

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

ANTIMICROBIAL PROGRAM BRANCH

IN 03/15/90 OUT 03/26/90
Reviewed by Srinivas Gowda *WGC*
Srinivas Gowda Date 3/29/90 03/26/90
EPA Reg. No. or File Symbol 777-TA
Date Division Received 02/20/90
Type Product (s): Hospital/General Disinfectant
MRID Nos. 413957-05 to 413957-16
Product Manager 31 (Lee)
Product Name Qu-Sol Brand Disinfectant
Company Name Lehn & Fink Products, Div. of Sterling Drug, Inc.
Submission Purpose New Application with efficacy data and
proposed label (Attached)*

Type formulation Liquid

Active Ingredient (s): %

Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) 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

*Conclusions: Satisfactory performance vs. test organisms except in Laundry Sanitizing Test. See 202.0.

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 ₁₄ , 40% C ₁₂ , 10% C ₁₆) 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: CORROSIVE
SEE BACK LABEL FOR ADDITIONAL PRECAUTIONS AND FIRST AID.

NET 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 to surface. 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. 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: Hazardous 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.

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

Disposal: Do not reuse empty container. Rinse bottle and put in trash.

Lehn & Fink Products
Div of Sterling Drug, Inc.
Montvale, NJ 07645

EPA Reg. #777-
EPA Est. #777-IL-1, -NJ-2
APM-LBD/EPALABEL/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

ACTIVE INGREDIENTS

Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) 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: CORROSIVE
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONS AND FIRST AID.

NET X FL. OZ. (X ML)

CARTON LABEL COPY FOR 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 Strength 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. Prevents regrowth.

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

Kills Staph, Strep and Salmonella germs

Kills lipophilic viruses such as Influenza Virus A2, Herpes Simplex, Vaccinia and Respiratory Syncytial Virus.

Reduces the hazard of cross infection.

Use Qu-Sol every time you clean
Use It Every Day

Lehn & Fink Products
Div. of Sterling Drug, Inc.
Montvale, NJ 07645

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

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 prevents 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. Prevents 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 FOR 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 to surface. 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. 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: Store in original container in areas inaccessible to small children.

Disposal: Do not reuse empty container. Rinse bottle, and put in trash.

Precautionary Statements: Hazardous 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.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 777-TA

Date Division Received 02/20/90

MRID Nos. 413957-05 to 413957-16

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 are acceptable to support effectiveness of the product as a hospital and/or general disinfectant against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa; as a disinfectant against Streptococcus faecalis, as fungicide against Trichophyton mentagrophytes; and as a virucide against Vaccinia, Herpes simplex types 1 & 2, Respiratory Syncytial virus and Influenza A₂/Japan/305/57 when used at a 1:100 dilution on moderately soiled, hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 10 minutes.

202.2 **Efficacy Not Supported by The data:**

The submitted Laundry Sanitizer Test data/report is incomplete and cannot be evaluated because the following procedural informations were not provided:

- a. Number of swatches used per jar.
- b. water to fabric ratio.
- c. Subculture medium/neutralizer/neutralization procedure employed and the results obtained.
- d. The actual amount of product added to the exposure chamber and the actual volume of solution employed.
- e. Compatibility of the product with other common laundry additives (e.g. soaps, detergent, bleach, starch, bluing, sours, fabrics softners) were not determined in the testing. Refer to item (a) of DIS/TSS-14 enclosure.

202.3 **Efficacy Not Related to Human Health**

The submitted data against Aspergillus niger to support efficacy as a fungistat is not considered to be directly related to human health. Therefore, under the efficacy data waiver, such data are not required to be submitted or reviewed.

203.0

Labeling:

- a. Include the major area (s) in which the product is recommend for use (e.g. homes, schools, hospitals).
- b. Under directions for disinfection change "...1-1/4 oz. (2-1/2 tbsp.)..." to read "...1-1/2 oz. (3 tbsp.)..."
- c. Under directions for toilet bowl disinfection change "Brush all surfaces" to read "Brush all surfaces including under the rim."
- d. Include method (s) of application (e.g. "by sponge, mop, or spray) followed by a statement such as "to wet all surfaces thoroughly").
- e. Revise the statement "Kills lipophilic viruses such as Influenza Virus A2, Herpes Simplex..." to read "Kills viruses such as Influenza A2/Japan/305/57, Herpes Simplex Types 1 & 2..."
- f. In lieu of data delete laundry sanitizing claims.
- g. Change "Reduces the hazard of cross infection" to read "Reduces the hazard of cross contamination from treated surfaces."