

PM 31

303-209

11/19/99

page 1 of 5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102-1390

NOV 19 1999

ATTENTION: Regulatory Services

SUBJECT: Ascend®
EPA Registration Number 303-209
Your Amendment Dated: August 17, 1999
EPA Received Date: August 27, 1999

The amendment referred to above, submitted in connection with registration under FIFRA as amended, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

A. As per the Label Review Manual, "all product labels are required to have appropriate storage instructions." Include the following statement along with the subheading **Pesticide Storage**: "Store product in locked area inaccessible to children and persons unfamiliar with its proper use. Store in original container."

B. Revise the first statement in the "Directions for Use" section of the label to read as follows: "Use Directions for Disinfecting and Fungicidal Activity: For use on hard..."

C. Your directions for "Disinfection and Deodorizing of Animal Housing Facilities (Barns, Kennels, Cages, Hutches, etc)" are insufficient. Replace the section on your label beginning "Remove animals and feed..." and ending "...before reintroducing animals." with the following as per DIS/TSS-18:

"Disinfection and Deodorizing of Animal Housing Facilities (Barns, Kennels, Cages, Hutches)

- 1) Remove all animals and feed from premise, vehicles, and enclosures.
- 2) Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls,

SYMBOL	7510e						
SURNAME	J. J. J.						
DATE	11/17/99						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

chutes, and other facilities and fixtures occupied or traversed by animals.

- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
- 6) 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.
- 7) Ventilate buildings, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been air dried.
- 8) Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse."

D. Include the following "Note to Physician": "Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed."

E. The label submitted to the Agency must include all possible language for this product. Those statements which will only appear on specific sized containers can be prefaced with such a comment ("for 5 and 55 gallon containers"). Your label must include the Environmental Hazards Statement as per PR Notice 93-10 and is not exempted under PR Notice 95-1 for the 5 and 55 gallon containers. Place the following statements on your label:

"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 Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office of the EPA."

F. Your label must include a "Container Disposal" statement which agrees with PR Notice 83-3 when this product is marketed in 2.5, 5 and 55 gallon containers. Include the following language on your label when the product is marketed in these sizes:

"Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."

G. The submitted pictogram, a picture of microorganisms with a slash through them, has been reexamined by the regulatory team as well as the efficacy team at the Agency. This graphic is still unacceptable based on PR Notice 95-2 section II (A), the Label Review Manual, Chapter 14 as well as the regulatory and efficacy teams. This product is a disinfectant and thus does not kill all organisms as is implied by your graphic. This graphic has been "blocked-out" on the stamped copy of the label and the same must be done on the labels which you print. This graphic may not appear on the label used to market this product.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

H. Include the following statement directly under the heading "Directions for Use" "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."

I. Upon your next submission of this label for amendment, revise your label such that it identifies the specific antibiotic resistance of each organisms claimed on your label. If all of the organisms identified with a 1 superscript are resistant to the same antibiotic then list that antibiotic as part of the superscript. The same applies to the superscript 2. Alternatively the antibiotic resistance must be identified specifically in parenthesis after each appropriate organism. Upon resubmission, this information will be reviewed by our efficacy team to verify that your referenced studies support these specific microorganisms.

2. Submit two (2) copies of your final printed labeling before you release the product for shipment.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415. A stamped copy of the labeling is enclosed for your records.

Sincerely,

Velma Noble

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure
7510C:T. Lantz:11/16/99:303-209c

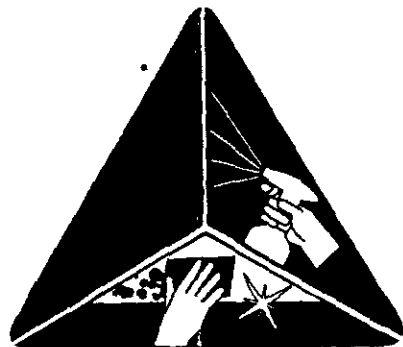
CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Huntington
brand**GERMICIDAL DETERGENT****Ascend**[®]**Germicidal Detergent****Disinfectant/Deodorizer/Fungicide****Virucide*/Detergent****ACTIVE INGREDIENTS:**

Didecyl Dimethyl	
Ammonium Chloride9.22%
n-Alkyl (C ₁₄ 50%; C ₁₂ 40%; C ₁₆ 10%)	
Dimethyl Benzyl	
Ammonium Chloride6.14%
INERT INGREDIENTS84.64%
TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN**DANGER**See side panel for additional
precautionary statements.**ECOLAB**[®]

Net Contents: 1 U.S. gal/3.78 L



main panel 25.6 picas

Inks: PMS 3256 green, 5485 green and black.
backup color: white - Form number: 716800/89

Cylinder

Ascend is a multi-purpose germicidal detergent and deodorant effective when diluted 1:256 in up to 400 ppm hard water (calculated as CaCO₃) plus 5% organic serum according to the AOAC Use-dilution and virucidal qualification tests. Disinfects, cleans, and deodorizes in one labor saving step. Recommended for use in hospitals, nursing homes, schools and colleges, veterinary clinics and animal life science laboratories, federally inspected meat and poultry establishments and breeding establishments. Effective against the following pathogens on hard, non-porous, inanimate surfaces when diluted 1:256 (1/2 ounce to 1 gallon):

Bactericidal against: *Pseudomonas aeruginosa*¹, *Staphylococcus aureus*¹, *Salmonella choleraesuis*, *Acinetobacter calcoaceticus*, *Bordetella bronchiseptica*, *Chlamydia psittaci*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Escherichia coli*¹, *Fusobacterium necrophorum*, *Klebsiella pneumoniae*¹, *Legionella pneumophila*, *Listeria monocytogenes*, *Pasteurella multocida*, *Proteus mirabilis*, *Proteus vulgaris*, *Salmonella enteritidis*, *Salmonella typhi*, *Salmonella typhimurium*, *Serratia marcescens*, *Shigella flexneri*, *Shigella sonnei*, *Staphylococcus aureus* (methicillin resistant), *Staphylococcus epidermidis*², *Streptococcus faecalis*¹, *Streptococcus pyogenes*, *Enterococcus faecalis* (Vancomycin Resistant) *Staphylococcus aureus* (Vancomycin Resistant). **Virucidal** against: *Adenovirus type 4, *Canine distemper, *Feline leukemia, *Feline picornavirus, *Herpes simplex type 1, *Herpes simplex type 2, *HIV-1 (AIDS virus), *Infectious bovine rhinotracheitis, *Infectious bronchitis (Avian IBV), *Influenza A/Hong Kong, *Pseudorabies, *Rabies, *Respiratory syncytial virus (RSV), *Rubella (German Measles), *Transmissible gastroenteritis virus (TGE), *Vaccinia. **Fungicidal** against: *Aspergillus niger*, *Candida albicans*, *Trichophyton mentagrophytes*,
¹ ATCC & antibiotic-resistant strain, ² antibiotic-resistant strain only.

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS****DANGER:** Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Harmful if absorbed through skin. Harmful if swallowed. Wear protective clothing, chemical goggles, and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

24.6 picas

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 19 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 303-209

8/12

4
5

STATEMENT OF PRACTICAL TREATMENT

If in Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

If on Skin: Wash with plenty of soap and water. Get medical attention.

If Swallowed: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

FOR EMERGENCY MEDICAL INFORMATION, CALL 1-800-328-0026.

DIRECTIONS FOR USE

Use Directions for Disinfecting: For use on hard, nonporous surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed ceramic tile, glazed porcelain, and plastic surfaces (such as polypropylene, polystyrene, etc.) and other nonporous environmental surfaces. Not for use on food preparation surfaces, medical devices or medical equipment surfaces. Remove gross filth and heavy soil deposits. Using 1/2 ounce per gallon of water, thoroughly wet surfaces for a minimum contact time of 10 minutes. Can be applied with a cloth, mop, sponge, coarse spray device or by soaking. The recommended use solution is prepared fresh for each use then discarded. Remove solution and entrapped soil with clean wet mop, cloth or wet vacuum pickup, or allow to air dry. Rinsing is not necessary unless used on floors that are to be waxed or polished.

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. Disinfect surfaces as described under Directions For Disinfecting. Ventilate buildings and other closed spaces. Allow to air dry before reintroducing animals.

USDA: For use in federally inspected meat and poultry plants on all hard, non-porous surfaces in inedible product processing areas, nonprocessing areas, and/or exterior areas.

Huntington Professional Products, A Service of Ecolab Inc.
370 Wabasha Street N., St. Paul, MN 55102

© 1999 Ecolab Inc. Made in U.S.A. 716800/8903/0899
All Rights Reserved

24.6 picas

Master Format: PPD 1 gal poly/epa/disinf

RECOMMENDED MINIMUM TYPE IS 8 PT.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 19 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 308-209

Mildewstatic Instructions: Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, non-porous surfaces such as walls, floors, and table tops.

Apply solution (1/2 ounce per gallon of water) with a cloth, mop, sponge, or coarse spray. Make sure to wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears.

***KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care setting or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of blood/body fluids and during decontamination procedures. **Cleaning Procedure:** Blood/body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant. **Contact Time:** HIV-1 (AIDS virus) is inactivated after a contact time of 4 minutes at 25°C (room temperature). Use a 10 minute contact time for other viruses, fungi, and bacteria listed. **Disposal of Infectious Materials:** Blood/body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

STORAGE & DISPOSAL

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

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 directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA/Regional office for guidance.

Container Disposal: Do not reuse empty container. Wrap container and put in trash.

EPA Reg. No. 303-209

EPA Est. 303-IN-1 (L), 1677-IL-2 (J), 1677-NJ-1 (W), 1677-TX-1 (D), 1677-GA-1 (M), 1677-MN-1 (P), 1677-CA-1 (S), 1677-PR-1 (B), 1677-OH-1 (H).

Superscript refers to first letter of date code.

For product information, call 1-800-332-6522.

Product No. 61027215

25.6 picas

1 gallon polyethylene specification with or without back up (cylinder) plate.

SIZE: 19" x 4 7/16" (back up cylinder) 18 5/8" x 4 1/16" copy/art print area.

10/98 Quark Xpress

5
5