



A Critique of Metrex's Claims about MetriCide OPA Plus™ Solution

PURPOSE

This document provides a critical review of the white paper issued by Metrex in support of their new *ortho*-phthalaldehyde-based high-level disinfectant (HLD).¹

MAIN POINTS

- Metrex has recently introduced a new high-level disinfectant with the same active ingredient as CIDEX® OPA *ortho*-Phthalaldehyde Solution.
- Metrex makes several claims about MetriCide OPA Plus™ Solution relative to CIDEX® OPA Solution. Metrex claims MetriCide OPA Plus™:
 - Remains effective for more reprocessing cycles than CIDEX® OPA Solution
 - Has easy-to-read test strips
 - Is as safe, as effective, and as compatible with medical materials as CIDEX® OPA Solution¹
- The white paper does not include scientific evidence to back up these claims.

SCIENTIFIC WRITING CONVENTIONS

Scientific papers typically include background information from other studies which set the context for the article. The Metrex white paper did not include citations for scientific articles.

The paper did have a brief bibliography with six references, however the citations included were:

- Not available (internal company documents)
- Not relevant (a patent document for glutaraldehyde)
- Not balanced (the MSDS and IFU for CIDEX® OPA Solution were cited, but there were no MetriCide documents)

REUSE EVALUATION

METREX'S CLAIM

"MetriCide OPA Plus™ Solution produced 32 additional disinfection cycles (40% more) in the Custom Ultrasonics System 83 Plus 2, than achieved with CIDEX® OPA Solution under similar test conditions."¹

METREX'S TEST METHODS AND RESULTS

Metrex paid a lab to compare the number of cycles MetriCide OPA Plus™ Solution and CIDEX® OPA Solution achieved before test strips indicated failure.

- One batch of each HLD was tested over 14 days
- Custom Ultrasonics AERs with a Pentax and an Olympus endoscope were used
- Seven cycles were run per day for 10 days and four cycles were run on the 11th day
- Bioburden was added to the AER basin daily
- Concentrations were monitored with test strips¹

The lab reported that:

- MetriCide OPA Plus™ achieved 74 cycles
- CIDEX® OPA Solution achieved 42 cycles¹

CRITIQUE OF METHODS AND FINDINGS

Scientific papers should include enough detail to allow other researchers to replicate the study. There are significant gaps that leave the reader without critical information, such as:

- Did observers have good visual acuity and color discernment?
- How much solution was used in the AER?
- What were the actual initial and final OPA concentrations?
- What was the composition of the bioburden?
- How much bioburden was added to the basin?
- What was the microbe-killing ability of each solution?
- When were the tests conducted?



Several aspects of the Metrex test procedure were scientifically flawed:

- Solution expiration dates were vastly different:
 - CIDEX® OPA *ortho*-phthalaldehyde Solution: November 2008
 - MetriCide OPA Plus™: August 2009¹
- Test strip expiration dates were very different:
 - CIDEX® OPA Solution: February 2008
 - MetriCide OPA Plus™: August 2008¹
- Since only test strips were used to test the solution,¹ it is not clear whether there was truly a difference in concentration of the solution, or issues with the accuracy of the test strips.
- Metrex chose to test each solution only once,¹ when replication of experiments is an essential part of scientific inquiry.

CONTRASTING METHODS AND FINDINGS IN CLINICALLY BASED PUBLISHED LITERATURE

In 2003, *Gastroenterology Nursing* published a study which tested CIDEX® OPA Solution at Massachusetts General Hospital (MGH).²

The methods of this study were more rigorous than the Metrex test, including:

- Reprocessing 1,839 endoscopes in 1,201 cycles in a Custom Ultrasonics AER
- Reprocessing clinically used endoscopes
- Testing solutions by:
 - Test strips
 - Chemical tests of concentration
 - Antimicrobial efficacy²

In contrast to the Metrex findings, the MGH study found that CIDEX® OPA Solution:

- Lasted the entire two-week reuse period
- Reprocessed an average of 80 endoscopes per batch (with a maximum of 98 cycles)²

Thus this larger, more rigorous clinical study does not substantiate Metrex’s test results.

TEST STRIP EVALUATION

METREX’S CLAIMS

“MetriCide OPA Plus™ Solution Test Strips offer significant advantages over that of the CIDEX® OPA Solution Test Strips. These advantages include:

- 33% faster test results than the CIDEX® OPA Test Strips.
- Easy interpretation of pass/fail results when compared to color blocks located on the MetriCide OPA Plus™ Solution Test Strip Bottle.
- MetriCide OPA Plus™ Solution Test Strips are more conveniently packaged in 100 test strips per bottle to enhance test strip availability.”¹

METREX’S TEST METHODS AND FINDINGS

The white paper does not describe any research process or findings that back up these claims.

CRITIQUE OF METHODS AND FINDINGS

- How was test strip speed assessed?
- How was ease of interpretation assessed?
- How does Metrex packaging enhance availability?

USE STABILITY TESTING

METREX’S CLAIM

Metrex claimed the pH, concentration, and appearance of their solution “remained relatively unchanged” over the 75-day test period.¹

METREX’S TEST METHODS AND RESULTS

Use stability appears to have been tested by leaving three containers of MetriCide OPA Plus™ Solution open for 75 days. During the test period, pH, concentration, and appearance were evaluated at Days 1, 30, and 75.

Metrex reported the following results:¹

Use Stability Test Results		
OPA Lot	% OPA (Day 1)	% OPA (Day 75)
A	0.64	0.67
B	0.66	0.71
C	0.63	0.65

Note: The increase in OPA concentration was attributed to water evaporation.



CRITIQUE OF METHODS AND FINDINGS

- How was appearance evaluated?
- How were pH and concentration tested?

MetriCide OPA Plus™ Solution's concentration was greater than the 0.60% advertised even at baseline. The increased concentration may partially explain the added number of cycles reported in reuse testing.³ The actual concentration of CIDEX® OPA *ortho*-phthalaldehyde Solution was not tested.

SAFETY TESTING

METREX'S CLAIM

"Test results point out the equivalent safety of these products." [MetriCide OPA Plus™ Solution and CIDEX® OPA Solution]¹

METREX'S TEST METHODS AND RESULTS

There are no descriptions or references for the safety test data for MetriCide OPA Plus™ Solution.

CIDEX® OPA Solution test results were taken from the product Material Safety and Data Sheet.

Metrex concluded the two high-level disinfectants were equivalent with respect to safety.¹ However, potential effects of using a higher initial concentration of MetriCide OPA Plus™ Solution were not addressed.

CRITIQUE OF METHODS AND FINDINGS

There is no explanation of the methods or results for the tests presented, so evaluation of the conclusions is not possible.

MICROBIOLOGICAL EFFICACY TESTING

METREX'S CLAIM

MetriCide OPA Plus™ Solution is equivalent to CIDEX® OPA Solution in efficacy against microbes.¹

METREX'S TEST METHODS AND RESULTS

Aside from mentioning the tests were conducted in accordance with EPA standards (which were not cited), there is no further information about test methods.¹

For microbes where both solutions were tested, the killing time results reported are equal. For example, both CIDEX® OPA Solution and MetriCide OPA Plus™ Solution reported to have killed HIV-1 in five minutes.¹

CRITIQUE OF METHODS AND FINDINGS

- How were the tests conducted?
- Were the organisms tested laboratory or clinical strains?
- Was the first evaluation of antimicrobial activity done at 5 minutes?
- Was MetriCide OPA Plus™ Solution able to kill the microbes at shorter time frames?

CONTRASTING METHODS AND FINDINGS IN PUBLISHED LITERATURE

CIDEX® OPA Solution has been tested extensively by independent researchers around the world using a variety of methods.^{4,5}

Japanese researchers tested CIDEX® OPA Solution against 21 strains of disease-causing microbes.⁴ CIDEX® OPA Solution at 0.50% concentration was able to kill:

- All vegetative bacteria within 15 seconds
- All mycobacteria within one minute
- All fungi within one minute

Spanish researchers tested CIDEX® OPA Solution against microbes that were freshly isolated from intensive care units patients under "worst case" conditions.⁵ Freshly isolated organisms may be more resistant to HLD killing action than the typically used laboratory strains which weaken over time.

"The increased susceptibility of laboratory-adapted organisms may allow any disinfectant product to pass the standard tests but the product may fail in the clinical setting."⁵

The "worst case" conditions included:

- Contaminating rough-surfaced instruments (files used on teeth)
- Allowing the contaminated files to dry

The contaminated files were exposed to CIDEX® OPA Solution for 10 minutes.⁵

The researchers conducted this experiment found CIDEX® OPA Solution was able to kill 77% of the organisms tested within 10 minutes.⁵

DISCUSSION AND CONCLUSIONS

There are technical flaws in the MetriCide OPA Plus™ Solution white paper. These include:

- Not clearly stating the methods used to conduct tests.
- Not referencing the sources for data used from others' work.
- Drawing conclusions based on conjecture or opinion.
- Testing solutions with very different expiration dates.
- Not conducting confirmatory tests of concentration during the reuse study.
- Not including relevant references.

Given that the two HLDs do have the same active ingredient at very similar concentrations, it is reasonable to assume the properties are very similar. However, the increased efficiency claims do not seem to be well supported by what is presented in the white paper, nor what is available in the published literature.



REFERENCES

1. Bruckner N. *Comparison of MetriCide OPA Plus Solution and CIDEX OPA Solution Use Properties*. Orange, CA: Metrex Research Corporation; October 2007.
2. Hession S. Endoscope disinfection by *ortho*-phthalaldehyde in a clinical setting. *Gastroenterology Nursing*. 2003;26(3):110-114.
3. Bruckner N, Gordon M, Howell R, Bruckner N, Gordon M, Howell R Bruckner N, Gordon M, Howell Rs. Odorless aromatic dialdehyde disinfecting and sterilizing composition and method of using the same. US patent 4,971,999. May 1987.
4. Akamatsu T, Minemoto M, Uyeda M. Evaluation of the antimicrobial activity and materials compatibility of *ortho*-phthalaldehyde as a high-level disinfectant. *J Int Med Res*. March-April 2005;33(2):178-187.
5. Herruzo-Cabrera R, Vizcaino-Alcaide MJ, Fernandez-Acenero MJ. The influence of laboratory adaptation on test strains, such as *Pseudomonas aeruginosa*, in the evaluation of the antimicrobial efficacy of *ortho*-phthalaldehyde. *J Hosp Infect*. July 2004;57(3):217-222.

ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.

a **Johnson+Johnson** company

MetriCide OPA Plus is a registered trademark of Metrex Corporation.
Olympus is a registered trademark of Olympus Corporation.
Pentax is a registered trademark of Pentax Medical Company.
© Ethicon, Inc. 2011

AD-080005-01-US_B