

42964-17

10/4/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OCT 4 2010

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Theodore Head
Airkem Professional Products
Division of Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: **Asepticare**
EPA Registration No. 42964-17
Application Date: June 4, 2010
Receipt Date: June 7, 2010

Dear Mr. Head:

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

Proposed Amendment:

- Adding new organisms and contact time reduction of existing organism

Data Summary

Data Requirement	Means of Support	Status
Viralsidal study for Influenza A (Hong Kong Strain)	Submitted study, MRID 48115901	Acceptable, RTU @ 1 minute.
Viralsidal study for Human Coronavirus (Strain 229E)	Submitted study, MRID 48115902	Acceptable, RTU @ 2minutes.

Conditions:

Revise the label as follows:

1. On page 2 of the label, you must change the First Aid Statement to read: "Kills the following germs on *pre-cleaned* hard non-porous surfaces."

		CONCURRENCES			
SYMBOL	2.	On page 3 of the label, under "To Disinfect" you must add:			
SURNAME	a.	directions for pre-cleaning (i.e. with detergent, product, cloth/sponge, etc.)			
DATE	b.	Specify a 10 minute contact time. Times for other organisms may appear in the table below, however disinfection with the representative bacterial organisms is only			

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proven at 10 minutes. Change the fourth sentence to read "Allow to remain wet for 10 minutes then allow to air dry without wiping."

3. In the table on page 3 change "Influenza A (Hong Kong Strain)" to "Influenza A *virus* (Hong Kong Strain)."
4. Revise "Personal Protection" statement under the HIV directions on page 3 by deleting the term "or" and stating "...masks, and eye coverings."
5. Revise "Pesticide Disposal" statement on page 4 to read "Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility."

General Comments

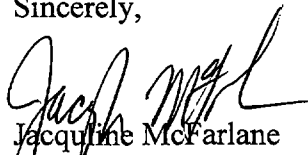
A stamped label with conditions is enclosed. Submit a copy of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for 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.

Should you have any questions concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by email at grigsby.stacey@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Jacqueline McFarlane
 (Acting) Product Manager (34)
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

ASEPTICARE

AEROSOL-DISINFECTANT VIRUCIDE*

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT - 4 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 42964-17

Active Ingredients:

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)	
Dimethyl Benzyl Ammonium Chlorides	0.15%
n-Alkyl (68% C12, 32% C14)	
Dimethyl Ethylbenzyl Ammonium Chlorides.....	0.15%
Ethanol.....	62.74%
Inert Ingredients:	<u>36.96%</u>
Total:	100.00%

(Includes Essential Oil Odor Control Agents)

KEEP OUT OF REACH OF CHILDREN WARNING



FLAMMABLE/INFLAMMABLE



CONTAINER MAY EXPLODE IF HEATED
CE CONTENANT PEUT EXPLOSER S'IL EST CHAUFFÉ

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial, but temporary eye injury or skin irritation. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield (safety glasses). Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash 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.

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 SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have a 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 INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026

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

PHYSICAL AND CHEMICAL HAZARDS: Flammable. Contents under pressure. Do not use in the presence of open flame or spark. Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container or store in temperatures over 54°C (130°C).

KILLS THE FOLLOWING GERMS –ON HARD NON-POROUS SURFACES:

Bacteria:

Salmonella enterica (ATCC 10708), Pseudomonas aeruginosa (ATCC 15442), Staphylococcus aureus (ATCC 6538), (MRSA - ATCC 33592), Mycobacterium tuberculosis (BCG vaccine strain), Enterococcus faecalis Vancomycin Resistant (ATCC 51299)

Fungi: Trichophyton mentagrophytes (the cause of athlete's foot fungus ATCC 9533).

Viruses: Feline Calicivirus (ATCC VR-782), Norovirus (ATCC VR-782), Human Corona Virus Strain 229E (ATCC VR-740), Polio Virus (ATCC VR-192), Sabin Strain Type 1, Influenza A2 (Aichi ATCC VR-547), Respiratory Syncytial (RSV) (ATCC VR-26), Rhinovirus Type 37(ATCC VR-1147), Adenovirus Type 2 (ATCC VR-846), Herpes Simplex Type 1 (ATCC VR-735) & 2 (ATCC VR-734) , HIV (Human Immunodeficiency Virus Strain HTLV-III_B), Parainfluenza I (ATCC VR-105) (Sendal), Avian Influenza A (H3N2) Virus (ATCC VR-2072), Influenza A Hong Kong Strain (ATCC VR-544).

Use **Asepticare** on door handles, clean-up carts, light switches, dressing or linen carts, hampers, diaper pails, toilet seats, bedpans, plastic mattress covers, and lockers. Asepticare is designed for use in hospitals, clinics, nursing homes, extended care, educational institutions, offices, pet care areas, motels and institutional and industrial facilities where odor and bacterial control is desired.

This product is suitable for use on materials such as:

Corian®, Glass, Glazed ceramic, Glazed enameled surfaces, Laminated surfaces, Linoleum, Stainless steel, Formica, and plastic.

Not to be used on food preparation surfaces or in food-handling areas.

CONTROLS MOLD & MILDEW-Asepticare controls mold and mildew on hard nonporous surfaces if not washed or rubbed off.

GENERAL PRECAUTIONS AND RESTRICTIONS

Do not spray in face.

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:

In the U.S.: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

To Control Mold & Mildew: Clean surface prior to application. Spray as described in the "To Disinfect" section. Repeat application in 7 days or as necessary to maintain control.

To Disinfect: Clean surface prior to application. Hold container 6-8 inches from the surface. Spray 3-5 seconds or until surface is wet. Allow to remain wet for required time according to the table below then allow to air dry without wiping. Avoid using spray on delicate fabrics, lacquered, shellacked, or other finished wood surfaces.

Bacteria	Time	Fungi	Time	Viruses	Time
Staphylococcus aureus (MRSA)	10 mins	Trichophyton mentagrophytes	10 mins	Feline Calicivirus	10 mins
Pseudomonas aeruginosa	10 mins			Norovirus	10 mins
Mycobacterium tuberculosis	10 mins			Human Corona Virus Strain 229E	40 mins 2 mins
Salmonella enterica	10 mins			Polio Virus	10 mins
Enterococcus faecalis Vancomycin Resistant	10 mins			Sabin Strain Type 1	10 mins
Staphylococcus aureus (ATTC 6538)	10 mins			Influenza A2 (Aichi)	10 mins
				Respiratory Syncytial (RSV)	5 mins
				Rhinovirus Type 37	5 mins
				Adenovirus Type 2	10 mins
				Herpes Simplex Type 1 & 2	10 mins
				Human Immunodeficiency Virus Type 1	30 secs
				Parainfluenza I (Sendai)	10 mins
				Avian Influenza A (H3N2) Virus	5 mins
				Influenza A (Hong Kong Strain)	1 min

***KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care 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 transmission of human immunodeficiency Virus Type 1 (HIV-1).

Special instructions for cleaning and decontamination against HIV-1 on surfaces/objects
Soiled with blood/body fluids.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex or vinyl gloves, gowns, masks or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

CONTACT TIME: 30 seconds (10 minutes for all other microorganisms.)

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

STORAGE & DISPOSAL:

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

Pesticide Storage: Store in cool, dry place away from flames, sparks or other sources of heat or ignition. Containers heated above 130° F (54° C) may burst.

Pesticide Disposal: Wastes are acutely hazardous. Improper disposal of excess product, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State, Provincial, or Environmental Control Agency, or the Hazardous Waste representative at the nearest U.S. EPA or Environment Canada Regional Office for guidance.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Do Not Puncture or Incinerate! **If empty:** This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label (DO NOT PUNCTURE!). If recycling option is not available, wrap the container and discard in the trash. **If partly filled:** Call your local solid waste agency for disposal instructions.

Net Weight/ Poids net: 14 oz / 397 g

EPA Reg. No. 42964-17

EPA Est.: 33595-MO-2

Distributed by:

Airkem Professional Products, Division of Ecolab Inc.
370 North Wabasha Street, St. Paul, MN 55102

Distributed in Canada by:

Ecolab Co
5105 Tomken Road, Mississauga, Ont. Canada L4W 2X5
Made in U.S.A./Fabriqué aux E.U.

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.