

The Q-Net™ Monthly

Volume 5, Number 11

November 1999

What's News

Last month's newsletter, which discussed the properties of several liquid chemical germicides recently cleared by the FDA, contained the following statement: "And Cidex® OPA may not be a sterilant (as previously defined and required by the FDA to be labeled as a high-level disinfectant)."

In an attempt to resolve any confusion that this statement may have caused, this month's issue publishes comments submitted by a representative of Advanced Sterilization Products, who sells Cidex® OPA. A closing commentary is also provided.

'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.

Cidex® OPA Revisited

Readership Feedback

On an internet list-server dedicated to perioperative nursing, an infection control coordinator recently wrote:

"I have seen publication of the passage of Cidex® OPA as a high level disinfectant. The information states that the sterilant claim is not applicable. Since my understanding of the FDA approval for a high level disinfectant was that it be sporicidal, I do not understand how the disinfectant can receive this classification. Hopefully, someone can explain the change in labeling."

Last month's issue of this newsletter discussed Cidex® OPA and may have been the publication to which this infection control coordinator is referring. Martin S. Favero, Ph.D., *Director of Scientific and Clinical Affairs, Advanced Sterilization Products (a Johnson and Johnson Company, Irvine, CA)*, asked that this newsletter publish in its entirety his response to this question.

Martin Favero: I would like to clarify the classification question of CIDEX® OPA Solution - High Level Disinfectant.

On October 8th, 1999, the Food and Drug Administration (FDA) cleared CIDEX® OPA, a high level disinfectant, for market under 510(k) number 991487. The active ingredient is 0.55% ortho-phthalaldehyde.

The FDA draft guidance document,

dated 12/18/97, defines a high level disinfectant as: "A germicide that inactivates all microbial pathogens, except large numbers of bacterial endospores, when used according to labeling (Rutala, 1996; Spaulding, 1972)".

The document further explains that: "In order to support a high level disinfection claim, the germicide must pass the AOAC Sporocidal Test as a sterilant as indicated under the Sterilization Claim."

I would like to point out that CIDEX® OPA passed the AOAC Sporocidal Test. After 14 days of simulated reuse CIDEX® OPA passed the AOAC Sporocidal test at 20°C in 32 hours. Full strength, unused product passed at 25°C in 10 hours. Complete data were submitted to and reviewed by the FDA.

The decision not to file for a sterilization claim for this product was based on discussions with and suggestions from the FDA. In addition liquid chemical germicides formulated as sterilants are very infrequently used as such, but rather are used as high level disinfectants.

Since the primary use for CIDEX® OPA is the high level disinfection of semi-critical medical devices in 12 minutes at 20°C, Advanced Sterilization Products agreed with the FDA and made the decision to pursue market clearance for CIDEX® OPA as a high level disinfectant only, and not as a sterilant.

CIDEX® OPA does in fact fit the Spaulding definition of a high level disinfectant as Dr. Spaulding first described it (Spaulding, 1971; Spaulding, 1972), and as it is referred to in the current CDC Guidelines on Handwashing and Environmental Control (Garner and Favero, 1985) and the APIC Guidelines (Rutala, 1996).

Walter Bond and I expanded
(Continued on page 22)

(Continued from page 21)

Spaulding's definitions and suggested that users employ the EPA registration criteria as a guide (Favero and Bond, 1991). At that time, the EPA registered chemical germicides formulated as sterilants and disinfectants used in health-care settings. The advantage of using this system was that trade names of products did not have to be used in official recommendations. Since 1996, the FDA has the regulatory authority over chemical germicides used on critical and semi-critical medical devices. The FDA also separately defined high level disinfectants. A high level disinfectant is still one that has sporicidal capabilities but does not necessarily need to be classified as a sterilant. In our most recent chapter Walter Bond and I have listed the actual formulations and products that have been cleared for marketing in the United States by the FDA (Favero and Bond, in press).

CIDEX® OPA has been tested for materials compatibility with a wide range of medical devices. Olympus and Pentax in particular have stated that CIDEX® OPA is compatible with their endoscopic instruments.

The FDA maintains a list on its website, "Sterilants and High Level Disinfectants cleared by FDA in a 510(k) with General Claims for Processing Reusable Medical and Dental Devices." The internet address for this website is:

<http://www.fda.gov/cdrh/ode/germlab.html>

References

1. Favero MS, Bond WW. Chemical disinfection of medical surgical material. In: SS Block, ed., Disinfection, Sterilization, and Preservation, 4th Edition, Lea and Febiger, Philadelphia, pp. 617-641, 1991.
2. Favero MS, Bond WW. Chemical disinfection of medical surgical material. In: SS Block, Ed. Disinfection, sterilization and preservation, 5th Ed. Williams and Wilkins, in press.
3. Garner, JS, and Favero, MS. Guidelines for handwashing and hospital environmental control. Atlanta, Centers for Disease Control. HHS publication No. 99-1117, 1985.
4. Rutala, WA. Guideline for selection and use of disinfectants. *Am J Infect Control* 1996;24:313-342.
5. Spaulding, EH. Role of chemical disinfection in the prevention of nosocomial infections. In Proceedings of the International Conference on Nosocomial Infections, 1970. Edited by P.S. Brachman and T.C. Eickhoff. Chicago, American Hospital Association, pp. 247-254, 1971.
6. Spaulding, EH. Chemical disinfection and antisepsis in the hospital. *J Hosp Res* 1972; 9:5-31.

Copyright © 1995-1999. All rights reserved. *It is a violation of federal copyright laws (17 U.S.C. Sec. 101 et seq.) to copy, fax, or reproduce any portion of this newsletter without its publisher's consent. Q-Net is a registered trademark of Custom Ultrasonics, Inc.* (v2_99)

Commentary: A Brief Response

Lawrence F Muscarella: I would like to thank Dr. Favero for providing this newsletter the opportunity to publish his response to a question about Cidex® OPA's sporicidal effectiveness and classification as a high level disinfectant.

In his response Dr. Favero clarifies several important issues. As he explains, Cidex® OPA passed the AOAC Sporidical Test in 32 hours at room temperature. And like Cidex® (2% glutaraldehyde), which is its 510(k) predicate device, Cidex® OPA passed this test in 10 hours at 25°C. Indeed, the FDA recommends that liquid chemical germicides (LCGs) labeled for high level disinfection also be sporicidal. According to its guidance document for 510(k) submission of LCGs, the FDA states: "In order to support a high level disinfection claim, the germicide must pass the AOAC Sporidical Test as a sterilant." As Dr. Favero points out, this criterion has been satisfied, albeit at an elevated temperature.

What may have been confusing to some readers of last month's newsletter is the rationale for *Advanced Sterilization Products (ASP)* deciding *not* to include a sporicidal claim on Cidex® OPA's label, its sporicidal properties notwithstanding. As some readers realized, this product's label claim marks an apparent departure from the FDA's heretofore policy for granting 510(k) clearances to manufacturers of LCGs. With the exception of Cidex® OPA, all LCGs currently cleared by the FDA for high level disinfection include on their label a sporicidal claim, in addition to a tuberculocidal claim.

So what is the clinical significance of Cidex OPA's label? While clinical data demonstrating its effectiveness is currently limited, Cidex® OPA appears to be an effective and rapid-acting LCG suitable for high level disinfection of flexible endoscopes and other semi-critical instruments. In short, ASP's decision to label Cidex® OPA as a high level disinfectant, and not also as a sterilant, is unlikely to be clinically significant. For, as Dr. Favero further explains, LCGs are generally used to achieve high-level disinfection, not 'sterilization.'

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:

Lawrence F Muscarella, PhD
Director, Research and Development
Chief, Infection Control

Custom Ultrasonics, Inc.

144 Railroad Drive
Ivyland, PA 18974

Tele: 215.364.8577; Fax: 561.258.8051

E-mail: q-net@email.msn.com

<http://www.myendosite.com>

