

DANGER:
Keep out of reach of children.

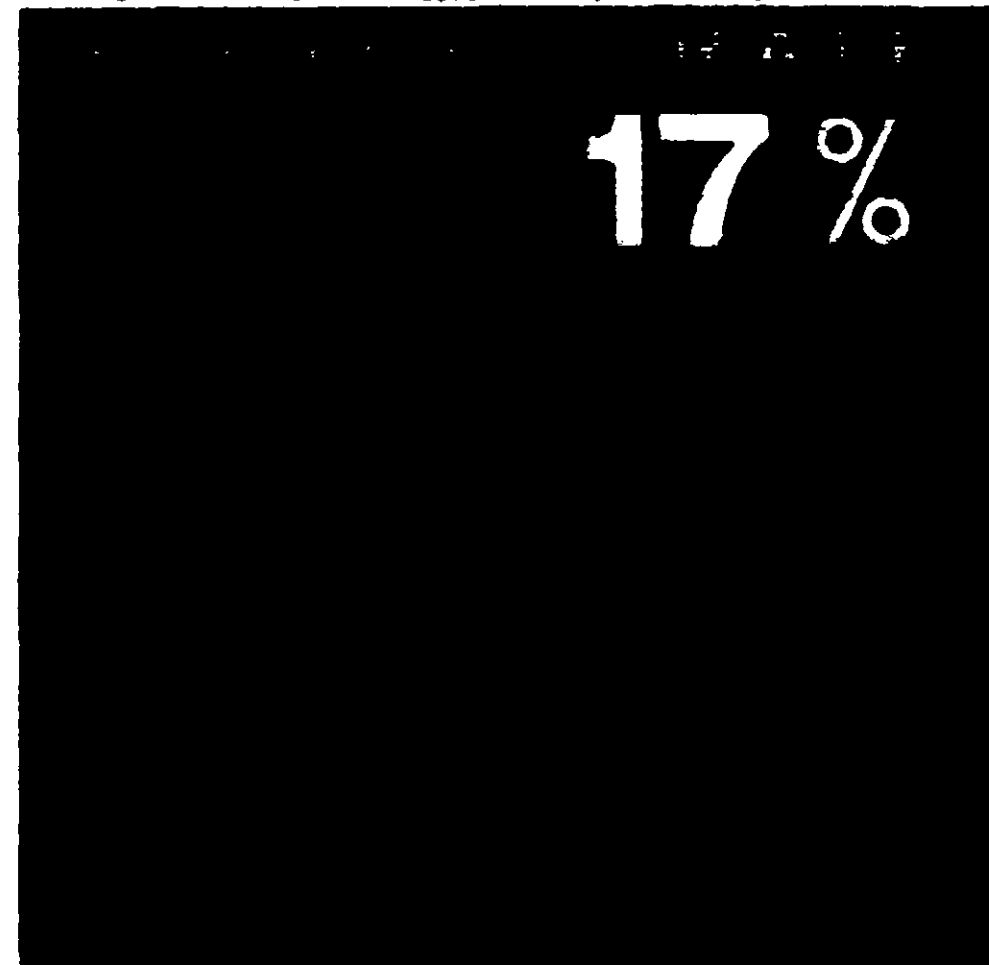
Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Protect eyes and skin when handling. Harmful if swallowed. Avoid contamination of food.

FIRST AID: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

Z-493 HRI 8024-253402
MUST BE DILUTED
Zephiran®
brand of **CHLORIDE**
benzalkonium chloride solution, USP
GERMICIDE and DISINFECTANT



Directions for Dilution
to prepare 1 gallon of Zephiran Chloride

AQUEOUS SOLUTION 1:750

Zephiran Chloride Concentrate... 1 fl. oz.
Distilled water 127 fl. oz.

TINCTURE 1:750

Zephiran Chloride Concentrate... 1 fl. oz.
Alcohol, USP 64 fl. oz.
Distilled water..... 63 fl. oz.

Read accompanying circular for uses and other dilutions.

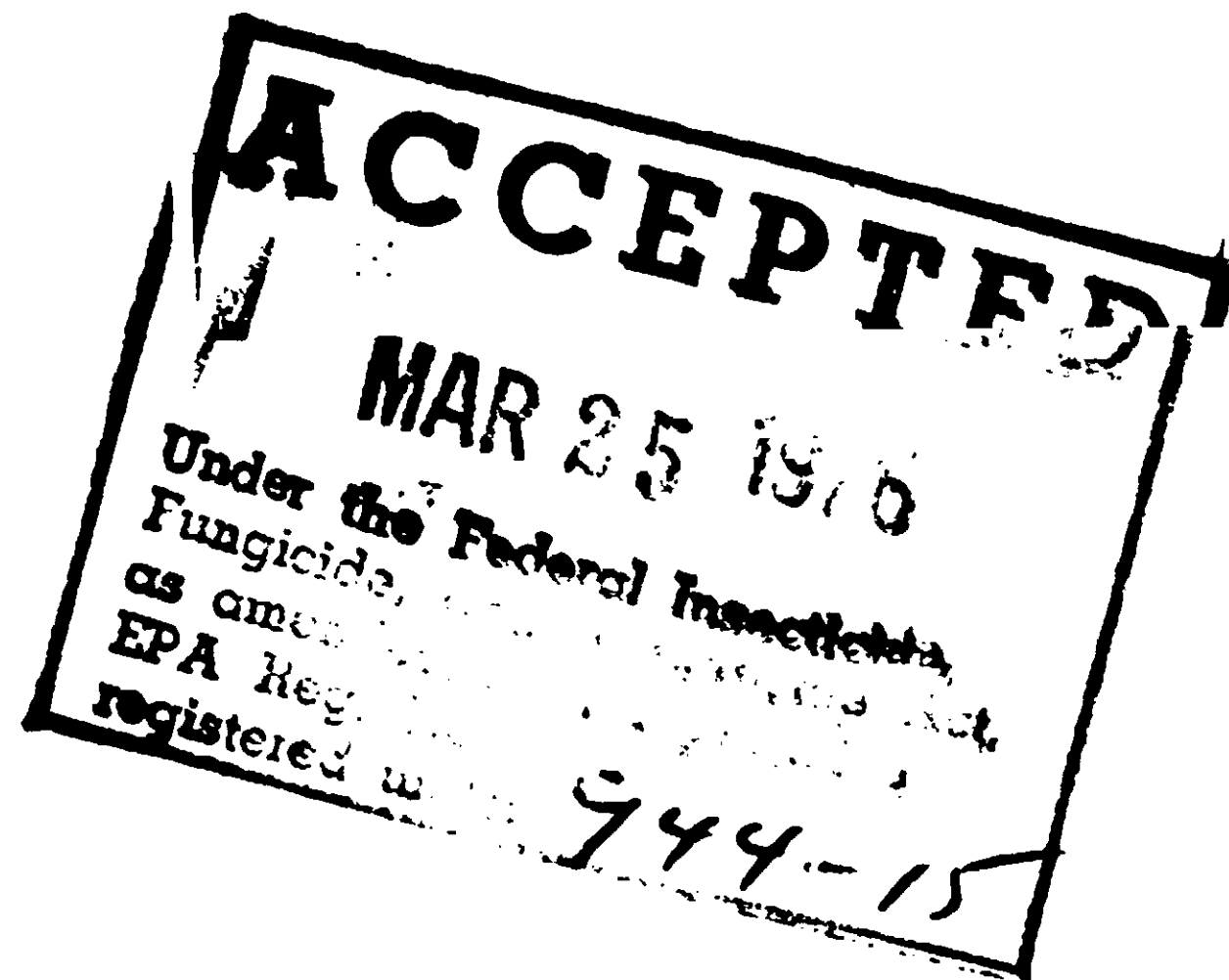
EPA Reg. No. 944-15-ZA
EPA EST. 944-PA-1



Winthrop Laboratories Division of Sterling Drug Inc.
New York, N. Y. 10016

MADE IN U. S. A.

ZW 77B



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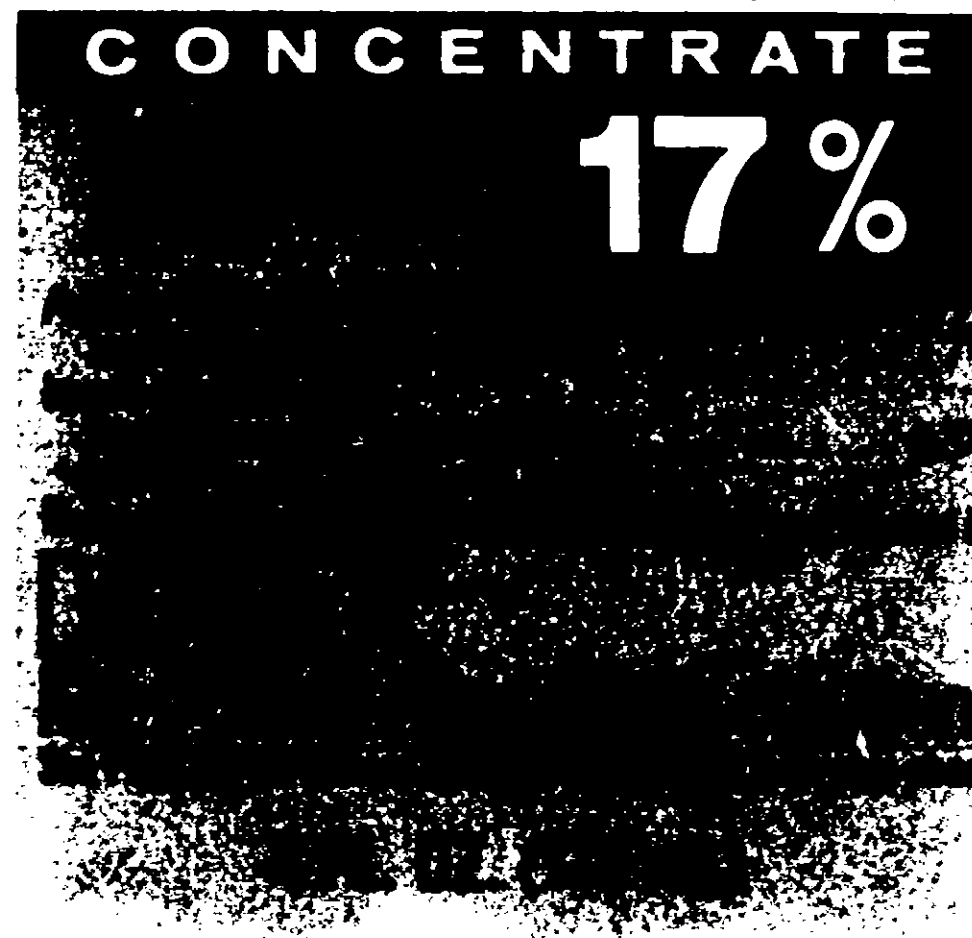
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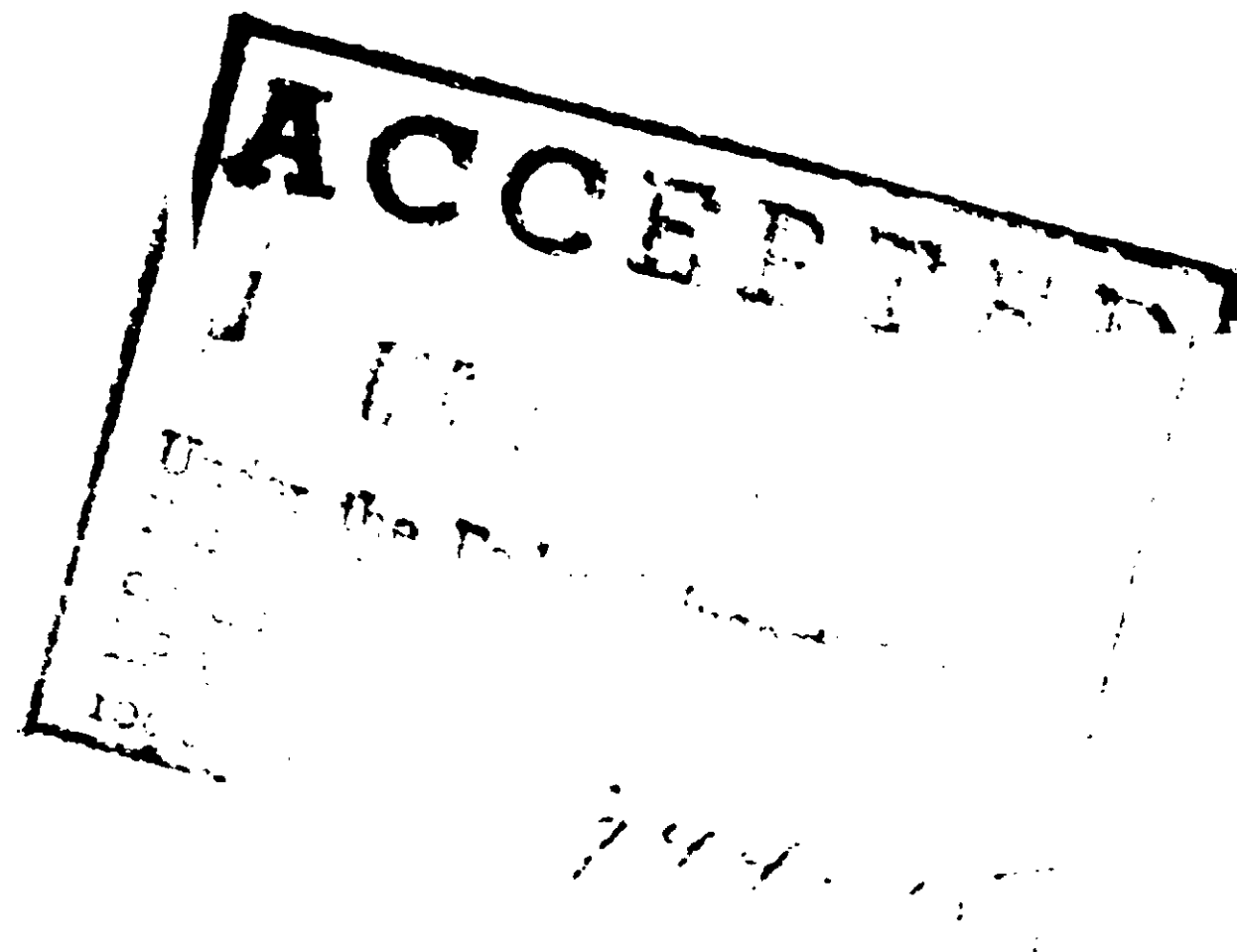
Read accompanying literature for uses and other directions.

EPA Reg. No. 433-ZA
EPA EST. 433402

Winthrop

Winthrop Laboratories, Division of Winthrop Chemical Company
New York, N.Y. 10022

MADE IN U.S.A.



ZEPHIRAN[®] CHLORIDE

Brand of
benzalkonium chloride solution, USP

Concentrate 17% Aqueous Solution

DESCRIPTION

Zephiran Chloride Concentrate, a cationic quaternary ammonium surface acting agent, is a mixture of alkylbenzyltrimethylammonium chlorides which meets USP specifications for benzalkonium chloride solution. The concentrate must be diluted to weaker solutions prior to use. These solutions are generally colorless, odorless, and nonstaining. They have a bitter taste, detergent properties, and foam when shaken.

ANTIMICROBIAL ACTIVITY

The activity of antimicrobial agents is measured by the A.O.A.C. Use-Dilution Test Procedure. Table 1 illustrates the bactericidal activity of Zephiran Chloride when it is evaluated by the Use-Dilution method using representative gram-positive and gram-negative contaminants including *Pseudomonas aeruginosa* (PRD-10).

TABLE 1
Use-Dilution

Test Organisms	P.P.M. Zephiran Chloride (100% Active Ingredient Basis)
<i>Staphylococcus aureus</i>	400
<i>Salmonella choleraesuis</i>	400
<i>Pseudomonas aeruginosa</i> (PRD-10)	1333

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INDICATIONS

Zephiran Chloride in appropriate dilutions is recommended as a disinfectant for hospital utensils and other environmental surfaces and for disinfection and storage of ampuls, thermometers, metal instruments, and catheters.

WARNINGS

Zephiran Chloride Concentrate 17 per cent Aqueous Solution must be diluted with distilled water, preferably freshly distilled water. Deionized water should *not* be used. The deionizing resins can carry pathogens (especially gram-negative bacteria), and also inactivate quaternary ammonium compounds.

Cotton, wool, and certain synthetic fiber materials adsorb some of the Zephiran Chloride from the disinfecting solution, thus greatly decreasing its concentration in the surrounding liquid. Therefore, it is recommended that these adsorbent materials not be stored in containers with Zephiran Chloride solutions.

Since Zephiran Chloride is inactivated by soaps and anionic detergents, thorough rinsing is necessary if these agents are employed prior to its use.

Chemical disinfectants, such as Zephiran Chloride, must not be relied upon to achieve complete sterilization, because they do not destroy all bacterial spores, *Mycobacterium tuberculosis*, and viruses, including the etiologic agent of infectious hepatitis.

IMPORTANT: Zephiran Chloride Concentrate is irritating to human and animal tissues. If Zephiran Chloride, in dilutions stronger than 1:3000 gets into the eyes, they should be immediately and repeatedly rinsed with water. Prompt medical attention is necessary. If Zephiran Chloride Concentrate is spilled on the skin, wash immediately and copiously with soap and water. If ingested, several glasses of milk or whites of eggs should be taken as first aid and a physician notified. (See ACCIDENTAL INGESTION.)

DIRECTIONS FOR USE

General: Zephiran Chloride Aqueous Concentrate is a 17 per cent solution, therefore, one gallon of a 1:750 solution, the usual use-dilution, may be prepared simply by adding 1 fluid ounce of the concentrate to 127 fluid ounces of distilled water, sterile water for injection, or equal parts of distilled water and alcohol.

Hospital Disinfection: For general disinfection of utensils, floors, walls, bathtubs, furniture, operating tables, and other environmental surfaces, first clean with a good cleansing agent. If a soap or an anionic detergent is used, rinse thoroughly with water before sanitizing. Then, wet the surface thoroughly by sponging, mopping, or wiping the surface carefully and completely with Zephiran Chloride Aqueous Solution 1:750.

Disinfection and Storage of Instruments and Supplies:
Warning: For sterilizing hospital articles, dry heat, steam under pressure, and ethylene oxide gas are the best known and most reliable agents. They should be employed in treating any article, instrument, or device that is introduced into the living body whenever possible. Destruction of all microorganisms (sterilization) cannot be achieved by any chemical agent represented as a disinfectant or germicide. Therefore, Zephiran Chloride solutions, like other chemical disinfectant agents, must not be relied upon to destroy bacterial spores, *Mycobacterium tuberculosis*, viruses, or the etiologic agent of infectious hepatitis. If special tuberculocidal effect is required, a tincture made from Zephiran Chloride may be used since it will destroy tubercle bacilli within 30 minutes. Under emergency conditions, or when normal sterilizing treatments are impractical or impossible, disinfecting solutions made from Zephiran Chloride may be employed (see Table 3). Disinfecting solutions must never be used to treat hypodermic syringes, needles, or other instruments introduced directly into the bloodstream or living muscular tissue.

Metallic instruments and ampuls: To disinfect, these must first be cleansed with soap, or a mild alkaline detergent, followed by thorough rinsing in water. Then immerse completely with Zephiran Chloride Aqueous Solution 1:750 for 30 minutes. (See WARNINGS.)

Storage of previously sterilized instruments: A 1:750 aqueous solution of Zephiran Chloride suffices for storage of instruments which have been previously sterilized by

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Metallic instruments and ampuls: To disinfect, these must first be cleansed with soap, or a mild alkaline detergent, followed by thorough rinsing in water. Then immerse completely with Zephiran Chloride Aqueous Solution 1:750 for 30 minutes. (See WARNINGS.)

Storage of previously sterilized instruments: A 1:750 aqueous solution of Zephiran Chloride suffices for storage of instruments which have been previously sterilized by

heat. **Important:** Zephiran Chloride solution should not be used for storage of instruments with lenses fastened by cement (such as cystoscopes or optical instruments), lacerated catheters, or some synthetic rubber goods.

To retard corrosion: Anti-Rust Tablets (containing sodium carbonate and sodium nitrite) should be added to Zephiran Chloride solutions that are to be used for the storage of metal instruments. To each quart of Zephiran Chloride Aqueous Solution, 4 crushed tablets should be added and the solution stirred well before instruments are immersed. Solutions should be changed at least once a week to maintain antioxidant action or when any particulate matter is visible. Instruments containing zinc or aluminum should not be stored in Zephiran Chloride solutions; these metals may react with the alkali in Anti-Rust Tablets. **Warning:** Zephiran Chloride solutions containing an anti-rust compound should be marked or labeled—"Zephiran Chloride with Anti-Rust contains Sodium Nitrite"—in order to prevent application to patients' skin or mucous membranes, since sodium nitrite may cause systemic toxicity or be irritating to the skin. Methemoglobinuria from absorption of the nitrite has been reported following such use in wet dressings over a large body area.

Clinical thermometers: After being washed clean or wiped downward toward the bulb, the thermometer should be immersed in Zephiran Chloride Aqueous Solution 1:750. If special tuberculocidal activity is desired, a tincture made from Zephiran Chloride Concentrate 17 per cent should be used (see Table 3). The solution should be changed frequently.

Adsorbent articles (including catheters): Adsorbent articles such as fabrics, fibers, or catheters, adsorb some of the Zephiran Chloride from the disinfecting solution, greatly reducing its concentration in the surrounding liquid. This will occur, for instance, when gauze is placed under instruments in storage and where cotton pledgets are placed in Zephiran Chloride solutions intended for preparation of the skin prior to hypodermic injections. It has been estimated that 3.5 mg. Zephiran Chloride is removed from 850 ml. of a 1:1000 solution per gram of gauze sponge in 26 hours and it has also been estimated that the reduction in benzalkonium concentration (original 0.643 mg./ml.) when 10 gauze sponges 8" x 4" were immersed for 41 hours, was about 20 per cent. Fabrics should not be placed in instrument solutions and cotton pledgets should only be

dipped in Zephiran Chloride solutions immediately prior to use. It is especially desirable to avoid storage of rayon pledgets since the adsorptive properties of this synthetic fiber are approximately 10 times that of natural cotton. There have been reports of contamination of Zephiran Chloride solutions by organisms when large amounts of fabrics have been stored in containers resulting in adsorption of almost all of the Zephiran Chloride onto the fabric. However, if storage of fabrics is essential, it is strongly suggested that original concentrations of Zephiran Chloride in recommended dilutions be made sufficiently great to allow for adsorption on immersed articles and to assure continued bactericidal activity in the residual solution. A concentration of 1:500 should be employed and replenished every few days, depending on the load placed on the solution.

Catheters and polyethylene tubing may be disinfected by cleansing and then immersion in Zephiran Chloride Aqueous Solution 1:500. The catheters should be thoroughly cleaned with plain soap or a mild alkaline detergent and then completely rinsed. The inner surface should be cleaned by flushing the solution through the lumen several times, using a needle and syringe. The catheter is then completely immersed in the germicide for a minimum of 30 minutes.

RECOMMENDED DILUTIONS

For specific directions, see Tables 2 and 3

Hospital Disinfection

Utensils, floors, walls, bathtubs, furniture, operating tables, and other environmental surfaces:

Aqueous solution 1:750

Storage of Instruments and Supplies

Catheters and other adsorbent articles:

Aqueous solution 1:500 (replenish frequently)

Metal instruments, ampuls, and thermometers:

Aqueous solution 1:750 (replenish frequently)

Prevention of rust:

To protect metal instruments stored in Zephiran Chloride solution, add crushed Anti-Rust Tablets (4 tablets per quart) to the disinfectant solution. Change solution at least once a week.

TABLE 2
Correct Use of Zephiran Chloride

Zephiran Chloride solutions, like any germicidal agent, must be prepared, stored, and used correctly to achieve and maintain their germicidal action. If these factors are not fully appreciated, serious inactivation and contamination of Zephiran Chloride solutions may occur.

CORRECT DILUENTS	CORRECT STORAGE	INCOMPATIBILITIES	PREFERRED FORM
<p>Freshly distilled water is recommended for storage of instruments.</p> <p>Resin deionized water should not be used because the deionizing resins can carry pathogens (especially gram-negative bacteria); they also inactivate quaternary compounds.</p> <p>Stored water is not recommended since it may contain organisms.</p> <p>Tap water may be used but only for general sanitizing purposes in areas where the main water is known to be reasonably clean and not excessively "hard" (under 500 ppm).</p> <p>Saline should not be used since it may decrease the antibacterial potency of Zephiran.</p> <p>Ethyl or isopropyl alcohol should be used where tuberculocidal action is required.</p>	<p>Change frequently: Instrument solutions should be changed frequently depending on the traffic in and out with the resultant accumulating contamination with fats, oils (from the hands), serum proteins, minerals, etc., which could eventually cause some loss in potency of the Zephiran. Solutions should also be discarded because Anti-Rust Tablets will only provide approximately one week's protection against rusting under average conditions.</p> <p>More Anti-Rust Tablets should not be added to solutions because large accumulations of nitrite can gradually decrease the potency of Zephiran.</p>	<p>Anionic detergents and soaps, especially those containing hexachlorophene, should be thoroughly rinsed from instruments or other materials prior to use of Zephiran solutions because they can inactivate Zephiran.</p> <p>Serum and protein material should be removed from instruments, etc. by cleaning with mild soap or an alkaline detergent and followed by a thorough rinse before immersion in Zephiran solutions.</p> <p>Filters or fabrics when stored in Zephiran solutions adsorb Zephiran from the surrounding liquid. Therefore, unless suitable increase in Zephiran concentration is made, the following materials should not be stored in Zephiran solutions containing instruments since a major reduction in Zephiran concentration can occur with possible bacterial contamination of the Zephiran solution:</p> <p>Cotton Gauze sponges Wool Rayon Rubber materials</p> <p>Under certain circumstances the following commonly encountered substances are incompatible with Zephiran:</p> <p>Iodine Aluminum Silver nitrate Caramel Fluorescein Kaolin Nitrates Pine oil Peroxide Zinc sulfate Lanolin Zinc oxide Potassium permanganate Yellow oxide of mercury</p>	<p>Aqueous solutions of Zephiran Chloride are recommended for the storage of previously sterilized instruments and supplies.</p> <p>Tincture of Zephiran is recommended when special tuberculocidal activity is desired.</p>

TABLE 3
Dilution of Zephiran Chloride 17% Concentrate to 1 Gallon

Final Concentration	Concentrate 17%	Alcohol (USP or isopropyl)	Distilled water*
AQUEOUS SOLUTION			
1:500 (0.2%)	1½ fl. oz. (45 ml.)	—	q.s. ad 1 gal.
1:750 (0.13%)	1 fl. oz. (30 ml.)	—	q.s. ad 1 gal.
1:1000 (0.1%)	¾ fl. oz. (22 ml.)	—	q.s. ad 1 gal.
1:2000 (0.05%)	¾ fl. oz. (11 ml.)	—	q.s. ad 1 gal.
1:3000 (0.03%)	¼ fl. oz. (7.4 ml.)	—	q.s. ad 1 gal.
TINCTURE			
1:750 (0.13%)	1 fl. oz. (30 ml.)	64 fl. oz.	q.s. ad 1 gal.
1:1000 (0.1%)	¾ fl. oz. (22 ml.)	64 fl. oz.	q.s. ad 1 gal.

*Freshly distilled water is preferable, since stored water may contain many organisms. Chemically deionized water should not be used.

ACCIDENTAL INGESTION

If taken internally, especially as a concentrated solution, marked local irritation of the gastrointestinal lining may occur with nausea, vomiting, collapse, and coma. Restlessness, apprehension, confusion, dyspnea, cyanosis, convulsions, and muscle weakness may occur. Death occurs as a result of paralysis of the respiratory muscles. **Treatment:** Administration of several glasses of a mild soap solution, milk, or egg white beaten in water is recommended. Because the 17 per cent concentrate is corrosive, gastric lavage is not advised. However, in the case of ingestion of more dilute solutions of Zephiran Chloride, gastric lavage with a mild soap solution is recommended. Alcohol should be avoided as it promotes absorption.

To support respiration, the airway should be clear and oxygen should be administered, with artificial respiration if necessary. If convulsions occur, a short-acting barbiturate may be given parenterally with caution.

If solutions containing Anti-Rust are ingested, the effects of sodium carbonate are manifested by gastric symptoms typical of locally irritant poisons. Nitrite poisoning may be serious and is manifested mainly by cardiovascular collapse,

TABLE 3
Dilution of Zephiran Chloride 17% Concentrate to 1 Gallon

Final Concentration	Concentrate 17%	Alcohol (USP or Isopropyl)	Distilled water*
AQUEOUS SOLUTION			
50 (0.2%)	1½ fl. oz. (45 ml.)	—	q.s. ad 1 gal.
50 (0.13%)	1 fl. oz. (30 ml.)	—	q.s. ad 1 gal.
500 (0.1%)	¾ fl. oz. (22 ml.)	—	q.s. ad 1 gal.
500 (0.05%)	¾ fl. oz. (11 ml.)	—	q.s. ad 1 gal.
500 (0.03%)	¼ fl. oz. (7.4 ml.)	—	q.s. ad 1 gal.
INJECTION			
50 (0.13%)	1 fl. oz. (30 ml.)	64 fl. oz.	q.s. ad 1 gal.
500 (0.1%)	¾ fl. oz. (22 ml.)	64 fl. oz.	q.s. ad 1 gal.

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If solutions containing Anti-Rust are ingested, the effects of sodium carbonate are manifested by gastric symptoms similar to those of locally irritant poisons. Nitrite poisoning may be fatal and is manifested mainly by cardiovascular collapse,

with rapid marked fall in blood pressure, tachycardia, muscular weakness, dyspnea, and slate-colored mucous membranes. If very large doses are taken, methemoglobinemia occurs and results in anoxia.

Sodium carbonate may be neutralized by large amounts of diluted acids in the form of diluted vinegar, lemon juice, or orange juice. Fixed oils such as olive oil may be given in small amounts to protect irritated mucous membranes.

For nitrite poisoning, the patient is kept in shock position and comfortably warm. Oxygen should be administered (especially if methemoglobinemia is present). Methylene blue has also been used to treat methemoglobinemia.

HOW SUPPLIED

Zephiran Chloride Concentrate 17% Aqueous Solution (Must be diluted with distilled water.) Bottles of 4 fl. oz. and 1 gallon

Also available are:

Zephiran Chloride Aqueous Solution 1:750 Bottles of 8 fl. oz. and 1 gallon

Anti-Rust Tablets Bottles of 50 and 500

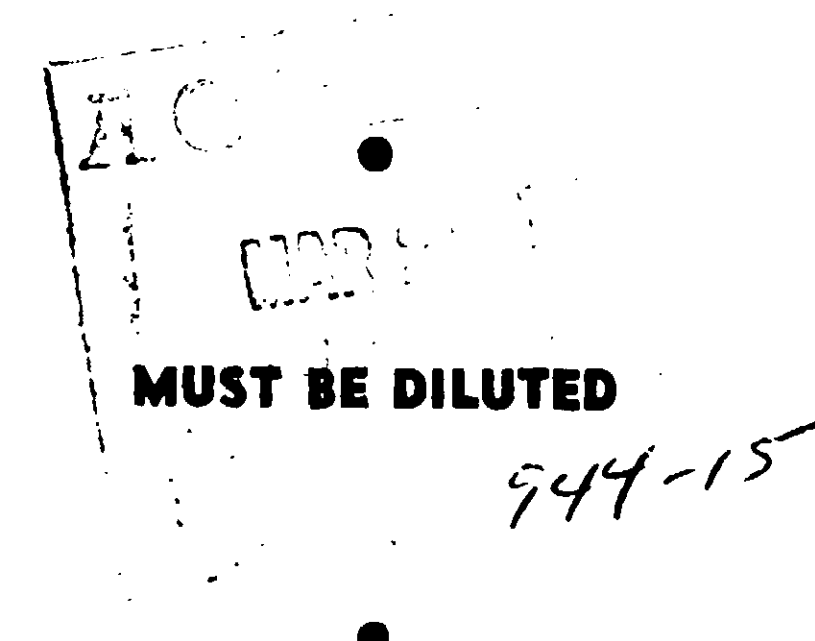


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