

PM 31

1064



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:
3838-51

Date of Issuance:
OCT 13 1999

NOTICE OF PESTICIDE:

- Registration
- Reregistration

Term of Issuance:
Conditional

Name of Pesticide Product:
Quat 20

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Essential Industries, Inc.
P. O. Box 12
Merton, WI 53056-0012

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 3838-51".
- b. Since this product is used in restaurants, you will need to include the following statement under "Disinfection" in the "Directions for Use":

"When used as a disinfectant on food contact surfaces such as counter tops, tables, and appliances, wash surfaces thoroughly with a potable water rinse. Do not use on utensils, dishes, or glasses.

Signature of Approving Official:

Velma Noble
Product Manager 31

Date:

OCT 13 1999

Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

- c. You will need to remove the MOU language from the middle of the HIV directions and placed it either before or after the "Disinfection" directions.
- d. Based on a review of the Lonza Acute Toxicology studies cited in support of this product's registration, the following acute toxicity categories were assigned.

<u>Guideline</u>	<u>Study</u>	<u>Category</u>
81-1	Acute Oral	III
81-2	Acute Dermal	III
81-4	Primary Eye Irritation	I
81-5	Primary Skin Irritation	I

Therefore, your precautionary labeling must be revised as follows:

Precautionary Statement Revisions:

Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or clothing. Wear protective eyewear (goggles, faceshield, or safety glasses), clothing, and rubber gloves. Harmful if swallowed and/or if absorbed through the skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Statements of Practical Treatment Revisions:

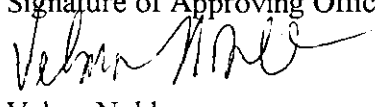
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink, promptly, large quantities of water. Avoid alcohol.

- 3. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec.6(e). Your release for shipment o the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

<p>Signature of Approving Official:  Velma Noble Product Manager 31 Regulatory Management Branch I Antimicrobials Division (7510C)</p>	<p>Date: OCT 13 1999</p>
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QUAT 20

KEEP OUT OF THE REACH OF CHILDREN
DANGER

For Commercial, Industrial and Institutional Use Only
See Side Panels For Additional Precautionary Statements

Cleaner · Disinfectant · Detergent
Deodorizer · Virucide*

EPA Reg. No. 3938-XX · EPA Est. No. 3938-WI-1

ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride.....	0.53535%
Dioctyl dimethyl ammonium chloride.....	0.26776%
Didecyl dimethyl ammonium chloride.....	0.26776%
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride.....	0.71393%
INERT INGREDIENTS	98.2155%
TOTAL	100.0000%

 **ESSENTIAL
INDUSTRIES**



XXXXX

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 13 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 3938-51

RECEIVED
6/15/99

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is a phosphate-free formulation designed to provide effective cleaning, deodorizing and disinfection specifically for hospitals, nursing homes, hotels, schools, restaurants and other institutions where housekeeping is of prime importance in controlling cross-contamination from treated surfaces.

This product, when used as directed, is formulated to disinfect hard, non-porous, inanimate, environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bath tubs and cabinets. For larger areas such as operating rooms, patient care facilities and restrooms, this product is designed to provide both general cleaning and disinfecting.

This product deodorizes those areas which generally are hard to keep fresh-smelling such as garbage storage areas, empty garbage bins and cans, toilet bowls, and other areas which are prone to odors caused by microorganisms.

This product is formulated to a neutral pH and will not dull high-gloss floor finishes with repeated use.

DISINFECTION: To disinfect inanimate, hard, non-porous surfaces add 6.4 ounces (1:20) of this product per gallon of water. Apply solution with a mop, cloth, sponge, or hand-pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

To disinfect toilet bowls, remove gross filth or soils from surfaces with bowl brush. Add 6.4 (1:20) ounces of product to the bowl water. Brush or swab the bowl completely using a scrub brush or toilet mop making sure to get under the rim. Let stand for 10 minutes and flush.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND VIRUCIDE IN WATER UP TO 400 PPM HARDNESS (AS CaCO₃) IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

DEODORIZATION: To deodorize, apply this product as indicated under the heading DISINFECTION.

BACTERICIDAL ACTIVITY: At the 6.4 (1:20) ounces per gallon dilution, this product demonstrates effective disinfectant activity against the organism: *Pseudomonas aeruginosa* PRD-10, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Staphylococcus aureus* (clinical isolate), *Bordetella bronchiseptica*, *Corynebacterium ammoniagenes*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Enterobacter cloacae* (clinical isolate), *Enterococcus faecalis*, *Enterococcus faecalis* (clinical isolate), *Escherichia coli*, *Escherichia coli* (clinical isolate), *Fusobacterium necrophorum*, *Klebsiella pneumoniae* subsp. *pneumoniae*, *Lactobacillus casei* subsp. *rhamnosus*, *Listeria monocytogenes*, *Pasteurella multocida*, *Proteus vulgaris*, *Proteus mirabilis* ATCC 9921, *Proteus mirabilis* ATCC 25933, *Salmonella choleraesuis* subsp. *choleraesuis* serotype paratyphi B, *Salmonella choleraesuis* subsp. *choleraesuis* serotype typhi, *Salmonella choleraesuis* subsp.

choleraesuis serotype typhimurium, *Salmonella choleraesuis* subsp. *choleraesuis* serotype pullorum, *Serratia marcescens*, *Shigella sonnei*, *Shigella flexneri* Type 2b, *Shigella dysenteriae*, *Staphylococcus aureus* subsp. *aureus*, *Staphylococcus epidermidis*, *Staphylococcus epidermidis* (clinical isolate), *Streptococcus pyogenes* (Clinical - Flesh eating strain BIRD M3), *Streptococcus pyogenes* Group A, *Xanthomonas maltophilia* (clinical isolate) and Vancomycin resistant *enterococcus faecalis* (ATCC 51575).

FUNGICIDAL ACTIVITY: At the 6.4 (1:20) ounces per gallon dilution, this product demonstrates effective fungicidal activity against the pathogenic fungi *Trichophyton mentagrophytes*, *Candida albicans* and *Aspergillus niger*.

***VIRUCIDAL ACTIVITY:** This product, when used on environmental, inanimate hard non-porous surfaces at 6.4 ounces per gallon of water, exhibits effective virucidal activity against Herpes Simplex Type 1 (causative agent of fever blisters), Herpes Simplex Type 2 (genital disease), Influenza A2/Hong Kong, Vaccinia, Pseudorabies, Bovine Rhinotracheitis, Feline Leukemia, Feline Picornavirus and Canine Distemper.

KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (hospitals, nursing homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Net Contents: One Gallon (3.8 Liters)

PRECAUTION HAZARDS TO HUMAN

DANGER. KEEP OUT OF REACH OF CHILDREN. Contact with eyes, on skin or on clothing. Wear goggles or face shield if swallowed. Avoid contamination of food. Wash thoroughly with soap and water after handling.

STATEMENT OF

In case of contact, immediately flush eyes or skin with water. Call a physician.

If swallowed, drink egg whites or gelatin solution with water. Avoid alcohol. Call a physician immediately.

NOTE

Probable mucosal damage may contraindicate the

STORAGE

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

STORAGE: Store in a dry place no lower in temperature than 40°F.

CONTAINER DISPOSAL: Do not reuse empty container for newspaper, and discard empty container in trash.

PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. If a spray or mixture or rinsate is a violation of Federal law, according to label instructions, contact your State Hazardous Waste representative at the nearest EPA

Essential

P.O. Box 12 - Merton, Wisconsin

ACCEPTED
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in EPA Letter Dated:

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Fungicide, and Rodenticide Act as
amended, for the pesticide,
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