

1677-226

10/8/2009

1/7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

OCT 8 2009

Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Attention: Theodore D. Head, Manager
Product Registration and Compliance

Subject: Virasept
EPA Registration No. 1677-226
Your Amendment Dated July 29, 2009

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, to add efficacy claims to the product labeling, is acceptable, provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3©(5) and sec. 4 when the Agency requires all registrants of similar products to submit such data.
2. The submitted efficacy study (MRID No. 478186-01) is acceptable regarding the use of the product, virasept, as a disinfectant with claims against Clostridium difficile spores on hard non-porous surfaces for a contact time of 10 minutes.
3. The proposed label is acceptable regarding the use of the product, as an disinfectant with claims against Clostridium difficile spores on hard non-porous surfaces for a contact time of 10 minutes..
4. Refer to the enclosed copy of the efficacy review under "CONCLUSIONS" and "RECOMMENDATIONS" for further comments.
5. Submit two (2) copies of final printed labeling before you release the product for shipment.

2/7

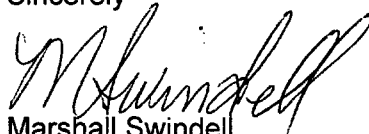
Page 2
EPA Registration No. 1677-226

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 of the product constitutes acceptance of these conditions.

A stamped copy of the "accepted" product labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely



Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Enclosure

3
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Virasept

Ready-to-Use

**"One-Step" Detergent-Disinfectant / Bactericide/Tuberculocide / Fungicide/
Virucide* / Deodorizer**

Broad-Spectrum Disinfectant

Sterilant

**Hospitals - Nursing Homes - Institutions - Schools - Daycare Centers -
Restaurants - Food Service - Beverage and Food Processing Plants -
Veterinary, Animal Housing and Industrial Use**

ACTIVE INGREDIENTS:

Hydrogen Peroxide.....	3.130%
Octanoic Acid.....	0.099%
Peroxyacetic Acid.....	0.050%

OTHER INGREDIENTS: 96.721%

TOTAL:..... 100.000%

ACCEPTED
with COMMENTS
EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1677-226

**KEEP OUT OF REACH OF CHILDREN
DANGER**

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Causes irreversible eye damage. Do not get in eyes or on clothing. Wear goggles, face shield, or shielded safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the restroom. Remove and wash contaminated clothing before reuse.

FIRST AID

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.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

FOR EMERGENCY MEDICAL INFORMATION IN USA OR CANADA, CALL 1-800-328-0026

FOR EMERGENCY MEDICAL INFORMATION WORLDWIDE, CALL 1-651-222-5352 (IN THE USA)

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

ENVIRONMENTAL HAZARDS (greater than 5 gallons): 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 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.

6
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Virasept is a patented ready-to-use, "one-step" Detergent-Disinfectant, Virucide, Bactericide, Tuberculocide and Fungicide that delivers effective cleaning, disinfecting and malodor control. The unique chemistry is formulated for use in daily maintenance programs and will not harm fixtures.

[Note to reviewer: The following is considered optional marketing language:]

- Virasept is effective in kitchens, bathrooms and other housekeeping areas.
- Virasept is an effective cleaner and disinfectant for food service operations.
- Virasept cleans and disinfects finished floors, sinks and tubs.
- Virasept provides non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.
- Effectively removes greasy soils.
- Virasept is effective yet economical.
- Virasept improves labor results by effectively controlling malodors.
- Virasept will not leave grit or soap scum.
- Virasept disinfects, cleans and deodorizes surfaces in rest rooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other listed places where bacterial growth can cause malodors.
- Virasept effectively cleans, disinfects and deodorizes hard, non-porous surfaces in hospitals, medical, dental and other health facilities.
- Virasept effectively cleans, disinfects and deodorizes bed rails, wheelchairs, wash basins, bed pans and non-critical medical equipment surfaces in hospitals (medical and healthcare) facilities. This product is not for use as a medical device sterilant or high level disinfectant.
- Virasept is effective against methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus faecalis* (VRE) that are associated with healthcare (hospital) acquired (associated) infections.
- Virasept is effective against Avian Influenza.
- Virasept is effective against Hepatitis B Virus.
- Virasept is tuberculocidal.
- Virasept meets AOAC efficacy standards for hospital-use disinfectants.
- Disinfectant activity with pleasant fresh scent (with pleasant green apple fragrance).
- Formulated with patented corrosion inhibitors.
- Virasept is gentle on fixtures.
- Virasept cleans and disinfects in one labor saving step.
- Virasept's non-corrosive formula is compatible with most health care surfaces.
- Effective in 4 minutes against the bacteria and viruses listed on the label.
- Virasept effectively kills many bacteria and viruses associated with food borne illness.
- Virasept is an excellent cleaner for use on non-food contact surfaces.

Virasept is recommended for disinfecting and cleaning floors, walls, and other hard non-porous environmental surfaces such as tables, chairs, countertops, bed rails, bathroom fixtures, sinks, shelves, racks, carts, the exterior of refrigerators, non-food contact surfaces of coolers, glazed tile, linoleum, vinyl, glazed porcelain, plastic (such as polyethylene, polypropylene, polyvinylchloride, and polycarbonate), metal, stainless steel, chrome, glass, and painted or varnished surfaces. **Virasept** will not harm finished floors.

[Note to reviewer: Language in () is considered optional or interchangeable.]

Areas of Use: Hospitals, nursing homes, other health care-facilities, (healthcare) (research) (industrial) (pharmaceutical) laboratories, daycare centers, schools and colleges, playground equipment, cafeterias, veterinary clinics, animal (housing) (care) facilities, animal life science laboratories, dental offices, industrial facilities, camp grounds, dietary areas, beverage and food processing plants, USDA inspected food processing facilities, restaurants, bars, hotels, motels, office buildings, public rest rooms, public facilities, cruise and transportation industry, taxis, emergency vehicles, (ambulances, fire trucks, helicopters, law enforcement vehicles), buses, airports, airplanes, food service facilities, food and beverage stores, recreational and athletic facilities, locker rooms, correctional facilities, retail and service establishments, dressing rooms, kitchens, shower and bath areas.

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with COMMENTS

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OCT - 8 2009

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

DIRECTIONS FOR USE

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

DISINFECTION / CLEANING / DEODORIZING DIRECTIONS:

For hospital disinfection, deodorizing and cleaning of hard non-porous surfaces according to the AOAC Use-Dilution Test, modified in the presence of 5% organic soil load. Apply **Virasept** with a coarse trigger sprayer, cloth, mop, brush, scrubber, or by soaking to thoroughly wet surface. Allow surface to remain wet for at least 4 minutes. Remove solution with a mop, cloth, sponge, or vacuum pickup or allow to air dry. For heavily soiled areas, a pre-cleaning step is required. Rinsing of non-food contact surfaces is not necessary.

BACTERICIDAL:

Virasept is effective against the following pathogenic bacteria at a contact time of 4 minutes in the presence of 5% organic soil load. Apply as directed in the Disinfection/Cleaning/Deodorizing directions for use.

Pseudomonas aeruginosa – ATCC 15442
Staphylococcus aureus – ATCC 6538
Serratia marcescens – ATCC 14756
Escherichia coli – ATCC 11229
Escherichia coli O157:H7 – ATCC 35150
Shigella flexneri – ATCC 9380
Enterobacter aerogenes – ATCC 13048

Klebsiella pneumoniae – ATCC 4352
Salmonella enterica – ATCC 10708
Staphylococcus aureus (MRSA) – ATCC 33592
Staphylococcus aureus (VISA) – HIP 5836
Enterococcus faecalis (VRE) – ATCC 51299
Proteus vulgaris – ATCC 13315

STERILANT / SPORICIDAL:

Virasept is an effective sterilant according to the AOAC Sporicidal Activity of Disinfectants Method, modified in the presence of 5% organic soil load, on hard non-porous surfaces such as plastics, stainless steel and glass. **Virasept** can be used on items such as glassware, laboratory instruments, containers, etc. Immerse items to be sterilized in a sufficient volume of **Virasept** to cover the items and fill all passages requiring treatment. **Virasept** is effective against *Clostridium sporogenes* and *Bacillus subtilis* endospores after a 60 minute exposure time. Surfaces must remain wet for the entire exposure time to achieve effectiveness against spores. Remove the items after 60 minutes and remove the **Virasept** solution with a clean cloth or clean sponge, rinse with sterile water and allow to air dry, or drain and allow to air dry. For heavily soiled items or areas, a pre-cleaning step is required.

Clostridium difficile

Virasept kills and/or inactivates spores of *Clostridium difficile* on hard, non-porous surfaces. Apply **Virasept** with a coarse trigger sprayer, cloth, mop, brush, scrubber, or by soaking to thoroughly wet surface. **Virasept** is effective against *Clostridium difficile* endospores after a 10 minute exposure time.

Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. A pre-cleaning step is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

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 DATED: 8/2009

7/6

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

TUBERCULOCIDAL:

Virasept is effective against *Mycobacterium bovis* – BCG at a contact time of 2.5 minutes in the presence of 5% organic soil load. Apply as directed in the Disinfection/Cleaning/Deodorizing directions for use.

VIRUCIDAL*:

Virasept inactivates Norovirus (Norwalk-like virus) and the following viruses at a contact time of 4 minutes in the presence of 5% organic soil load. Apply as directed in the Disinfection / Cleaning / Deodorizing directions for use.

- *Norovirus (Feline Calicivirus tested surrogate)
- *Hepatitis B Virus (HBV)
- *HIV-1 (AIDS Virus)
- *Respiratory Syncytial Virus
- *Human Coronavirus
- *Rhinovirus Type 37
- *Rotavirus
- *Influenza A Virus
- *Avian Influenza A
- *Adenovirus Type 4

***KILLS HIV-1 (AIDS VIRUS) and HBV (HEPATITIS B VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare settings 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 the transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) or HBV (Hepatitis B Virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) AND HBV (HEPATITIS B VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: Disposable latex or vinyl gloves, gowns, face masks, or eye coverings must be worn during all cleaning of body fluids, blood, and decontamination procedures.

CLEANING PROCEDURES: Blood/body fluids must be thoroughly cleaned from surfaces and objects before application of **Virasept**. This cleaning may be accomplished with any cleaning solution, including this product.

CONTACT TIME: HIV-1 is inactivated after a 30 second contact time. HBV is inactivated after a four minute contact time.

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

FUNGICIDAL:

VIRASEPT is effective against *Trichophyton mentagrophytes* (the athlete's foot fungus) at a contact time of 4 minutes in the presence of 5% organic soil load. **Virasept** is effective against yeast *Candida albicans* (yeast) at a contact time of 5 minutes. Apply as directed in the Disinfection/Cleaning/Deodorizing directions for use.

MILDEWICIDAL:

Virasept is effective against *Aspergillus niger* at a contact time of 4 minutes in the presence of 5% organic soil load. Apply as directed in the Disinfection/Cleaning/Deodorizing directions for use.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARN, KENNELS, CAGES, HUTCHES, ETC): Remove animals and feed from facilities. Remove litter, waste matter, and gross soils. Empty all troughs, rack and other feeding and watering equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for

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2009

7/7

removing litter and manure. Disinfect surfaces as described under **Disinfection/Cleaning/Deodorizing Directions**. Ventilate buildings and other closed spaces. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse. Allow to air dry before reintroducing animals.

Containers 1 gallon or less:

STORAGE & 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.

Containers greater than 1 gallon:

STORAGE & DISPOSAL

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

Pesticide Storage: Store this product in a cool, dry area, away from direct sunlight and heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray 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.

Container Disposal:

(≤ 55-gallons rigid) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying.

(2.5 gal bladder in box) Nonrefillable container. Do not reuse or refill this container. Remove empty bladder from outer corrugated box. Triple rinse bladder (or equivalent). Offer box and bladder for recycling, if available.

EPA Reg. No. 1677-226

EPA Est.: 303-IN-1 (L), 1677-MN-1 (P), 1677-CA-2 (R), 1677-CA-1 (S), 1677-TX-1 (D), 1677-OH-1 (H), 1677-IL-2 (J), 1677-PR-1 (B), 1677-GA-1 (M), 1677-WV-1 (V)

Superscript refers to first letter of date code

Ecolab Inc.
370 North Wabasha Street
St. Paul, MN 55102-1390

Net Contents:
1 U.S. quart (946 ml)
1 U.S. gallon (3.78 L)
2.5 U.S. gallons (9.45 L)
5 U.S. gallons (18.9 L)

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with COMMENTS
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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1677-226