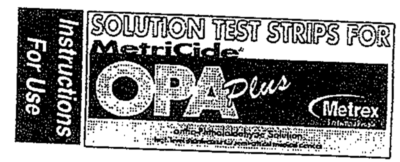

Metrex
Protecting People

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Made in U.S.A.

For technical
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1-800-841-1428

70-6005-1

MetriCide® OPA Plus Solution Test Strips

. Intended Use

letriCide OPA Plus Solution Test Strips are semi-quantitative hemical indicators for use in determining whether the concentration of *rtho*-phthalaldehyde, the active ingredient in MetriCide OPA Plus olution, is above or below the Minimum Recommended Concentration MRC) established for MetriCide OPA Plus Solution.

letriCide OPA Plus Solution Test Strips cannot be used to validate e disinfection process.

. Explanation of the Test

letriCide OPA Plus Solution Test Strips were developed exclusively r monitoring the Minimum Recommended Concentration (MRC) of letriCide OPA Plus Solution. It is recommended that MetriCide OPA lus Solution be tested before each usage with the MetriCide OPA Plus olution Test Strips in order to guard against dilution, which may lower e *ortho*-phthalaldehyde level of the solution below its MRC of 0.3%.

. Chemical Principle of the Test Procedure

rtho-Phthalaldehyde reacts with sodium sulfite in the test strip to form sulfite addition product and an equivalent amount of base (STEP 1). If fficient *ortho*-phthalaldehyde is present, the increase in pH causes a lor change in the pH indicator (STEP 2).

TEP 1

$C_6H_4(CHO)_2$ + $2Na_2SO_3$ + $2H_2O$ → $C_6H_4(CH(SO_3Na)OH)_2$ + $2NaOH$

tho-phthalaldehyde + Sodium sulfite + Water → lfite addition product + Sodium hydroxide

TEP 2

OH + pH Sensitive dye → MAGENTA dye color

A yellow background dye is included in the reagent pad. When the concentration of *ortho*-phthalaldehyde is sufficient, a color change from light yellow to magenta occurs on the reagent pad at the end of the strips.

D. Reagents/Storage and Stability

The reagent pad at the end of the test strip is composed of paper impregnated with two reactive agents, sodium sulfite, a pH-sensitive dye and a non-reactive yellow background dye.

Store MetriCide OPA Plus Solution Test Strips in the original bottle with the cap tightly closed. Store at controlled room temperature, 15-30°C (59-86°F), and in a dry place. The shelf life (expiration date) for the unopened MetriCide OPA Plus Solution Test Strips is stamped on the bottom of the container. When opening the bottle for the first time, record the date opened on the bottle label.

PRECAUTIONS:

- Do not use any remaining strips 90 days after first opening the bottle. Improper storage or use of test strips may result in false readings.
- Tightly close the cap on the bottle after removing a strip or when not in use.
- Do not refrigerate or freeze.
- Protect strips from exposure to light, heat, and moisture.
- Tightly re-cap test strip bottle after each use to minimize exposure to humidity.
- The indicator strips from opened or unopened bottles should not be used after the expiration date.
- A strong acid or base may interfere with the efficacy of the test strip.

E. Specimen Collection and Preparation

MetriCide OPA Plus Solution Test Strips can be used to test MetriCide OPA Plus Solution directly in the tray, bucket or other container holding the solution. When this is not feasible, remove a sufficient volume (~20 ml) of MetriCide OPA Plus Solution to fully submerge the MetriCide OPA Plus Solution Test Strip indicating pad area, and place into a clean plastic container (polyethylene or polypropylene). Appropriate safety precautions should be taken according to label instructions and the Material Safety Data Sheet of the MetriCide OPA Plus Solution.

F. Directions for Use

1. Ensure that the solution to be tested has been dispensed according to labeling instructions.
2. Always note the date the bottle was opened and the "do not use after" date in the space provided on the bottle.
3. Ensure that appropriate safety precautions are observed when testing MetriCide OPA Plus Solution. refer to product labeling and the Material Safety Data Sheet for MetriCide OPA Plus Solution.
4. Remove one test strip from the bottle and replace the bottle cap immediately.
5. Use a watch or timer to monitor the following steps.
6. Timing control is critical to accurate reading.
7. Completely Submerge indicating pad at the end of the test strip into the container of the solution being tested. Hold for two seconds and remove. It is important to hold strip in solution for two seconds. Do not "stir" the test strip in the solution. Incorrect dipping technique, such as very short hold times of a second or less can cause a lack of magenta color formation and indicate a FAIL when testing a solution that will normally test as PASS.
8. Remove excess solution from the indicating pad by shaking excess from the pad.
9. Read the results of the color reaction present on the indicating pad at 60 seconds after the test strip is removed from the solution. If read in less than 60 seconds, the color change may be incomplete and may be interpreted incorrectly. If read past 60 seconds, color will gradually change to indicate "FAIL".

   To indicate an effective concentration of the solution, the indicating pad will be completely magenta. Any shade of magenta is acceptable: the intensity will vary due to concentration variation. If any yellow appears on the indicating pad, the solution should be discarded. Refer to the color chart on the test strip bottle for interpretation of test results. Record the result of the test in a suitable logbook. See Section 1. Test Results Interpretation, for additional important information on the use of this product.
10. Dispose of the used test strip in a waste bin or per clinic or hospital policy.

G. Materials Required

The following materials are not provided with the MetriCide OPA Plus Solution Test Strips but will be needed for the test:

- watch or timer
- a clean polyethylene or polypropylene container will be required to hold the solution sample if the solution cannot be tested directly in the tray, bucket or container in which it is being held.

H. Quality Control Procedures

1. Preparation of Control Solutions

   To prepare positive and negative control solutions for testing, first verify that the labeled expiration date for the solution is appropriate. This solution may be used as a positive control. To prepare a negative control, dilute two parts of full strength solution with three parts of water. Label each control solution appropriately.
2. Testing Procedure

   Following the Directions for Use, submerge three test strips in each of the above freshly prepared solutions for two seconds each. Remove. The three strips dipped in the full strength positive control solution should exhibit a complete magenta color on the indicating pad at 60 seconds. The three strips dipped in the diluted negative control should either be yellow or exhibit an incomplete color change, mixture of yellow and magenta, when read at 60 seconds. Refer to the color chart on the test strip bottle for interpretation of results.
3. Testing Frequency

   It is recommended that the testing of positive and negative controls be performed on each newly opened test strip bottle of MetriCide OPA Plus Solution Test Strips. After this initial testing, it is recommended that testing of freshly prepared positive and negative controls be performed on a regular basis as established by your own quality control procedures and program. This testing program will serve to minimize errors between different users, use of outdated materials or product that has been improperly stored or handled.
4. Unsatisfactory QC Test Performance

   If the results obtained from using the positive and negative controls indicate the test strip is not functioning properly, discard the remaining strips. Do Not Use Strips. For technical product information, contact Metrex at 800-841-1428.

I. Test Results Interpretation

•wing the two-second submersion in the MetriCide OPA Plus tion being tested, remove excess solution from the pad by shaking ıss solution from the pad. The **MetriCide OPA Plus Solution Test** ɔ should then be compared to the color chart provided on the test · bottle at 60 seconds. The entire indicating pad must be completely ɹenta to pass the test indicating an effective concentration of the ıtion. If any yellow appears on the indicating pad, this is a failure. fying the solution is below MRC and should be discarded. The ıtion must be discarded if the Test Strip indicates FAIL.

.imitations

ıough **MetriCide OPA Plus Solution Test Strips** may give a color ıction with *ortho*-phthalaldehyde and glutaraldehyde-based infectants from other manufacturers, their use is limited to the ıtriCide OPA Plus Solution. Disinfectants from other manufacturers ıy claim different MRCs which will lead to inaccurate test results using ıtriCide OPA Plus Solution Test Strips.

ıtriCide OPA Plus Solution Test Strips will not work with ɔinfectant solutions other than **MetriCide OPA Plus Solution.**

Performance Characteristics

ıe performance characteristics of **MetriCide OPA Plus Solution Test** ɔrips are based on testing the strips using samples of MetriCide OPA ɩus Solution with known concentrations of *ortho*-phthalaldehyde at the RC and above the MRC. The analytical method used to determine the *rtho*-phthalaldehyde concentrations in these samples utilized High ressure Liquid Chromatography. The performance of **MetriCide OPA** lus Solution Test Strips has been designed to indicate FAIL 100% of ıe time at the MRC of *ortho*-phthalaldehyde shown below:

DISINFECTANT SOLUTION	MRC (% *ortho*-phthalaldehyde)
MetriCide OPA Plus Solution	0.3%

The accuracy and sensitivity limit of MetriCide OPA Plus Solution Test Strips is approxinvately +0.05% at concentrations of 0.05% above the MRC. The test strips will indicate FAIL some of the time and PASS some of the time at a concentration of 0.35%. This provides the user with a margin of safety. The solution must be discarded if the test strip indicates FAIL.

L. Warnings & Precautions

1. Always follow the instructions for use.
2. THIS PRODUCT IS MOISTURE SENSITIVE AND WILL NOT PERFORM PROPERLY IF STORED INCORRECTLY. Close the bottle immediately after each use.
3. Test Strips should not be returned to the bottle after being removed due to their moisture sensitivity – dispose of any unused Test Strips.
4. Keep out of reach of children.
5. Do not ingest the strip and/or expose it to the eye.
6. Chemical indicators such as **MetriCide OPA Plus Solution Test** Strips cannot be relied upon as a means of validating the sterilization or disinfection process. Chemical indicators can only verify if the MRC is present.
7. Each Test Strip must be discarded after use and not reused.
8. Ensure that appropriate safety precautions are observed when testing MetriCide OPA Plus Solution, refer to product labeling and the Material Safety Data Sheet for MetriCide OPA Plus Solution.

M. Disposal

Dispose of used or expired test strips and their bottle in a waste bin or per clinic or hospital policy.

N. How Supplied

PRODUCT CODES	DESCRIPTION	PACKAGE INFORMATION
10-602	MetriCide OPA PLUS Solution Test Strips	100 Strips/Bottle 2 Bottles/Shipper

Composition: MetriCide OPA Plus Solution Test Strips consist of sodium sulfite and dyes impregnated and dried on filter paper.