675-26 3-8- 4/8

ACCEPTED
675-26
3-8-74
UNDER THE FEDERAL INSECTICIDE FUNGICIDE AND RODENTICIDE ACT FOR ECONOMIC POISON REGISTERED UNDER NO. [redacted] SUBJECT TO ATTACHED COMMENTS. [redacted]

Quatsyl* 256

CLEANER
DISINFECTANT

E.P.A. Registration No. 675-26-AA

A Super Concentrated Germicide Based on a Unique Blend of Quaternaries

DISINFECTS - CLEANS - DEODORIZES

LABORATORIES

Lehn & Fink Industrial Products Division of Sterling Drug Inc.

America's foremost manufacturer of disinfectants and disinfectant-detergents for environmental sanitation

*Trademark

Quatsyl* 256

Not only hospitals, but schools, offices, factories, and institutions of all types must constantly combat the threat of cross-contamination. QUATSYL 256 is formulated to reduce this problem. Add ½ ounce of QUATSYL 256 to a gallon of water and apply to environmental surfaces. When used as directed, it is germicidal against Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella choleraesuis, Trichophyton interdigitale, and such viruses as Influenza A_2, Herpes simplex, Adenovirus Type 2, and Vaccinia. QUATSYL 256 kills other pathogenic organisms on environmental surfaces, listed in Bacteriology section, page 3.

QUATSYL 256 may be used for:

Hospitals
- Housekeeping Services
- Nursing Services
- Operating Rooms
- (does not adversely affect conductive floors)
- Physical Therapy Departments
- Autopsy Facilities
- Dietary Departments

Schools

Nursing Homes

Food Service Facilities

QUATSYL 256 kills bacteria on surfaces which cause objectionable odors. These bacteria are often found under sinks and counters, in garbage cans and garbage storage areas, and in restrooms. QUATSYL 256 also neutralizes many odors of non-bacterial origin.

Government Registration
QUATSYL 256 Cleaner-Disinfectant
EPA Registration No. 675-26-AA

The use of antimicrobial agents is regulated by the Federal Government through the Federal Environmental Pesticide Control Act of 1973. This act amends the Federal Insecticide, Fungicide and Rodenticide Act of 1964. The new law requires that all "economic poisons" (disinfectants are included in this category) carry labels with adequate directions for recommended uses. It is illegal, under this statute, to ship these types of products in interstate and intrastate commerce unless the label has been reviewed and accepted by the Environmental Protection Agency. Only upon acceptance and registration by the EPA can the product be sold.

When disinfectants are recommended for hospital use, as is QUATSYL 256, the EPA requires that they demonstrate their effectiveness against Staphylococcus aureus and Salmonella choleraesuis. If a disinfectant does not kill Pseudomonas aeruginosa — QUATSYL does — a prominent disclaimer must appear on the label. QUATSYL 256 is also effective against many other pathogens, listed in the Bacteriology section.

QUATSYL 256 is also registered, where required, with state and local health authorities. It is also authorized for use in plants operating under the U.S. Department of Agriculture, Poultry, Meat, Rabbit and Egg Products Inspection Programs, Category "F" (Sanitizers and Sanitizing Cleaners for All Surfaces).

*Trademark

3/8

BACTERIOLOGY

USE-DILUTION METHOD

Procedure: Official — as described by the Official Methods of Analysis of the Association of Analytical Chemists: pages 61-63, 11th Edition, Washington, D.C. 1970. The dilution of QUATSYL 256 used for these tests was 1:256.

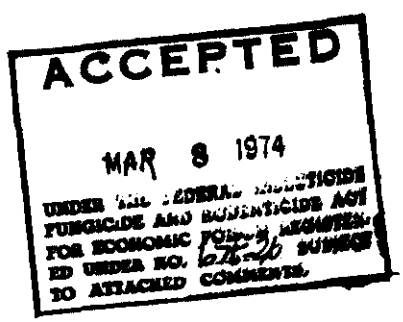
	Number of Carriers	
	Exposed	Showing Growth
Staphylococcus aureus	240	0
Salmonella choleraesuis	90	0
Pseudomonas aeruginosa	90	0
Enterobacter aerogenes	10	0
Klebsiella pneumoniae	10	0
Escherichia coli	10	0
Salmonella schottmuelleri	10	0
Streptococcus faecalis	10	0
Shigella dysenteriae	10	0
Brevibacterium ammoniagenes	10	0

VIRUCIDAL

Procedure: 0.9 ml. of QUATSYL 256 diluted 1:256 was mixed with 0.1 ml. of undiluted virus. The contact time was 10 minutes at room temperature. The titer of the treated virus was compared with that of untreated viral controls. This method was described by Stuart, L. S., Testing Sterilizers, Disinfectants, Sanitizers and Bacteriostatic Chemicals, Proceedings of the Chemical Specialties Manufacturers Association: pages 123-125, May 1969.

Test Virus	Titer	Grown In
Herpes simplex	10^7 TCID/50	Rabbit kidney cells
Vaccinia	10^7 TCID/50	Rabbit kidney cells
Influenza A_2	10^7 TCID/50	Chick embryo

Results: All viruses treated with QUATSYL 256 were completely inactivated. Complete inactivation indicates at least three logs of virus were inactivated with no residual virus detected within limits allowed by the toxicity of the germicide.



*Trademark

4/8

Procedure: Official — as described by the Official Methods of Analysis of the Association of Analytical Chemists: pages 65-66, 11th Edition, Washington, D.C., 1970. The dilution of QUATSYL* used for these tests was 1:256.

Germicidal Activity in 5, 10, 15 minutes
Trichophyton interdigitale

Test 1			Test 2		
5′	10′	15′	5′	10′	15′
—	—	—	—	—	—

Test methods described in "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics," published by the association of Food and Drug Officials of the United States.

Oral (Concentrate)	— LD 50 - White Rats - 2.3 ml./kg. of body weight.
Sub-Acute Dermal (Use-Dilution 1:256)	— Rabbits (abraded and intact skin). Transitory hyperemia. Transitory edema developed only in rabbits treated with 4 ml./kg. No systemic toxicity was observed.

QUATSYL 256, like all quarternary disinfectant formulas, is not active against the tubercle bacillus. Today, many authorities question the significance of surface disinfection in the epidemiology of tuberculosis. One such authority is the American Thoracic Society which has stated:

"The tubercle bacillus is a nonmotile organism that is readily killed by heat, drying, sunshine, and ultraviolet light. It is transmitted from one person to another by air in the residues of minute droplets of moisture during coughing, sneezing, laughing, etc.

"Only the more minute particles are able to penetrate into the lungs. The larger particles fall to the ground close to the expeller.

"Available evidence suggests that tubercle bacilli lodged on fomites — linen, furniture, books, and floors — do not constitute a significant infection hazard. Most of them die quickly through the action of drying, heat, or sunlight. Dried secretions are very difficult to fragment and suspend in the air; and, furthermore, those airborne particles which do arise from surfaces, are ordinarily innocuous. They are too large to penetrate into the lung. Hand washing is efficient in removing organisms possibly picked up from fomites or direct contact with infectious sputum or other discharges."

*Trademark

5/8

DESCRIPTION

QUATSYL* 256 destroys odor-causing bacteria on hard, non-porous environmental surfaces such as areas around toilets, sinks and counters, and garbage cans and garbage storage areas. It eliminates stale odors from kitchen surfaces. In addition, QUATSYL 256 chemically neutralizes most odors of non-bacterial origin.

HOW TO USE QUATSYL 256

The recommended use-dilution of QUATSYL 256 is 1:256 (0.39%) in hot tap water. This is a solution of ½ ounce of QUATSYL 256 per gallon of water.

Use-Dilution Table

Use-Dilution	1:512	1:256
Percent	0.2%	0.39%
ppm Active Ingredients	244	488
Ounces of QUATSYL per 1 gallon of water	¼	½
Ounces of QUATSYL 256 per 3 gallons of water	¾	1½

½ ounce equals 1 tablespoon or 15cc.

METHODS OF DISPENSING

QUATSYL 256 may be dispensed by using:

½-ounce Pumps

National Laboratories can supply a pump which fastens to the top of the one gallon bottle. One stroke of the pump will dispense exactly ½-ounce of QUATSYL 256.

Economix® Proportioners

This measuring device attaches to a water faucet and is connected by a tube to a QUATSYL 256 container. When the water is turned on and a button pressed, a 1:256 solution of QUATSYL 256 is dispensed. Economix Proportioners are available from National Laboratories.

METHODS OF APPLICATION

Even an excellent detergent such as QUATSYL 256 will not perform to its fullest capacity if it is improperly used. The best results and the lowest cost result only when correct application techniques are employed. The most important of these are as follows:

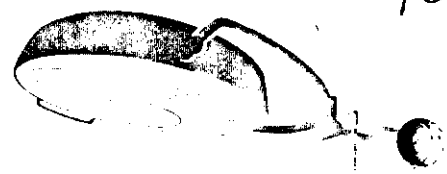
Wiping — Only freshly laundered cloths or disposable wipes should be used in this procedure. A 1:256 solution of QUATSYL 256 should be prepared and placed in a clean container. The cloth is then saturated with the solution and lightly wrung out. This cloth or wipe is then used on the surfaces to be cleaned and disinfected. A fresh solution should be prepared as soon as the old solution becomes noticeably contaminated with soil. All surfaces should be allowed to air dry. Wipe in one direction and fold under the soiled side of the cloth.

Double Basin Wiping — A dual compartment pail is recommended in this procedure. Both compartments should contain a 1:256 solution of QUATSYL 256. One compartment is used for rinsing the soil from the cloth which is then wrung out before immersing it in the second compartment. The cloth is then lightly wrung out and applied to the surface to be cleaned and disinfected. Using this method, the solution in the wash compartment remains fresh.

Mopping Procedure — Damp mopping is not recommended because floors do not remain wet for a sufficient period of time to assure disinfection. A better technique is to use a wet mop and a two-bucket system. Each bucket should contain a 1:256 solution of QUATSYL 256. One of the buckets is used only for rinsing the mop. After each mopping operation, the mop is rinsed and lightly wrung before immersion in the second bucket, which contains the solution being used on the floor. Using this method, the solution applied to the floor will be considerably less contaminated with soil. The mop should only be wrung lightly prior to application to the floor. The floor should be allowed to remain wet as long as possible to assure maximum germicidal activity.

*Trademark

6/8



WHERE TO USE QUATSYL* 256

Flooding and Wet Vacuum Pick-up — No currently known method is more effective for the disinfecting of floors. By this technique, the floors are sprayed with a 1:256 solution of QUATSYL 256 followed by a wet vacuum pick-up. Be sure the vacuum pick-up squeegee blade is cleaned frequently and is in good condition.

Spray Bottle Method — For small areas, it is recommended that a 1:256 solution of QUATSYL 256 be placed in a bottle fitted with a trigger sprayer. Spray the area and then wipe lightly with a sterile cloth or wipe.

Spray-Mop Technique — A pump-up stainless steel garden-type sprayer is used to apply the QUATSYL 256 solution to the floor. The solution is then removed from the floor with a clean mop, rinsing and wringing the mop out in a bucket of QUATSYL 256 solution.

The following factors should be considered relative to maximizing results from any quality disinfectant.

1. The bactericidal properties of any germicide stop when the treated surface becomes dry. Wet mopping or flooding with a wet vacuum pick-up is more effective than damp mopping because the surface remains wet for a longer period.
2. The higher the temperature of the disinfectant solution, the faster its germicidal action. The water should be as hot as practical.
3. The greater the quantity of a disinfectant solution on a given area, the more complete is its germicidal action. Get surfaces wet — not just damp — with the germicidal solution.
4. The manufacturer's use-dilution recommendations should be followed. Making solutions stronger than recommended is expensive and wasteful and will not significantly improve germicidal action.

Operating, Delivery and Recovery Rooms — All areas and equipment should be regularly treated with a disinfectant.

Floors — The flooding — wet vacuum technique is recommended but, if this is not possible, the double pail mopping system or spray-mop procedure are good alternatives. QUATSYL 256 does not adversely affect conductive floors. Rinsing is not required.

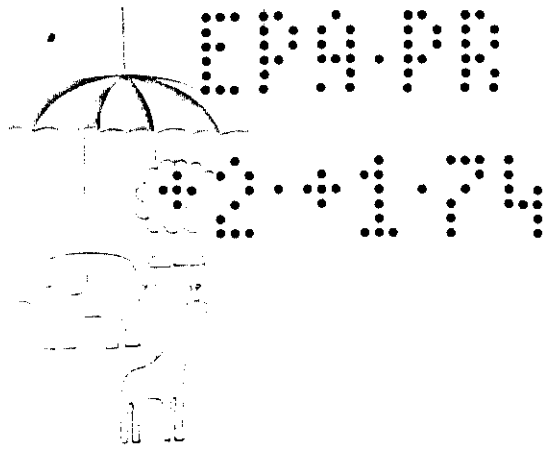
Equipment and Surfaces — Spray and wipe with a 1:256 solution of QUATSYL 256. Areas which are hard to reach such as wheels, casters and the underside of tables and shelves are best disinfected by the spray method.

Surgical Instruments — After removal of all adhering blood and serous exudates, instruments should be immersed in a 1:256 solution of QUATSYL 256.

Heat-Sensitive Instruments — Since many of these cannot be sterilized in an autoclave, they should be cold-disinfected by soaking for fifteen minutes in a 1:256 solution of QUATSYL 256.

Isolation Rooms — Surfaces in these rooms should be cleaned and disinfected by any of the appropriate techniques mentioned previously.

*Trademark



Nurseries — QUATSYL 256 at a 1:256 use-dilution is recommended for all surfaces in the nursery such as floors, bassinets and other equipment.

Housekeeping — Where the flooding/wet vacuum pick-up method is not convenient for disinfecting and cleaning floors, it is recommended that the double pail mopping method be used. Surfaces other than floors should be cleaned and disinfected using the double-pail or spray-bottle wiping method.

For spot cleaning and disinfecting of such objects as bedsprings, doorknobs and bedroom fixtures, use the spray-bottle technique.

Food Service — QUATSYL 256 is an effective sanitizer for food service use. A 1:512 solution (244 ppm) should be used for sanitizing food contact surfaces. After application to food contact surfaces, rinse off with potable water. Non-food contact surfaces can also be cleaned and disinfected at 1:256 solution of QUATSYL 256. Rinsing not necessary.

QUATSYL 256 fulfills the criteria of Appendix F of the Grade A Pasteurized Milk Ordinance 1965 Recommendations of the U.S. Public Health Service in waters up to 500 ppm hardness calculated as $CaCO_3$, when tested by the AOAC Germicidal and Detergent Sanitizers Official Method.

Quatsyl* 256

Disinfects — Cleans — Deodorizes

EPA Registration No. 675-26-AA

Available in:

- 1 gallon plastic bottles (6 to a case)
- 2½ gallon bottles (2 in a case)
- 55 gallon drum

ACTIVE INGREDIENTS:	
Octyl Decyl Dimethyl Ammonium Chloride	3.750%
Dioctyl Dimethyl Ammonium Chloride	1.875%
Didecyl Dimethyl Ammonium Chloride	1.875%
Alkyl (C_{14} 50% - C_{12}, 40% - C_{16}, 10%) Benzyl Dimethyl Ammonium Chloride	5.000%
Tetrasodium Ethylenediamine Tetraacetate	3.420%
Isopropyl Alcohol	3.000%
Ethyl Alcohol	1.000%
INERT INGREDIENTS:	80.080%
	100.000%

Read directions and precautionary statements on label.

Let us help you with any disinfection problem you have. Technical assistance is available to your Committee on Cross-Infection or to your individual department heads on request.

NATIONAL LABORATORIES
Lehn & Fink Industrial Products Division
of Sterling Drug Inc.
225 Summit Avenue, Montvale, New Jersey 07645

*Trademark

MEDICAL LABORATORIES

Lehn & Fink Industrial Products Division
of Sterling Drug Inc.
225 Summit Avenue, Montvale, N. J. 07645

N-240-093