

1677-226

10/02/2012

1/7



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT - 2 2012

Ms Rhonda Schulz
Director of Product Registration and Compliance for,
Ecolab, Inc
370 North Wabasha Street North
Saint Paul, MN 55102-1309

Subject Virasept
EPA Registration Number 1677-226
Your Amendment Dated June 28, 2012
EPA Received Date July 5th, 2012

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to correct the ATCC number for *Escherichia coli* as per California Department of Pesticide Regulations (CDPR) request, is acceptable

A stamped copy of the labeling is enclosed

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)

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.

ACCEPTED
with COMMENTS
in EPA Letter Dated

OCT 2 2012

Under the Federal Insecticide
Fungicide and Rodenticide Act as
amended for the pesticide
registered under EPA Reg No

1677-226

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
- *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

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 of instrument that (1) is introduced directly into the human body either into or in contact with the blood stream

ACCEPTED
with COMMENTS
EPA Letter Dated
October 2, 2012

4/7

Virasept label

7/19/2012

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 ~~35450~~ 43895
- Shigella flexner* – ATCC 9380
- Enterobacter aerogenes* – ATCC 13048
- Acinetobacter baumannii* – ATCC 19606
- Klebsiella pneumoniae* – ATCC 4352
- Klebsiella pneumoniae* (CRKP) – 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 Sporidical 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

ADDITIONAL COMMENTS
in EPA Letter Dated
OCT - 2 2012

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
- *Rhinovirus Type 37
- *Rotavirus
- *Adenovirus Type 4
- *Avian Influenza A

2 minutes

- *Human Coronavirus

1 minute

- *Influenza A Virus

***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

ACCEPTED
with COMMENTS
in EPA Letter Dated
OCT - 2 2012

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 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)

ACCEPTED
with COMMENTS
in EPA Letter Dated.

OCT - 2 2012

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

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
with COMMENTS
in EPA Letter Dated
OCT - 2 2012

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