

SEP - 4 2003

Ms: Kimberly Johnson
QC/Regulatory Technician
Essentials Industries, Inc.
P.O. Box 12
Merton, WI 53056

Subject: Quat 20
EPA Registration No. 3838-51
Application Date: 5/28/03
Receipt Date: 6/13/03

Dear Ms. Johnson:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with comments:

Update First Aid statements

LABEL COMMENTS

1. You must submit separate "Cleaning and Deodorizing" directions. They must be clearly separated from the Directions of Use.
2. The Agency assumes that the only container size for this product is one gallon or less. Revise your Storage and Disposal statement to read as follows: If you are marketing this product in larger sized containers, notify the Agency so that the proper language may be added to your label.

GENERAL COMMENTS

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

| CONCURRENCES | | | | | | | |
|--------------|---------|--|--|--|--|--|--|
| SYMBOL | 75100 | | | | | | |
| SURNAME | Johnson | | | | | | |
| DATE | 8-19-03 | | | | | | |

Should you have any questions or comments concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

QUAT 20

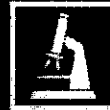
KEEP OUT OF THE REACH OF CHILDREN
DANGER

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

**Cleaner · Disinfectant · Detergent
Deodorizer · Virucide***

EPA Reg. No. 3838-51 · EPA Est. No. 3838-WI-1

 **ESSENTIAL
INDUSTRIES**



2311DN

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

SEP 4 - 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 3838-51

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, bathtubs, shower stalls, bath tubs and railings. 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.

NOTE: A rinse with potable water is required for surfaces in direct contact with food.

DISINFECTANT: 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 toilet brush. Add 6.4 (1:20) ounces of product to the bowl water. Brush or sweep the bowl completely using a scrub brush or toilet mop making sure to get under the rim. Let stand for 10 minutes and flush.

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 enamel, dishes, or glasses.

This product is not to be used as a terminal disinfectant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, or (2) contacts intact mucous membranes for which does not ultimately 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.

NOTE: This product should not be used to clean food contact surfaces, utensils, glassware and dishes.

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

DEODORIZANT: 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 organisms: *Providentia aerogenes* PD-10, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Staphylococcus aureus* (clinical isolate), *Bordetella bronchiseptica*, *Corynebacterium aneurorhaceum*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Enterobacter cloacae* (clinical isolate), *Enterococcus faecalis*, *Enterococcus faecalis* (clinical isolate), *Escherichia coli*, *Escherichia coli* (clinical isolate), *Fusobacterium necrophorum*, *Moraxella pneumoniae* subsp. *pneumoniae*, *Lactobacillus casei* subsp. *ruminantium*, *Listeria monocytogenes*, *Pasteurella multocida*, *Proteus vulgaris*, *Proteus mirabilis* ATCC 9721, *Prevotella mirabilis* ATCC 25733, *Salmonella choleraesuis* subsp. *choleraesuis* serotype paratyphi B, *Salmonella choleraesuis* subsp. *choleraesuis* serotype typhi, *Salmonella choleraesuis* subsp. *choleraesuis* serotype typhimurium, *Salmonella choleraesuis* subsp. *choleraesuis* serotype typhimurium, *Serratia marcescens*, *Shigella sonnei*, *Shigella flexneri* Type 2b, *Shigella dysenteriae*, *Staphylococcus aureus* subsp. *aureus*, *Staphylococcus epidermidis*, *Staphylococcus epidermidis* (clinical isolate), *Streptococcus pyogenes* (Clinical - Flack eating strain BIRD MS), *Streptococcus pyogenes* Group A, *Xanthomonas melleophilis* (clinical isolate) and *Yersinia enterocolitica* (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 (nervous agent of fever blisters), Herpes Simplex Type 2 (genital disease), Influenza A2/Hong Kong, Vaccinia, Pseudorabies, Bovine Rhinotracheitis, Feline Leukemia, Feline Panleukopenia 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).

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 recaptured and disposed of according to local regulations for infectious waste disposal.

Net Contents: One Gallon (3.0 Liters)

PRECAUTIONS

KEEP OUT OF REACH OF CHILDREN. CONTAINERS SHOULD BE KEPT IN ORIGINAL CONTAINER. READ LABEL CAREFULLY. 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.

Have the product container or label with you when calling for medical assistance or hospital admission. Do not use if the container is damaged or the contents are not as labeled.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Wash thoroughly with soap and water.

IF IN EYES: Flush eyes open and rinse slowly and gently with water for 5 minutes. Then continue rinsing eye. Call a poison center for more information.

IF SWALLOWED: Call a poison center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison center or doctor.

IF INHALED: Remove person to fresh air. If person is not breathing, call 911 or a poison center or hospital immediately. If breathing is difficult, call a poison center for more information.

IF ON SURFACE: Wipe off contaminated surface. Wash thoroughly with soap and water.

IF ON FLOOR: Sweep up and dispose properly. Do not flush down drain. Do not pour into sewer.

IF ON CONTAINER: Do not contaminate water, food, or feed. Store in a dry place not lower in temperature than 50°F (10°C). Triple rinse (or equivalent). Then discard and recycle container. Do not reuse container.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. If they cannot be disposed of properly, contact your local, state, or federal environmental control agency for the most appropriate disposal method.

HAZARDOUS WASTE DISPOSAL: This product contains phosphorus. Do not discharge into sewer.

STORAGE: Store in a dry place not lower in temperature than 50°F (10°C). Triple rinse (or equivalent). Then discard and recycle container. Do not reuse container.

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Essential

P.O. Box 12 - Mertoni, Wisconsin 53656-