UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 221996

National Laboratories L&F Products 225 Summit Avenue Montvale, NJ 07645

Attention: Ruth Trager

Registration Administrator

Subject:

Tergisyl Detergent Disinfectant EPA Registration Number 675-17

Your Amendment Dated August 4, 1993

This is in response to your amendment submitted in accordance with PR Notice 91-7.

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable provided that you make the following revision before you release the product for shipment bearing the amended labeling.

Under the "Statement of Practical Treatment" after "If Swallowed" delete "promptly drink a large quantity of milk, egg whites, or gelatin solution. If these are not available".

A stamped copy is enclosed for your records. Submit one copy of the final printed label before you release the product for shipment bearing the amended label.

The proposed product name change has been made a part of our records.

If you have any questions concerning this letter, please contact me at (703) 305-7964.

Sincerely.

Ruth G. Douglas Product Manager (32)

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675-17 FRONT LABEL

TERGISYL DETERGENT DISINFECTANT

CLEANS AND DISINFECTS IN ONE OPERATION

For Use Only In Institutional and Industrial Facilities

GERMICIDAL, 'Staphylocidal 'Pseudomonacidal 'Tuberculocidal (Against pathogenic fungi) FUNGICIDAL^{*} VIRUCIDAL (Against most Lipophilic viruses)

*On Environmental Surfaces

ACTIVE INGREDIENTS: o-Phenylphenol 5.7%

p-tert-Amylphenol 1.8%

INERT INGREDIENTS:

92.5%

Total

100.0%

(Includes detergent, other cleaning agents and no phosphorous compounds)

EPA REG. NO. 675-17 EPA Est. No. 777-OH-1

KEEP OUT OF REACH OF CHILDREN

WARNING: See back panel for additional

precautions and Statement of Practical Treatment

NET CONTENTS: One Gallon (3.79 Liters)

5 Gallons (18.95 Liters)

55 Gallons (208.45 Liters)

NATIONAL LABORATORIES L & F PRODUCTS MONTVALE, NJ 07645

ACCEPTED with COMMINTS in EPA Letter Dated:

FEB 22 1996

Under the general insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registered under EPA Reg. No.

675-17

675-17 BACK PANEL

TERGISYL DETERGENT DISINFECTANT

HOW TO USE TERGISYL DETERGENT DISINFECTANT

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

No need to add soap or other detergents. TERGISYL does a complete job: cleans, disinfects, decdorizes. Avoid waste; dilute as directed. For complete directions, refer to Technical Brochure.

TERGISYL IS IN CONCENTRATED FORM. DILUTE ACCORDING TO DIRECTIONS.

ONE TABLESPOON EQUALS ABOUT 1/2 FLUID OUNCES OR 15 CC.

To prepare proper dilutions in required quantities, add full strength TERGISYL to water as below:

PURPOSE	SOLUTION STRENGTH	TERGISYL	WATER
FOR GENERAL	1%	10 œ.	1 quart
CLEANING AND	(1:100)	40 œ.	1 gallon
DISINFECTING		4 oz.	3 gallons
		7 oz.	5 gallons

SAVES TIME, LABOR, WEAR & TEAR ON FLOORS AND EQUIPMENT

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

WARNING: Harmful if swallowed. Causes skin and severe eye irritation. Avoid contact with concentrate or dilution with skin or eyes. Wear rubber gloves when handling. In case of contact flush immediately with water and contact a physician. Avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT: Remove and wash contaminated clothing before reuse. If swallowed, promptly drink a large quantity of milk, egg whites, or gelatin solution. If these are not available, drink large quantities of water. Avoid alcohol. Call a physician.

STORAGE & DISPOSAL (For containers one gallon or less)

Storage: Store in original container in areas inaccessible to small children. Keep away from food or feed.

Disposal: Do not re-use empty container. Rinse thoroughly with water and detergent. Discard in trash.

STORAGE & DISPOSAL (For containers greater than one gallon)

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in original container in areas inaccessible to small children.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

For 55 gallon container:

This label is printed on 50% recycled paper (10% post-consumer)

40/11

Tergisyl®

DETERGENT-DISINFECTANT

E.P.A. Registration No. 675-17

A PREMIUM FORMULATION WITH BROAD-SPECTRUM ANTIMICROBIAL ACTIVITY AND EXCELLENT CLEANING POWER



Tergisyl® DETERGENT-DISINFECTANT

Cross contamination is an ever-present danger in hospitals and nursing homes. These facilities must constantly strive to utilize the most effective techniques and products to insure that this problem is held to a minimum.

The serious nature of staphylococcal, pseudomonal and tuberculous infections focuses attention on the vital function housekeeping plays in total patient welfare. How to do more of the needed disinfecting without adding complicated procedures or increasing labor costs is a perplexing problem to health facilities of every size. This problem is magnified in large hospitals where heavy traffic increases the potential for spreading contamination. A highly effective product is required to clean and disinfect all areas in one operation.

TERGISYL Detergent-Disinfectant solves this problem.

Hospitalproves Detergent Disinfectants aves labor costs

TERGISYL Detergent-Disinfectant combines comprehensive microbiocidal (staphylocidal, tuber-culocidal, pseudomonacidal, fungicidal* and virucidal**) activity with a degree of detergency which removes even heavy soil. This permits cleaning and disinfection in a single procedure. An independent research organization has confirmed this under actual hospital conditions.

Two patient-area corridors similar in size, physical layout and traffic conditions were chosen as test sites. The objectives were to determine the actual savings in time and labor and to compare the relative detergency and germicidal efficiency of the methods given below:

)Mop and Pail Technique

TERGISYL

Detergent-Disinfectant one-step vs. washing and disinfecting.

The one-step method reduced the man-time by 47%. Actual time saved was approximately 25 minutes per 1,000 square feet of floor area - a labor savings of 125 man hours or 15 man days per week in a 300 bed hospital.

Machine Scrubbing/Mop Disinfecting Technique

TERGISYL Detergent-Disinfectant one-step vs. machine scrubbing-vacuum pickup followed by mop-and-pail application of disinfectant.

The one-step method reduced the man-time by 22%. Actual time saved was approximately 23 minutes per 1,000 square feet of floor area - a labor savings of 20 man hours or 2½ man days per week in areas of heavy soil in a 300 bed hospital.

- * Against pathogenic fungi
- ** Against most Lipophilic viruses carried on inanimate environmental surfaces.



TESTS AGAINST VARIOUS ORGANISMS



TEST PROCEDURE:

Use-Dilution Method - Official - as described by Official Methods of Analysis of the Association of Official Analytical Chemists: pages 59-60, 12th Edition, Washington, D.C., 1970. In the Federal Register, "EPA Guidelines for Registering Pesticides," June 25, 1975, Vol. 40, No. 123, pp 26836-26837.

Dilution of

TERGISYL*

Detergent-Disinfectant: 1:100

	No. Cylinders		No. Cylinders
Test Organisms	Out of 20	Test Organisms	Out of 20
Salmonella choleraesuis ATCC10708	0	Neisseria catarrhalis ATCC8176	0
Salmonella paratyphi ATCC9281	0	Serratia marcescens ATCC8195	0
Salmonella schottmuelleri ATCC10719	0	Staphylococcus aureus 209 ATCC6538	0
Shigella dysenteriae ATCC11835	0	Staphylococcus aureus 80/81 (Penicillin resis	tant) 0
Enterobacter aerogenes ATCC13048	0	Streptococcus pyogenes ATCC12384	0
Escherichia coli AMC198 (ATCC11229)	0	Streptococcus salivarius ATCC9222	0
Proteus vulgaris ATCC9920	0	Corynebacterium diphtheriae ATCC11913	0
Pseudomonas aeruginosa ATCC15442	0	Candida albicans ATCC10231	0
Klebsiella pneumoniae ATCC9997	0	Trichophyton interdigitale ATCC9533	0

TEST PROCEDURE:

Fungicidal Test - Official - as described by Official Methods of Analysis of the Association of Official Analytical Chemists: page 63, 12th Edition, Washington, D.C., 1970.

		Tricho	rdigitale	gitale			
Dilution of	TERGISYL		Test 1			Test 2	
	Detergent-Disinfectant	5'	10'	15'	5'	10'	15'
	1:80	_	_	-	_	_	_
	1:100	_	_	-	_	_	-
	1:150	+	+	-	+	+	-
	1:200	+	+	+	+	+	+
	Phenol						
	1:45	_	-		-	_	
	1:60	+	+	_	+	+	-
	1:70	+	+	+	+	+	+

TEST PROCEDURE:

Tuberculocidal Activity - Official - Final Action - as described by Official Methods of Analysis of the Association of Official Analytical Chemists: pages 69-70, 12th Edition, Washington, D.C., 1970.

Mycobacterium: tuberculosis var. bovis (BCG) Number Subculture Tubes + Out of 10 Tested

Dilution of	TERCICAL	110111021	sadeantale labes :	5010110165	
Dilution of	TERGISYL Detergent-Disinfectant	Media:	Proskauer-Beck	Kirchner	Middlebrook
	1:100		0	0	0
	Phenol				
	1:50		0	0	0
	1:75		0	5	5

1621 PROCEDURE:

Virucidal Activity - 0.9 ml. of

TERGISYL

Detergent-Disinfectant diluted 1:100 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.

VIRUCIDAL ACTIVITY

Test Virus	Titer	Grown In
Herpes simplex	107 TCID/50	Trypsinized rabbit cells
Vaccinia	106 TCID/50	HeLa cells
Influenza A ₂	10 ⁷ TCID/50	Chick embryo

RESULTS:

All viruses treated with TERGISYL Detergent-Disinfectant, diluted 1:100, 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.

ELERGENTACTIVITY

In concentration as supplied,

TERGISYL

Detergent-Disinfectant is a sparkling clear, light yellow liquid with a slightly fruity odor. In the recommended 1:100 (1%) dilution with water it is a sudsy, fast-wetting detergent which quickly emulsifies and removes soil on every type of surface. The synthetic detergent agent in the formulation does not leave a film, therefore no rinsing is necessary. This is important for two reasons: first, it reduces the labor necessary for effective cleaning and second. it avoids removal of the disinfectant.

By all standards, its detergency is excellent. But the best test is use in your own hospital—to remove tracked-in dirt in areas of heavy traffic, to remove fingerprint smudges and cart-tire 7ks from woodwork, to wipe down walls, and for routine one-step cleaning and disinfection of all corridors and rooms.





FLOORS, WALLS & WOODWORK

Floors

Once over with the recommended 1% (1:100) dilution of TERGISYL Detergent-Disinfectant, and the floor is clean of soil and pathogenic organisms which could be redispersed into the air.

NO RINSING IS NECESSARY.

Just add TERGISYL

Detergent-Disinfectant to water for mopping. Use 2½ tablespoons or 1½ ounces to each gallon.

For waste-free metered mixing, use the Economix* Proportioner which attaches to the water faucet and dispenses the proper dilution at the touch of a button. (See page 7)

Walls

If dust, smoke, and grease are allowed to collect on walls, not only is their appearance affected but they may also become sources for redispersal of airborne organisms.

Using a 1% solution of TERGISYL Detergent-Disinfectant, wash down walls either by hand or machine. Do not rinse.

Start at floor level and work upward to prevent streaking. Best method is to include entire wall and ceilings.

TERGISYE Detergent-Disinfectant dissolves soil rapidly. The synthetic detergent agents in the Professional TERGISYE Hospital Type Detergent-Disinfectant formula have a well-established reputation for removing grease efficiently.

TERGISYE Detergent-Disintectant inhibits formation of bacterial growth in high-humidity rooms.

TERGISYL Detergent-Disinfectant can be used on any wall surface not harmed by water. The pH of the use-dilution is slightly alkaline.

Woodwork

Fingerprints and other accumulations of grease and dirt on woodwork, window sills, etc., are quickly, easily removed by TERGISYL Detergent-Disintectant. Wash without rinsing.

PATIENT ROOMS

Concurrent disinfection

In addition to daily damp sweeping or mopping with 1% TERGISYL Detergent-Disinfectant, use it to disinfect all surfaces in the room.

Wipe off the bed frames with a clean cloth wrung out in TERGISYL Detergent-Disinfectant solution. Be sure to reach all crevices which can harbor dust or dried organic matter. Don't forget the bed rails as they are frequently touched and near the face of both patient and attendants.

Wipe off dressers and other furniture in room. In addition to the germicidal effectiveness, the resulting cleanliness adds to the patient's feeling of being well cared for.

It should be remembered that equipment and devices used for patient treatment, such as oxygen tents, fracture frames, etc., are isually contaminated. This equipment should be thoroughly disinfected with TERGISYL Detergent-

Disinfectant after use.

Terminal Disinfection

Between patients, TERGISYL

Detergent-Disinfectant is used for thorough cleaning.

Wash bed frame and any articles used by patient with 1% product solution.

If mattress is plastic covered, wipe off on all sides with TERGISYL Detergent-Disinfectant. Also wipe plastic pillow covers.

Wash entire bedstand and wipe springs.

Mop floors thoroughly with 1% TERGISYL Detergent-Disinfectant. Do not rinse.

Wipe off radiators, dressers, chairs, and any other equipment or furniture on which airborne dust or spray from mouth or nose can settle.

The TERGISYL Detergent-Disinfectant-clean room is ready for the next patient immediately after cleaning.



Detergent-Disinfectant. Also use the product to wash walls, ceilings, and woodwork.

Accidents or spills should be cleaned up immediately with TERGISYL Detergent-Disinfectant solution. It is pleasantly clean smelling and removes odor-causing bacteria from floors or furnishings.

Thoroughly wipe bassinets inside and out with 1% solution, being sure to include legs and rollers. Rinse.

Wipe off any areas where babies are placed temporarily for attention. Rinse.

Pediatric Wards

Mop floors with 1%

TERGISYL

Detergent-Disinfectant as frequently as possible.

Keep the product solution handy for cleaning up her "accidents", vomiting, or other spills.

. ¿RGISYL Detergent-Disinfectant retains its detergent and disinfectant activity in the presence of organic matter.

Follow all recommendations mentioned on preceding pages for cleaning walls, ceilings, and woodwork with TERGISYL Detergent-Disinfectant.

While bed is occupied, wipe off bed frame with TERGISYL Detergent-Disinfectant. Between patients, follow recommendations given for other patient rooms.

BATHROOMS

Toilets and Urinals

Regular use of 1% TERGISYL

Petergent-Disinfectant solution keeps porcelain fixtures shining clean, disinfected, and deodorized.

Be sure to use the product solution for cleaning and disinfecting toilet seats and exterior bowl surfaces. One ounce of concentrated TERGISYL

Detergent-Disinfectant should be added to the water in the toilet bowl.

The product spreads easily into crevices where toilets and urinals meet floor and thoroughly disinfects these problem areas.

Wipe off metal fixtures with TERGISYL
Detergent-Disinfectant. Wash floors and walls with 1% TERGISYL
Detergent-Disinfectant.

Bathtubs

Use 1% TERGISYL Detergent-Disinfectant to clean bathtub between uses by patients.





OPERATING ROOMS

Routine Cleaning

Use 1% TERGISYL Detergent-Disinfectant to mop floors, clean walls and ceilings. Recommended for flooding O.R. floors before wet vacuum pickup.

Wipe off all tables and furniture, including lamps and fixtures, with 1% TERGISYL

Detergent-Disinfectant.

Between Patients

The operating room can be ready for a new patient quickly if thoroughly cleaned with this product.

Give special attention to area under and around operating table as well as table itself and accessory parts. Wipe off mattress-pad on all sides.

Wash kick-bucket thoroughly with 1% TERGISYL Detergent-Disinfectant.

This product has no adverse effect on conductive flooring.

HOUSEKEEPING EQUIPMENT

A clean hospital is not possible to achieve unless the equipment being used is also clean. Otherwise dust and possible contamination can be spread from one part of the hospital to another as mops and cloths become breeding places for pathogenic organisms.

After use, wash mops in 1% TERGISYL

Detergent-Disinfectant. Its sudsing removes dirt freely because of its superior detergency and keeps mops and cleaning cloths sweet smelling.

Wipe off mechanical equipment such as vacuums, floor and wall scrubbers, etc. with 1% TER-GISYL Detergent Disinfectant.



OTHERUSES

Sinks and wash basins throughout the hospital should be cleaned with 1% TERGISYL®

Detergent-Disinfectant-every sink from the utility type "just off the corridor" to the scrub sinks off the operating room.

Wipe off fixtures, too.

Give particular attention to any sinks used for rinsing contaminated utensils or equipment.

Mop floors of room containing sink or basin with 1% TERGISYL Detergent-Disinfectant solution.

Wipe down stretchers frequently. If they have been contaminated, wash thoroughly with this product.

TERGISYL Detergent-Disinfectant is particularly practical for cleaning cast rooms where handling of contaminated dressings may create both an odor problem and a source for spreading contamination.

Keep TERGISYL

Detergent-Disinfectant available for the Recovery Room where incontinence and gastrointestinal upsets may necessitate frequent cleaning and deodorizing.

Read directions and caution statements on label accompanying product carefully before using.

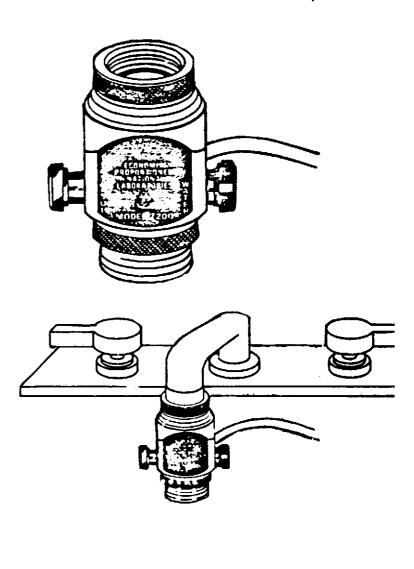


For metered mixing of TERGISYL Detergent-Disinfectant and water in the proper proportions directly from the faucet

Use the ECONOMIX³ PROPORTIONER

The Economix Proportioner is an automatic push button liquid proportioner made of stainless steel. It attaches to the water faucet to draw the concentrated disinfectant from an adjacent container. When the water is turned on, and the button pushed, the properly proportioned mixture is dispensed, ready for use. Waste of materials is avoided. Time-consuming measuring is eliminated. Faucet is still usable for clear water.

Installation instruction included with shipment.



Tergisyl*

DETERGENT-DISINFECTANT

Active Ingredients: o-Phenylphenol	5.7% 1.8%
Inert Ingredients: Includes detergent, other cleaning agents and compounts.	92.5%* no phosphorus

ENVIRONMENTAL DISINFECTION

Dependable disinfection of all inanimate surfaces in the hospital is an important part of controlling cross contamination. Other measures are, of course, necessary, but hospitals that have increased environmental disinfection are finding that cross contamination is prevented from becoming a problem. Existing problems have been brought under control. Let us help you with any disinfection problem you have. Technical assistance is available to your Infection Control Committee or to individual department heads on request.

PACKAGING DESCRIPTION

ITEM #	SIZE	CASE CUBE
8401-000	6/1 gal. plastic bottles	1.82
8411-000 5 gal. plastic pail		1.26
8452-000	55 gal. drum	11.42

GUARANTEE

Careful laboratory control assures materials of uniform quality at all times. All National Laboratories' products are guaranteed to give complete satisfaction, when used as directed, or they may be returned for credit.

