

1677-226

12/17/2009

1 of 10



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Theodore Head
Product Registration Manager for Regulatory Affairs for,
Ecolab, Inc.
370 North Wabasha Street
Saint Paul, MN 55102

DEC 17 2009

Subject: Virasept
EPA Registration Number 1677-226
Your Notification Dated November 11th, 2009
EPA Received Date November 19th, 2009

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to add labeling claims against Pandemic 2009 H1N1, is acceptable.

The notification has been made part of the file

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in black ink, appearing to read "M Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)

2010



Unit rates
Environmental Protection Agency
 Washington, DC 20460

Register on
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1677-226	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
3. Company/Product (Name) Virasept	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to 2/10/03 Agency letter.
 Resubmission in response to Agency letter dated _____. "Me Too" Application.
 Notification - Explain below. Other - Explain below.

Explanation: Use additional Page(s) if necessary. (For section I and Section II)

Optional Marketing Claims in accordance with EPA guidance for labeling against Pandemic 2009 H1N1 for EPA Reg. No. 1677-226. Also adding tote container sizes of 275 gallons, 300 gallons and 330 gallons.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Package wgt. No. Per Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 32 ounces, 1 gallon, 2.5 gallons, 5 gallons, 275 gallons, 300 gallons and 330 gallons	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Other _____ <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application.)

Name Theodore D. Head	Title Manager, Product Registration & Compliance	Telephone No. (Include Area Code) (651) 293-2848
Certification I certify that the statements which I have made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, Product Registration & Compliance	
4. Typed Name Theodore D. Head	5. Date 11-13-09	


Certification with Respect to Label Integrity

version: 9/11/02

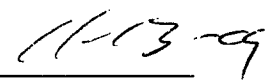
I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
1677-226	11/11/2009	001677-00226.20091111_v01.H1N1.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



 Signature



 Date

Theodore Head

 Name (typed)

Product Registration Manager

 Title

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%

**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.

60910

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, 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.

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 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.

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

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.