

42964-17

12/09/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

DEC 9 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

Subject: **Asepticare**
EPA Registration Number: 42964-17
Application Dated: July 16, 2009
Receipt Date: July 30, 2009

Dear Mr. Head:

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

Proposed Amendment:

Add an alternate propellant to the alternate CSF, add new organisms and additional contact times

Efficacy Comments

1. References to human hepatitis B Virus must be deleted from the label. Efficacy data (MRID 478187-08) does not currently support the use of the product as a disinfectant with virucidal activity against Duck Hepatitis B virus on hard non-porous surfaces in the presence of a 100% organic soil load for a 5-minute contact time. Although complete inactivation (no growth) was indicated in all dilutions tested, confirmatory data, a requirement for this novel virus was not provided in the data package. Human hepatitis B virus on pre-cleaned hard, non porous surfaces for a 5 minute contact time, confirmatory data, a requirement for this novel virus was not provided in the data package
2. Per DIS/TSS-15, label must be revised to include a description of the types of surfaces of which the product may be used, (e.g., stainless steel, chrome, etc.)

Efficacy Label Comments

1. Add page numbers to each page of the label.
2. Under the "for Emergency Medical Information" section, revise "or label with when" to read "or label with you when."

3. Under the "physical and Chemical Hazards" section, revise "50°C (130°C) to read "54°C (130°F)."
4. Under the list of bacteria on page 2, add " Staphylococcus aureus (ATCC 6538)."
5. Under the "To Control Mold & Mildew" section, revise "Spray as above" to read "Spray as described in the "To Disinfect" section."
6. In the table on page 3, add information for Staphylococcus aureus (ATCC 6538).
7. On page 3, revise "Enviornmental" to read "Environmental."
8. On page 3 under the "Contact Time" section specific to HIV-1 cleaning procedures, revise "to minutes" to read "30 seconds (10 minutes for all other microorganisms)."
9. On page 2 and 3 of the Data Matrix revise "Pseuedomonas aeruginosa" to read Psuedomonas aeruginosa".
10. ATCC designated numbers must be in one of the following locations:
 - on the data matrix;
 - on the master label (as optional text) with the listing of the organisms claimed; or
 - as the final page of the master label (as optional text).

Accepted Efficacy Data

Data Requirement	Means of Support	Status
Methicillin Resistant <i>Staphylococcus aureus</i>	Submitted study, MRID 478187-01	Acceptable, contact time 10 minutes, no soil
<i>Salmonella enterica</i>	Submitted study, MRID 478187-02	Acceptable, contact time 10 minutes, no soil
<i>Enterococcus faecalis</i> Vancomycin Resistant	Submitted study, MRID 478187-03	Acceptable, contact time 10 minutes, no soil
<i>Staphylococcus aureus</i>	Submitted study, MRID 478187-09	Acceptable, contact time 10 minutes, no soil
<i>Salmonella enterica</i>	Submitted study, MRID 478187-09	Acceptable, contact time 10 minutes, no soil

<i>Pseudomonas aeruginosa</i>	Submitted study, MRID 478187-09	Acceptable, contact time 10 minutes, no soil
Avian Influenza A (H3N2), virus	Submitted study, MRID 478187-04	Acceptable, contact time 5 minutes, with soil
Rhinovirus type 37	Submitted study, MRID 478187-06	Acceptable, contact time 5 minutes, with soil
Respiratory syncytial virus	Submitted study, MRID 478187-07	Acceptable, contact time 5 minutes, with soil

Please see the attached DER for additional details regarding the review of the submitted data.

Product Chemistry Comments

Revise CAS no. 102-71-6 to read 112-27-6 on the CSF.

A stamped copy of the accepted label is enclosed for your records.

Should you have any questions concerning this letter, please contact me at (703) 308-6427 or via email at carlisle.sharon@epa.gov or Lisa McKelvin at (703) 308-7496 or via email at mckelvin.lisa@epa.gov.

Sincerely,



ShaRon Carlisle
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Stamped Label & Efficacy DER D-368157

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ASEPTICARE

AEROSOL-DISINFECTANT VIRUCIDE*

DIN 00801828
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:	36.96%
Total:	100.00%

(Includes Essential Oil Odor Control Agents)

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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 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 50°C (130°C).

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KILLS THE FOLLOWING GERMS ON HARD NON-POROUS SURFACES:

Bacteria:

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

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

Viruses: Feline Calicivirus, Norovirus, Human Corona Virus, Polio Virus, Sabin Strain Type 1, Influenza A2 (Aichi), Respiratory Syncytial (RSV), Rhinovirus Type 37, Adenovirus Type 2, Herpes Simplex Type 1 & 2, HIV (Human Immunodeficiency Virus), Parainfluenza I (Sendal), Human Hepatitis B Virus, Avian Influenza A (H3N2) Virus.

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.

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 above. Repeat application in 7 days or as necessary to maintain control.

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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 10 minutes 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	10 mins
Salmonella enterica	10 mins			Polio Virus	10 mins
Enterococcus faecalis Vancomycin Resistant	10 mins			Sabin Strain Type 1	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 (Sendal)	10 mins
				Human Hepatitis B Virus	5 mins
				Avian Influenza A (H3N2) Virus	5 mins

***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: 10 minutes.

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

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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 Est.: 706-IL-1

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.

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