

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

ANTIMICROBIAL PROGRAM BRANCH

IN 08/08/90 OUT 09/12/90  
Reviewed by Srinivas Gowda Date 09/12/90 *WEC 9/19/90*  
EPA Reg. No. or File Symbol 777-TA  
Date Division Received 07/04/90  
Type Product (s): Hospital/General Disinfectant  
MRID Nos. 415520-01 to 415520-02  
Product Manager 31 (Lee)  
Product Name Qu-Sol Brand Disinfectant  
Company Name Lehn & Fink Products, Div. of Sterling Drug, Inc.  
Submission Purpose Resubmission in response to Agency letter  
dated 05/25/90 with revised laundry  
sanitizing data and revised label (Attached)  
Type formulation Liquid  
Active Ingredient (s): %  
Alkyl (50% C<sub>14</sub>, 40% C<sub>12</sub>, 10% C<sub>16</sub>) dimethyl benzyl  
ammonium chlorides.....2.00  
Octyl decyl dimethyl ammonium chloride.....1.50  
Didecyl dimethyl ammonium chloride.....0.90  
Dioctyl dimethyl ammonium chloride.....0.60

200.0 **Introduction**

200.1 **Uses (s)**

Refer to the proposed labeling dated 07-04-90.

200.2 **Background Information**

The submission received 07-04-90, is in response to Agency letter dated 05-25-90 with requested revised laundry sanitizing data and revised proposed labels.

201.0 **Data Summary**

201.1 **Brief Description of Tests**

"Petrocci & Clarke Method for Antimicrobial Laundry Additives In the Presence of Organic Soil" by Joseph Rubino and Diane Albano, Lehn & Fink Products Group, Microbiology Laboratory, 225 Summit Avenue, Montavale, NJ 07645, dated 11-06-89 (MRID No. 415520-01).

"Laundry Compatibility Study" by Joseph Rubino and Diane Albano, Lehn & Fink Products Group, Microbiology Laboratory, 225 Summit Avenue, Montavale, NJ 07645, dated 06-20-88 (MRID No. 415520-02).

201.2 **Test Summaries:**

**Laundry Sanitizer Test**

- a. The methodology employed and test results are attached.
- b. Conclusions: Satisfactory performance vs. test organisms.

BOTTLE LABEL COPY FOR QU-SOL BRAND DISINFECTANT

Front Label

NEW! (Will be dropped in six months)  
Qu-Sol Brand Disinfectant

Deodorizes  
Cleans

Concentrated  
Use It Every Day!

ACTIVE INGREDIENTS

Alkyl (50%C <sub>14</sub> , 40%C <sub>12</sub> , 10%C <sub>16</sub> ) dimethyl benzyl ammonium chlorides	2.00%
Octyl decyl dimethyl ammonium chloride	1.50%
Didecyl dimethyl ammonium chloride	0.90%
Diocetyl dimethyl ammonium chloride	0.60%
INERT INGREDIENTS	95.00%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN  
DANGER

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS X FL. OZ. (X ML)

BOTTLE LABEL COPY FOR QU-SOL BRAND DISINFECTANT

Back Label

NEW! (Will be dropped in six months)  
Qu-Sol Brand Disinfectant

Fast Action Formula

Kitchen Floors o Walls o Woodwork o Baby's Room o Sickrooms o  
Porcelain o Linoleum o Bathrooms o Floor Tiles o Garbage Cans o  
Diaper Pails o Storage Areas o Pet Areas

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

TO OPEN CHILD RESISTANT CAP: Place bottle on a flat horizontal surface. With one hand, grasp bottle firmly near top. With other hand, while pushing cap down, turn cap counter-clock-wise. AVOID SQUEEZING BOTTLE WHEN OPENING. To reseal, twist cap until tightly locked.

DIRECTIONS: To disinfect/deodorize hard, non-porous surfaces remove heavy soil first, then add 1-1/4 oz. (2 1/2 tbsp.) to one gallon water and apply with a sponge or mop wetting all surfaces thoroughly. Let stand 10 minutes, then wipe away excess. To clean and disinfect the toilet bowl, flush first. Add 1 oz. (2 tbsp.) to bowl water. Brush all surfaces including under the rim. Let soak 10 minutes. Flush. For Laundry, after filling the washer with water, add one cup of Qu-Sol to each washerload to sanitize your wash, let washer agitate for one minute before adding laundry detergent.

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

DANGER: CORROSIVE. CAUSES EYE AND SKIN DAMAGE. DO NOT GET IN EYES OR ON CLOTHING. WEAR EYE PROTECTION AND RUBBER GLOVES. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING. REMOVE CONTAMINATED CLOTHING AND WASH BEFORE REUSE.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, immediately flush eyes thoroughly with water. Remove any contact lenses and continue to flush eyes with water for at least 15 minutes. Get medical attention for eyes. In case of skin contact, wash immediately with soap and water. If irritation occurs, consult a doctor. If swallowed, drink promptly a large quantity of water to dilute product. Get medical attention. Do not induce vomiting.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

cont. back label

STORAGE and DISPOSAL: Store in original container in areas inaccessible to small children. Do not reuse empty container. Rinse bottle and put in trash.

Lehn & Fink Products  
Montvale, NJ 07645

EPA Reg. #777-  
EPA Est. #777-IL-1,NJ-2

CARTON LABEL COPY FOR QU-SOL BRAND DISINFECTANT

Front Panel

NEW! (Will be dropped in six months)  
Qu-Sol Brand Disinfectant

Deodorizes  
Cleans

Concentrated  
Use It Every Day!

ACTIVE INGREDIENTS

Alkyl (50%C <sub>14</sub> , 40%C <sub>12</sub> , 10%C <sub>16</sub> ) dimethyl benzyl ammonium chlorides .....	2.00%
Octyl decyl dimethyl ammonium chloride .....	1.50%
Didecyl dimethyl ammonium chloride .....	0.90%
Diocetyl dimethyl ammonium chloride .....	0.60%
INERT INGREDIENTS .....	<u>95.00%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN  
DANGER

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NET CONTENTS X FL. OZ. (X ML)

CARTON LABEL COPY FOR QU-SOL BRAND DISINFECTANT

Back Panel

NEW! (Will be dropped in six months)  
Qu-Sol Brand Disinfectant

Bathroom

Use Qu-Sol to disinfect and deodorize all your bathroom fixtures. Qu-Sol disinfects and deodorizes the toilet bowl, and controls the growth of mold, mildew and athlete's foot fungus when applied regularly to shower walls and floors.

Nursery

In the baby's room Qu-Sol cleans toys, crib and highchair surfaces. Rinse with water. Qu-Sol disinfects and deodorizes diaper pails. Use recommended dilution (see side panel).

Laundry

Significantly reduce the spread of household germs and washing machine odors by cleaning washer tub often with the recommended Qu-Sol dilution.

All Around the House

Use Qu-Sol daily, as recommended, to clean and deodorize your entire house; kitchen floors, walls, woodwork. Controls the growth of mold and mildew in basements, closets, storage areas or similar damp or musty places. Repeat application as necessary.

Use It Every Day!

CARTON LABEL COPY OF QU-SOL BRAND DISINFECTANT

Left Side Panel

NEW! (Will be dropped in six months)  
Qu-Sol Brand Disinfectant

Directions for use: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Disinfect/Deodorize: To disinfect/deodorize hard, non-porous surfaces remove heavy soil first, then add 1-1/4 oz. (2 1/2 tbsp.) to one gallon water and apply with a sponge or mop wetting all surfaces thoroughly. Let stand 10 minutes, then wipe away excess. To clean and disinfect the toilet bowl, flush first. Add 1 oz. (2 tbsp.) to bowl water. Brush all surfaces including under the rim. Let soak 10 minutes. Flush. For laundry, after filling the washer with water, add one cup of Qu-Sol to each washer load to sanitize your wash. Let washer agitate for one minute before adding laundry detergent.

Storage and Disposal: Store in original container in areas inaccessible to small children. Do not reuse empty container. Rinse bottle, and put in trash.

Precautionary Statements: Hazards to Humans and Domestic Animals.

Danger: CORROSIVE. CAUSES EYE AND SKIN DAMAGE. DO NOT GET IN EYES OR ON CLOTHING. WEAR EYE PROTECTION AND RUBBER GLOVES. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING. REMOVE CONTAMINATED CLOTHING AND WASH BEFORE REUSE.

Statement of Practical Treatment: In case of eye contact, immediately flush eyes thoroughly with water. Remove any contact lenses and continue to flush eyes with water for at least 15 minutes. Get medical attention for eyes. In case of skin contact, wash immediately with soap and water. If irritation occurs, consult a doctor. If swallowed, drink promptly a large quantity of water to dilute product. Get medical attention. Do not induce vomiting.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

CARTON LABEL COPY OF QU-SOL BRAND DISINFECTANT

Right Side Panel

NEW! (Will be dropped in six months)  
Qu-Sol Brand Disinfectant

Kills Household Germs

Qu-Sol is a Hospital Type Disinfectant which kills a wide variety of harmful microorganisms. It's the fast, easy effective way to kill household germs including germs that cause odors found even in the cleanest homes.

On environmental surfaces Qu-Sol:

Kills mold and mildew and the odors they cause.  
Inhibits regrowth.

Kills both gram-positive and gram-negative germs including Psuedomonas aeruginosa.

Kills Staph, Strep and Salmonella germs

Kills viruses such as Influenza A<sub>2</sub>/Japan/305/57, Herpes Simplex Type 1 & Type 2, Vaccinia and Respiratory Syncytial Virus.

Reduces the hazard of cross contamination from treated surfaces.

Use Qu-Sol every time you clean

Use It Every Day

Lehn & Fink Products  
Montvale, NJ 07645

EPA Reg. No. 777 -  
EPA Est. No. 777-IL-1,NJ-2  
(See bottom of bottle)

Qu-Sol  
AD4-109A  
Petrocci & Clarke Laundry Sanitizer Test  
Activity in the Presence of Organic Soil

PROCEDURE

Petrocci & Clarke Method for Antimicrobial Laundry Additives,  
Journal of the AOAC, Volume 52, #4, 1969.

Modifications

- . All testing was conducted at 25°C.
- . All swatches were inoculated with 0.02 ml of a 9.5 ml test suspension with 0.5 ml blood serum and incubated for 20 minutes at 35°C.
- . The Use dilution on all products tested was 1:250 (2 ml of product was diluted in 498 ml DI water.) 225 ml of this dilution was tested against each organism using three fabric swatches per test. Fabric weight equals 15 gm.
- . DI water used as untreated control.
- . Contact time = 10 minutes.
- . Lethen broth was used as a neutralizer.
- . All plates were incubated at 35°C for 72 hours.

SAMPLES:

1. AD4-109A- Micro # 759, 12/1/87
2. AD4-109A- Micro # 1891/1, 1/21/88
3. AD4-109A- Micro # 1891/2, 10/2/89

Qu-Sol  
AD4-109A  
Petrocci & Clarke Laundry Sanitizer Test  
Activity in the Presence of Organic Soil

RESULTS

Organism: Staphylococcus aureus - ATCC 6538

SAMPLE	SWATCH		WASH WATER	
	Average Count	%Reduction	Bacteria/ml	%Reduction
Test Date: DI WATER #759	3/18/88 $5.03 \times 10^5$ 0	----- 100%	$2.01 \times 10^4$ 0	----- 100%
Test Date: DI WATER #1891/1 #1891/2	10/27/89 $7.66 \times 10^5$ 0 0	----- 100% 100%	$4.05 \times 10^3$ 0 0	----- 100% 100%

Organism : Klebsiella pneumoniae - ATCC 4352

SAMPLE	SWATCH		WASH WATER	
	Average Count	%Reduction	Bacteria/ml	%Reduction
Test Date: DI WATER #759	3/18/88 $4.02 \times 10^5$ 0	----- 100%	$2.95 \times 10^3$ 0	----- 100%
Test Date: DI WATER #1891/1 #1891/2	10/27/89 $6.86 \times 10^6$ 0 6	----- 100% 99.99%	$2.5 \times 10^4$ 0 0	----- 100% 100%

COMMENT: EFFECTIVE LAUNDRY SANITIZER ACTIVITY EQUALS 99.90%  
REDUCTION FOR BOTH SWATCH AND WASH WATER.

Conclusion

All formulations tested do exhibit satisfactory laundry sanitizing activity when tested against Staphylococcus aureus and Klebsiella pneumoniae.

*Diane Albano*

Diane Albano  
Sr. Bacteriologist, Microbiology

*Joseph Rubino*

Joseph Rubino  
Group Leader, Microbiology

Qu-Sol  
AD4-109A  
Laundry Compatibility Study

PROCEDURE

Petrocci & Clarke Method for Antimicrobial Laundry Additives,  
Journal of the AOAC, Volume 52, #4, 1969.

Modifications

- . Laundry swatches were tested one minute with Qu-Sol AD4-109A followed by the addition of the listed Laundry detergents with a 9 minute agitation.
- . All testing was conducted at 25°C.
- . All swatches were inoculated with 0.02 ml of a 9.5 ml test suspension with 0.5 ml blood serum and incubated for 20 minutes at 35°C.
- . The Use dilution of test products are as follows:
  - (a) AD4-109A - 1:250 (2 ml product diluted in 498 ml DI water).
  - (b) All liquid detergents tested - 1:500 (1 ml product diluted in 499 ml DI water). 0.45 ml of this 1:500 dilution was added to 225 ml Qu-Sol.
  - (c) Powder detergents Use dilution as listed below:
    - 1. Bold 3 - 0.38 gm added to 225 ml Qu-Sol
    - 2. Surf - 0.40 gm added to 225 ml Qu-Sol
    - 3. Tide - 0.32 gm added to 225 ml Qu-Sol
- . Each organism was tested using three fabric swatches. Fabric weight equals 15 gm.
- . DI water used as untreated control.
- . Contact time = 10 minutes.
- . Lethen broth was used as a neutralizer.
- . All plates were incubated at 35°C for 72 hours.

- SAMPLES:
- 1. AD4-109A - Micro # 759, 12/1/87
  - 2. Surf, Liquid
  - 3. Dynamo 2, Liquid
  - 4. Tide, Liquid
  - 5. Wisk, Liquid
  - 6. Bold 3, Powder
  - 7. Surf, Powder
  - 8. Tide, Powder

Qu-Sol  
AD4-109A  
Laundry Compatibility Study

RESULTS

ORGANISM: Staphylococcus aureus-ATTC 6538

SAMPLE	SWATCH		WASH WATER	
	Average Count	%REDUCTION	BACTERIA/ML	%REDUCTION
Test Date: 5/19/88				
DI Water	5.06 X 10 <sup>5</sup>	-	2.4 X 10 <sup>4</sup>	-
AD4-109A/Dynamo 2	0	100%	0	100%
AD4-109A/Surf-Liquid	0	100%	0	100%
Test Date: 5/26/88				
DI Water	5.63 X 10 <sup>5</sup>	-	1.7 X 10 <sup>4</sup>	-
AD4-109A/Tide-Liquid	0	100%	0	100%
AD4-109A/Wisk-Liquid	0	100%	0	100%
AD4-109A/Bold 3-Powder	0	100%	0	100%
AD4-109A/Surf-Powder	33	99.99%	0	100%
AD4-109A/Tide-Powder	0	100%	0	100%

COMMENT: EFFECTIVE LAUNDRY SANITIZER ACTIVITY EQUALS 99.90%  
REDUCTION FOR BOTH SWATCH AND WASH WATER.

Qu-Sol  
AD4-109A  
Laundry Compatibility Study

RESULTS: KLEBSIELLA pneumoniae - ATCC 4352

SAMPLE	SWATCH		WASH WATER	
	Average Count	%REDUCTION	BACTERIA/ML	%REDUCTION
Test Date: 6/9/88				
DI Water	1.45 X 10 <sup>6</sup>	-	1.20 X 10 <sup>4</sup>	-
AD4-109A/Dynamo 2	0	100%	0	100%
AD4-109A/Surf-Liquid	15	99.99%	0	100%
AD4-109A/Tide-Liquid	0	100%	0	100%
AD4-109A/Wisk-Liquid	9.5	99.99%	0	100%
Test Date: 6/16/88				
DI Water	1.20 X 10 <sup>6</sup>	-	1.02 X 10 <sup>4</sup>	-
AD4-109A/Bold-Powder	2.26 X 10 <sup>2</sup>	99.98%	9 (<10)	99.91%
AD4-109A/Surf-Powder	9.66	99.99%	0	100%
AD4-109A/Tide-Powder	90	99.99%	9 (<10)	99.91%

COMMENT: EFFECTIVE LAUNDRY SANITIZER ACTIVITY EQUALS 99.90%  
REDUCTION FOR BOTH SWATCH AND WASH WATER.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 777-TA

Date Division Received 07/04/90

MRID Nos. 415520-01 to 415520-02

Product Manager 31 (Lee)

Product Name Qu-Sol Brand Disinfectant

Company Name Lehn & Fink Products, Div. of Sterling Drug, Inc.

202.0 Recommendations

202.1 Efficacy Supported By the Data

The submitted data by the Petrocci & Clarke Laundry Sanitizer Test are adequate to support efficacy of the product against Staphylococcus aureus and Klebsiella pneumoniae (with 5% blood serum as organic soil) for sanitizing moderately soiled laundry fabrics and wash water at a 1:250 dilution in the washing cycle in home and coin operated washers (non-medical areas).

The submitted data also exhibits satisfactory laundry sanitizing activity when combined with the various detergents (e.g. liquid Surf, liquid Dynamo 2, liquid Tide, liquid Wisk, powder Bold 3, powder Surf, and powder Tide).

203.0 Labeling

- a. Under directions for disinfection change "...1-1/4 oz. (2-1/2 tbsp.)..." to read "...1-1/2 oz. (3 tbsp.)..."
- b. The directions for laundry sanitizing should specify that the product is to be used in the wash cycle of home and coin-operated automatic washers.
- c. The directions for laundry sanitizing should indicate that heavily soiled items (such as diapers) should be rinsed to remove gross filth prior to sanitization.

Data supports 1 1/2 oz not 1 1/4 oz.  
because data actually shows

1 1/4 = 1:100

Data was 1:100

Therefore increased to 1 1/2 oz

1:100 3