

1677-226

(08/18/2011)

1/8

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



Office of Pesticide Programs

Theodore D. Head
Ecolab Inc.
St. Paul, MN
55102

AUG 18 2011

Subject: Virasept
EPA Registration No: 1677-226
Application Date March 18, 2011
Receipt Date: March 28, 2011

The following amendment, submitted in connection with the registration under section 3 (c) (7) (A) the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended to add additional efficacy claim, is acceptable.

General Comments

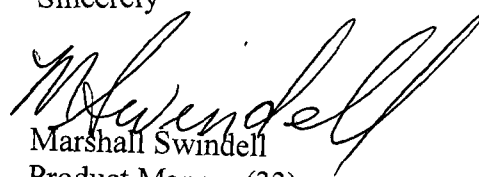
Based on a review of the submitted material dated March 18, 2011, to add the organisms *Klebsiella pneumonia* and *Acinetobacter baumannii* under the Directions for use on the label is acceptable. A stamped copy of the accepted labeling is enclosed. Please submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

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

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

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080.

Sincerely



Marshall Swindell
Product Manger (33)
Regulatory Management Branch I
Antimicrobial's Division (7501P)

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:]

ACCEPTED
with COMMENTS
EPA Letter Dated:

- *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.
- *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, 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.

August 2011
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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1677-226

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, convenience stores, recreational and athletic facilities, locker rooms, correctional facilities, retail and wholesale establishments, dressing rooms, kitchens, shower and bath areas.

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.

ACCEPTED
with COMMENTS
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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.

AUG 18 2011

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.

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

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
- Acinetobacter baumannii* – ATCC 19606

- Klebsiella pneumoniae* – ATCC 4352
- Klebsiella pneumoniae* – ATCC BAA-1705
- 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 Sporocidal 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 product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention 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.

6/8

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 after a 2.5 minute contact time at ambient temperature (20-25°C) 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 the contact times listed below in the presence of 5% organic soil load. Apply as directed in the Disinfection / Cleaning / Deodorizing directions for use.

- 4 minutes:
- *Norovirus (Feline Calicivirus tested surrogate)
- *Hepatitis B Virus (HBV)
- *HIV-1 (AIDS Virus)
- *Respiratory Syncytial Virus

- 2 minutes:
- *Human Coronavirus

- 1 minute:
- *Influenza A Virus

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***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, and 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.

MILDEWCIDAL:

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 (BARNs, 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 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.

(275 gallon, 300 gallon and 330 gallon tote) Verify that tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

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-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)
275 U.S. gallons (1,041 L)
300 U.S. gallons (1,136 L)
330 U.S. gallons (1,249 L)

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Optional marketing language:

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus.
- This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

**ACCEPTED
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