Z-463 HRI 8024 253104

Zephiran®

CHLORIDE

brand of

benzalkonium chloride, USP, refined

GERMICIDE and DISINFECTANT

1:750

Winthrop

For disinfection of hospital utensils, disinfection of environmental surfaces, and for storage of previously sterilized instruments (with Anti Rust Tablets)

Read accompanying circular.

Rinse empty container thoroughly with water and discard

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

EPA Reg. No. 9444-16-AA

ZW 73

ACCEPTED

JUL 2 1974

UNDER THE FEDERAL INSECTICIDE FUNGICIDE AND RODENTICIDE ACT FOR ECONOMIC POISON REGISTERED UNDER NO. 7044-16

Z-463 HRI

Zephiran®

brand of

benzalkonium chloride, USP, refined

GERMICIDE and DISINFECTANT

AQUEOUS SOLUTION 1:750

Active ingredients—n-alkyl* dimethyl benzyl ammonium chlorides	0.13%
Inert ingredients	99.87%

*C14 (50%), C12 (40%), C16 (10%)

CAUTION:

Keep out of the reach of children.

8 FL. OZ. (236 ML.)

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 STORAGE	INCOMPATIBILITIES	PREFERRED FORM
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. **More Anti-Rust Tablets** should not be added to solutions because large accumulations of nitrite can gradually decrease the potency of Zephiran.	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. 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 Fibers 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: Cotton — Gauze sponges Wool — Rayon Rubber materials Under certain circumstances the following commonly encountered substances are incompatible with Zephiran: Iodine — Aluminum Silver nitrate — Caramel Fluorescein — Kaolin Nitrates — Pine oil Peroxide — Zinc sulfate Lanolin — Zinc oxide Potassium permanganate — Yellow oxide of mercury	Aqueous solutions of Zephiran Chloride are recommended for the storage of previously sterilized instruments and supplies.

HOW SUPPLIED

Zephiran Chloride Aqueous Solution 1:750	Bottles of 8 fl. oz. and 1 gallon
Also available are:	
Zephiran Chloride Concentrate 17% Aqueous Solution, buffered with ammonium acetate (Must be diluted with distilled water.)	Bottles of 4 fl. oz and 1 gallon
Anti-Rust Tablets	Bottles of 50 and 500

Winthrop

ZW-72

ZEPHIRAN® CHLORIDE

Brand of

benzalkonium chloride, USP, refined

Aqueous Solution 1:750

Germicide and Disinfectant

EPA Reg. No. 944-16-AA

DESCRIPTION

Zephiran Chloride is a mixture of alkyldimethylbenzyl ammonium chlorides whose formula meets USP specifications for benzalkonium chloride solution. Solutions are colorless and usually nonstaining. They have a slight aromatic odor and acrid taste, detergent properties, and may foam when shaken. After tests of stability were performed by freezing Zephiran Chloride in dry ice and storing in this state, its efficacy was unchanged. Zephiran Chloride Aqueous Solution 1:750 may be autoclaved for 30 minutes without affecting its chemical or microbiological properties, providing this is done in a suitable inactive container and closure. However, as certain types of rubber may inactivate Zephiran Chloride, they should be tested for compatibility.

ANTIMICROBIAL ACTIVITY

The activity of antimicrobial agents is measured by the A.O.A.C. Use-Dilution method. 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)
Staphylococcus aureus	1333
Salmonella choleraesuis	1333
Pseudomonas aeruginosa (PRD-10)	1333

INDICATIONS

Zephiran Chloride Aqueous Solution is recommended as a disinfectant for hospital utensils and other environmental surfaces, and for the disinfection and storage of ampuls, thermometers, and metal instruments.

WARNINGS

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 ingested, several glasses of milk or whites of eggs should be taken as first aid and a physician notified. (See ACCIDENTAL INGESTION.)

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.

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.

Generally, when dilutions of Zephiran Chloride Aqueous Solution 1:750 are desired, distilled water, preferably freshly distilled, must be used. Deionized water should *not* be used. The deionizing resins can carry pathogens (especially gram-negative bacteria) and also inactivate quaternary ammonium compounds

ACCIDENTAL INGESTION

If Zephiran Chloride Aqueous Solution is taken internally, local irritation of the gastrointestinal tract may occur and be manifested by nausea and vomiting. If sufficient quantities are absorbed, the toxicity of quaternary ammonium compounds is manifested by 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 whites of eggs beaten in water should be followed by gastric lavage with a weak soap solution. 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, 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 a shock position and comfortably warm. Oxygen should be administered (especially if methemoglobinemia is present). Methylene blue has also been used to treat methemoglobinemia.

DIRECTIONS FOR USE

Hospital 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 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 Aqueous 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. Under emergency conditions, or when normal sterilizing treatments are impractical or impossible, Zephiran Chloride Aqueous disinfecting solutions may be employed. 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 in 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 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), lacquered 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. The solution should be changed frequently.

RECOMMENDED USE OF THIS DILUTION

For specific directions, see Table 2

Hospital Disinfection

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

Aqueous solution 1:750

Storage of Instruments and Supplies

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.