCGs) will be marketed for reprocessing medical instruments: Sporox® (Reckitt and Colman, Inc., 1-888-4SPOROX) and Peract™ 20 (Minntech Corp., 1-800-328-4944).

The ideal LCG destroys all microorganisms, is inexpensive, does not cause instrument damage, and is environmentally safe and personnel-friendly. While neither of these LCGs (nor any other) will likely satisfy all of these criteria, both are likely to be popular for both automated and manual instrument reprocessing.

Is either of these germicides a sterilant, or are they both high-level disinfectants? Before answering this question, some background information is needed.

What is a sterilant? A sterilant is a biocidal agent that destroys high numbers of resistant bacterial endospores, using a standardized AOAC (Association of Official Analytical Chemists) sporicidal test.

And what is a high-level disinfectant?

It's a sterilant that, usually during a shorter exposure time than required to kill endospores, destroys mycobacteria, using a standardized tuberculocidal test. (Most mycobacteria are easier to destroy than bacterial endospores. Refer to this newsletter's October 1996 issue.)

That is, to be labeled as a high-level disinfectant, the LCG must be a sterilant. Also, simulated in-use tests are necessary to show that the LCG destroys mycobacteria inoculated onto the internal surfaces of a complex medical instrument, such as a flexible endoscope.

The soaking time and temperature necessary to achieve a 6 log reduction of mycobacteria dictates the LCG's high-level disinfectant claim. While it may take several hours for a LCG to be a sterilant, less than one hour is usually sufficient to be a high-level disinfectant.

The labels of Sporox® and Peract™ 20 indicate that an immersion time of 6 and 8 hours, respectively, is required to be a sterilant (at room temperature). And an immersion time of 30 and 25 minutes is required for Sporox® and Peract™ 20, respectively, to be a high-level disinfectant (see Table 1 on the next page).

While convenient to use, LCGs have their limitations. (Refer to this newsletter's June 1997 issue.) For example, according to the Food and Drug Administration's "Guidance on the content and format of

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premarket notification [510(k)] submissions for liquid chemical germicides,” published both in 1995 and 1997, LCGs cannot be routinely monitored biologically. (Refer to this newsletter’s January 1996 issue.)

For this reason and others, the labels of both Sporox® and Peract™ 20 (and Cidex™; see Table 1) indicate that LCGs should not be used to sterilize medical instruments that are compatible with other available sterilization methods, such as heat, ethylene oxide, and peroxide gas plasma, which can be biologically monitored.

Also published in these FDA guidance documents is the following: “Data is not yet available to validate that liquid chemical germicides can achieve a defined sterility assurance level.” (A process is required to demonstrate a sterility assurance level, or SAL, of 10⁻⁶ in order to be considered appropriate for the sterilization of medical instruments.)

In order to explain whether LCGs should be labeled as sterilants or high-level disinfectants, I will make a distinction between a ‘sterilant,’ which is a biocidal agent that destroys...

... all microorganisms, and ‘sterilization,’ which is a process that uses a sterilant. Indeed, a sterilant destroys spore-forming bacteria (in a laboratory setting). But will exposure to a sterilant yield a sterile instrument in the clinical setting? Not necessarily. Factors, such as time, temperature, the presence of organic debris, and the complexity of the instrument’s internal design (*Does the instrument facilitate or hinder cleaning?*), can affect the sterilization process’s outcome.

To be sure, a sterilization process requires the successful completion of several steps, not just exposure of the instrument to the sterilant. Some of a sterilization process’s other important steps include thorough cleaning to remove organic debris, monitoring with a biological indicator to validate the process’s effectiveness, and instrument wrapping to prevent recontamination during handling and storage.

And it is because of the limitations of LCGs, as well as the complex internal designs of many instruments that do not facilitate cleaning or microbiological sampling to confirm sterility (refer to this newsletter’s February 1997 issue), that, in my opinion, the labels of liquid sterilants should be limited to a high-level disinfection, rather than sterilization, claim.

Happy Holidays! ☺

TABLE 1: Characteristics of liquid chemical germicides

Name of liquid germicide*	Active chemical ingredient(s)	Immersion time for high-level disinfection**	Immersion temperature	Sterilant claim	Maximum reuse life	Activation required?
Peract 20	0.08% peroxyacetic acid and 1% hydrogen peroxide	25 minutes	20 C***	8 hours at 20 C	14 days	No
Sporox	7.5% hydrogen peroxide	30 minutes	20 C	6 hours at 20 C	21 days	No
Cidex	2.4% glutaraldehyde (alkaline)	45 minutes	25 C	10 hours at 25 C	14 days	Yes

TABLES 1’s LEGEND:

* Peract™ 20 is marketed by the Minntech Corp.; Sporox® is marketed by Reckitt and Colman, Inc.; and Cidex™ is marketed by Johnson and Johnson Medical, Inc.

** The indicated immersion time assumes that the instrument has not been pre-cleaned prior to high-level disinfection.

*** 20° C is considered to be room temperature.

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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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