

OCT - 4 2004

Ms. Maureen Smith
Quality & Regulatory Manager
Essentials Industries, Inc.
P.O. Box 12
Merton, WI 53056

Subject: Nutral Q
EPA Registration No. 3838-50
Application Date: 3/9/04
Receipt Date: 3/17/04

Dear Ms. Smith:

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

Add new claims to label for Hepatitis B Virus (HBV) and Bovine Viral Diarrhea Virus (HCV)

EFFICACY

1. The proposed label claims that the product, Nutral Q, is an effective disinfectant against the Hepatitis C Virus in the presence of 400 ppm hard water and 5% serum when used at 1 ounce per gallon for a contact time of 10 minutes. This claim is supported by your data.
2. The proposed label claims that the product, Nutral Q, is an effective disinfectant against the Hepatitis B Virus in the presence of 400 ppm hard water and 100% serum when used at 1 ounce per gallon for a contact time of 10 minutes. You provided data to support a claim in the presence of 5% serum, however; you have not provided data to support a claim in the presence of 100% serum. You must delete this reference to 100% serum from the label.

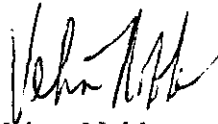
GENERAL COMMENTS

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	7510C						
SURNAME	J. Jones						
DATE	4-29-04						

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)

NUTRAL Q

KEEP OUT OF THE REACH OF CHILDREN
DANGER

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

Disinfectant · Cleaner · Deodorizer Fungicide · Virucide*

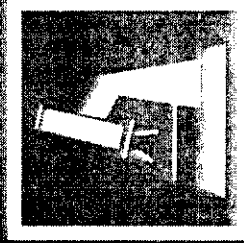
EPA Reg. No. 3838-50 · EPA Est. No. 3838-WI-I

ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride	3.255%
Dioctyl dimethyl ammonium chloride.....	1.628%
Didecyl dimethyl ammonium chloride.....	1.628%
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride.....	4.339%

INERT INGREDIENTS	89.150%
TOTAL	100.000%

ESSENTIAL
INDUSTRIES



705DN

838-50

DIRECTIONS FOR USE

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

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, either into or in contact with the blood stream or normally sterile areas of the 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.

This product is a phosphate-free formulation designed to provide effective cleaning, deodorizing and disinfection for hospitals, nursing homes, hotels, schools 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 non-porous inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs and cabinets. For larger areas such as operating rooms and patient care facilities, 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 1 ounce 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 1 ounce of product to the bowl water. Brush or scrub 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).

CLEANING/DEODORIZATION: Apply use solution, 1 oz. per gallon of water, to hard nonporous surfaces with mop, cloth, sponge, or hand trigger sprayer. Allow to air dry.

BACTERICIDAL ACTIVITY: At the 1 ounce per gallon dilution, this product demonstrates effective disinfectant activity against the organisms: *Pseudomonas aeruginosa*, *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), Vancomycin resistant *Enterococcus faecalis* and Methicillin resistant *Staphylococcus aureus*.

MOLD AND MILDEW CONTROL: At 1 oz. per gallon of water, this product effectively controls the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Apply use solution with a cloth, mop, sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth appears.

FUNGICIDAL ACTIVITY: At the 1 ounce per gallon of dilution, this product demonstrates effective fungicidal activity against the pathogenic fungi, *Trichophyton mantagrophytes*, in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, or clean hard, nonporous surfaces commonly contacted by barefeet. Follow disinfectant directions.

***VIRUCIDAL ACTIVITY:** This product, when used on environmental, inanimate hard non-porous surfaces at 1 ounce per gallon of water, exhibits effective virucidal activity against HIV-1, HIV-2, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), 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.

~~At 1 ounce per one gallon (or equivalent use dilution) in the presence of 400 ppm hard water (CaCO₃) and 100% serum this product was proven to be effective against Hepatitis B Virus with a contact time of 10 minutes.~~

At 1 ounce per one gallon (or equivalent use dilution) in the presence of 400 ppm hard water (CaCO₃) and 5% serum this product was proven to be effective against Hepatitis C Virus with a contact time of 10 minutes.

KILLS HIV-1, HIV-2, HBV AND HCV 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 or Type 2 (HIV-1 or HIV-2) (associated with AIDS) and HBV.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HIV-2, HBV AND HCV 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 containing HIV-1, HIV-2, HBV and HCV should be autoclaved and disposed of according to local regulations for infectious waste disposal.

If container is 5 gallons or larger the following statement must appear on the label.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Net Contents: Five Gallons (18.9 Liters)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves and protective clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID

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

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
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. Call a poison control center or doctor for treatment advice.

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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Remove person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

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

If the container is greater than one gallon use the following statements.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

PESTICIDE STORAGE: Store in a dry place no lower in temperature than 50°F or higher than 120°F.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

If the container is one gallon or less use the following statements.

STORAGE AND DISPOSAL

Do not store on side. Avoid creasing or impacting of side walls. Store in dry place at a temperature no lower than 50°F or higher than 120°F. Do not reuse container. Discard in the trash.

Essential Industries, Inc.

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