

11292-7

6-20-2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Linda Kirk Campbell
Director of Regulatory Compliance
Carroll Company
2900 West Kingsley Road
Garland, TX 75041

JUN 20 2002

Subject: Amendment per FIFRA
Quat Sanitizer Rinse
EPA Registration No. 11292-7
Application Date: March 11, 2002
EPA Received Date: March 29, 2002

Dear Ms. Campbell:

The following amendment, submitted in connection with registration under 3(c)(7)(A) of the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), as amended, is acceptable with the comments listed below.

Proposed Amendment

- Update First Aid Statements per PR Notice 2001-1

Label Comments

1. Since your label includes hospitals and lists unqualified surfaces like metal and plastic surfaces, the MOU from PR Notice 94-4 is required on your label; therefore, you must revise the Directions for Use section to include the following statement:
This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.
2. Revise the Precautionary Statements to read:
DANGER. Keep out of Reach of Children. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. Harmful if swallowed. Harmful if inhaled. Avoid breathing spray mist. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before

reuse.

CONCURRENCES

SYMBOL	7510C						
SURNAME	Gray						
DATE	10-14-02						

3. Revise the heading "For Industrial, Commercial or Medical Use Only" to read: **"FOR INDUSTRIAL, COMMERCIAL OR INSTITUTIONAL USE ONLY"** by deleting the word "medical."
4. Revise the sentence beginning "Surfaces must remain moist for 10 minutes...." to read "Surfaces must remain *wet* for 10 minutes...."
5. Bold and separate the heading **"SANITIZATION OF FOOD CONTACT SURFACES, GLASSWARE, SILVERWARE, DISHES, COOKING UTENSILS, MILK CANS AND EQUIPMENT IN FOOD PROCESSING PLANTS, MEAT PLANTS, DAIRIES AND RESTAURANTS"** from the "For Industrial, Commercial or Institutional Use Only" directions.
6. Delete, from Directions for Use section, the phrase "Do not use a towel."
7. Revise the First Aid Statements to include the following statement:
If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
8. Since this product is sold in 1 gallon containers, you must revise your storage and disposal instructions accordingly:

Storage and Disposal

Store in original container in areas inaccessible to children and persons unfamiliar with its proper use. Do not reuse container. Wrap container and discard in the trash.

General Comments

A stamped copy of the label is enclosed for your records. Please submit one(1) final printed label before releasing this product shipment. Should you have any questions regarding this letter, please contact me at 703-308-6233.

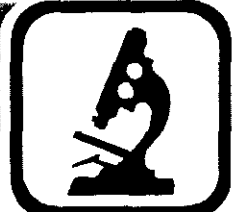
Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510 C)

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DISINFECTANT



Quat Sanitizer Rinse

A DISINFECTANT & DEODORIZER THIS DISINFECTANT IS AN EFFECTIVE VIRUCIDE AGAINST INFLUENZA VIRUS TYPE A, BRAZIL AT 1 OZ./GAL ON PRECLEANED, NON-POROUS HARD SURFACES.

ACTIVE INGREDIENTS:
 Alkyl (C₁₂, 50%, C₁₄, 40%, C₁₆, 10%) dimethyl
 benzyl ammonium chloride 10.00%
 INERT INGREDIENTS: 90.00%
 TOTAL: 100.00%

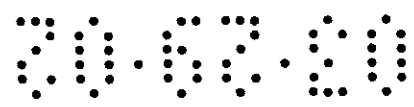
DANGER
KEEP OUT OF REACH OF CHILDREN
See back panel for additional precautions

PROFESSIONAL
PRODUCTS

CARROLL

3.0 LITERS
IN 1 GALLON

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Monday, March 11, 2002 2:02:23PM



ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 20 2002
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 11292-7

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**USE DIRECTIONS
GENERAL CLASSIFICATION**

Use according to directions. It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This disinfectant has not been tested for effectiveness against Mycobacterium tuberculosis and must not be relied upon when tuberculocidal activity is intended.

**DISINFECTION IN HOSPITALS, RESTAURANTS,
COMMERCIAL AND INDUSTRIAL OFFICES, AND RESTROOMS:**

This product may be used on floors, walls, woodwork and furnishings. Types of surfaces suitable for disinfection include glass, smooth metal, washable painted wood or metal, vinyl, glazed porcelain, plastic, finished leather, finished wood and similar non-porous hard smooth surfaces. Always preclean surfaces with a suitable detergent and rinse well with water before disinfection. After cleaning apply a solution containing 1 ounce of disinfectant per gallon of water for usual disinfecting applications. For disinfecting contaminated inanimate areas use 1-1/2 ounces per gallon of water.

This disinfectant is effective at 1 oz./gal. against Pseudomonas aeruginosa PRD-10, Salmonella choleraesuis ATCC 10708, and Staphylococcus aureus ATCC 6538 when tested by the A.O.A.C. Use Dilution Test Method for precleaned, non-porous hard surfaces.

This disinfectant is an effective virucide against Influenza virus, Type A, Brazil at 1 oz./gal. on precleaned, non-porous hard surfaces.

FOR INDUSTRIAL, COMMERCIAL OR MEDICAL USE ONLY

The use solution should be applied using a clean mop, sponge, or by a mechanical spraying device. Surfaces must remain moist for at least 10 minutes to assure proper germicidal action. Food contact surfaces treated with this concentration of disinfectant must be rinsed with potable water before reuse. Prepare fresh solutions daily. Discard solutions when visibly soiled.

SANITIZATION OF FOOD CONTACT SURFACES, GLASSWARE, SILVERWARE, DISHES, COOKING UTENSILS, MILK CANS AND EQUIPMENT IN FOOD PROCESSING PLANTS, MEAT PLANTS, DAIRIES AND RESTAURANTS: Scrape or flush away gross soils and clean with a suitable detergent. Rinse thoroughly with potable water then apply a sanitizing treatment of 1 ounce of this product in 4 gallons of water (200 PPM active sanitizer). The sanitizing treatment may be applied by immersion, flooding, flushing, spraying or with a clean cloth or mop. All surfaces must be thoroughly wet for 1-2 minutes for proper sanitization. Allow treated items to drain thoroughly and air dry. Do not use a towel. No rinsing is required. Where possible invert treated items (glassware, dishes, utensils, milk cans, etc.) and let them drain and air dry on a clean surface. Prepare fresh solutions daily or more often if solutions become diluted or soiled.

**FOR DEODORIZING GARBAGE CANS, GARBAGE TRUCKS, INDUSTRIAL WASTE
RECEPTACLES, AND GARBAGE HANDLING EQUIPMENT:**

Preclean with a suitable detergent and rinse well. Then apply a wetting solution of 2 oz. of this product per gallon of water.

DISPOSAL

Store only in tightly closed, original container in a secure area inaccessible to children and away from food or feed.

Do not reuse empty container. Rinse thoroughly before discarding in trash.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER

Causes eye damage and skin irritation. Do not get in eyes, on skin or clothing. Harmful if swallowed. Avoid contamination of food. Avoid breathing spray mist.

FIRST AID

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

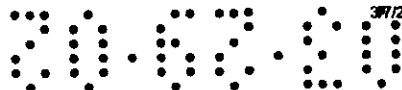
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. **IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. **IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

E.P.A. REG. NO. 11292-7
E.P.A. EST. NO. 11292-CA-1

CARROLL
COMPANY

2903 W. Kingsley Rd. ♦ Garland, Texas 75041
606.527.5722 ♦ www.carrollco.com



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