

SEP - 4 2003

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

Subject: Readiquat TB
 EPA Registration No. 3838-52
 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. Since this product may be used in hospitals and nursing homes on unqualified surfaces such as "stainless steel", the Memorandum of Understanding from PR 94-4. You must add the following text to the "Directions for Use": 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 bloodstream 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.
2. Qualify the surface, porcelain, as hard nonporous by stating "glazed" porcelain.
3. 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 container, notify the Agency so that the proper language may be added to your label.

CONCURRENCES							
SYMBOL	7510C						
SURNAME	J. Jones						
DATE	8-19-03						

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.

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)

READIQUAT TB™

KEEP OUT OF THE REACH OF CHILDREN
WARNING

For Commercial, Industrial and Institutional Use Only.
See Side Panel for Additional Precautionary Statements

Ready-To-Use Tuberculocidal
Disinfectant Cleaner

EPA Reg. No. 383B-52 · EPA Est. No. 383B-WI-1

 ESSENTIAL
INDUSTRIES



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DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is designed specifically as a general non-acid cleaner and disinfectant for use in hospitals, nursing homes, schools, hotels and restaurants. It is formulated to disinfect hard, non-porous, inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs and cabinets. May be used in the kitchen on counters, sinks, appliances and stove tops. In addition, this product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, basements, restrooms and other areas which are prone to odors caused by microorganisms.

NOTE: A clean with potable water is required for surfaces in direct contact with food.
DISINFECTION AND CLEANING: Remove gross dirt or heavy soil prior to application of the product. Hold container six to eight inches from surface to be treated. Spray area until it is covered with the solution. Allow product to penetrate and remain wet for 10 minutes. No scrubbing is necessary. Wipe off with a clean cloth, mop or sponge. The product will not leave grit or soap scum.

One-step cleaning and disinfection of toilet bowls and urinals: Remove water from bowl by forcing water over trap with a scrub mop applicator. Press scrub mop against side of the bowl to remove excess water from applicator. Apply 1 to 2 ounces of this product evenly, allowing sufficient time for product to cover entire surface of bowl for maximum cleaning. Scrub bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand 10 minutes and flush.

NOTE: This product should not be used to clean food contact surfaces, utensils, glassware and dishes.
TUBERCULOCIDAL ACTIVITY: This product exhibits disinfectant efficacy against *Mycobacterium tuberculosis* (MCS) in 10 minutes at 20° C when used as directed on previously cleaned hard non-porous inanimate surfaces.

ANTIBACTERIAL ACTIVITY: When used as directed, this product exhibits effective disinfectant activity against the organisms: *Staphylococcus aureus*, *Serratia marcescens*, *Pseudomonas aeruginosa*, *Escherichia coli* 0157:H7 and meets the requirements for hospital use.

MILDEWASTERS: To control mold and mildew on pre-cleaned, hard, non-porous surfaces spray surface to be treated making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

FUNGICIDAL ACTIVITY: This product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (Athlete's Foot Fungus) when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms or other clean, non-porous, hard surfaces commonly contacted by bare feet.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (7% BLOOD SERUM).

***ANTIVIRAL ACTIVITY:** This product, when used on environmental, inanimate, non-porous surfaces, exhibits effective virucidal activity against HIV-1 (associated with AIDS) and *Cytomegalovirus*.

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: Wear disposable latex gloves and/or body fluids use disposable latex gloves,

gown, mask 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 Quart (946 Liters)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING - KEEP OUT OF REACH OF CHILDREN. Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Avoid contamination of food. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

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 UNABLE: 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: Prohibit medical drainage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL

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

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

CONTAINER DISPOSAL: Do not reuse container. Rinse thoroughly, securely wrap in several layers of newspaper and discard empty container in trash.

Essential Industries, Inc.

P.O. Box 12 · Norton, Wisconsin 53056-0012 USA · (262) 536-1122 · www.essential.com

ACCEPTED
COMMENTARY
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. 3838-52

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